

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

Table 14.3.1.28 Percentage of doses with unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI							
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL				
	At least one symptom	3399	30.0	29.1	30.8	431	3.8	3.5	4.2	2857	24.2	23.4	25.0	470	3.9	3.5	4.2	613	20.3	18.9	21.7	105	3.7	3.1	4.5	24	21.2	14.1	29.9	6	4.4	1.6	9.4
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	15	0.1	0.1	0.2	2	0.0	0.0	0.1	5	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymph node pain (10025182)	5	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymphadenitis (10025188)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymphadenopathy (10025197)	9	0.1	0.0	0.2	1	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thrombocytosis (10043563)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Cardiac disorders (10007541)	At least one PT related to the corresponding SOC	9	0.1	0.0	0.2	2	0.0	0.0	0.1	8	0.1	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute myocardial infarction (10000891)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Angina pectoris (10002383)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arrhythmia (10003119)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Palpitations (10033557)	5	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tachycardia (10043071)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Ear and labyrinth disorders (10013993)	At least one PT related to the corresponding SOC	8	0.1	0.0	0.1	2	0.0	0.0	0.1	11	0.1	0.0	0.2	2	0.0	0.0	0.1	6	0.2	0.1	0.4	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Deafness neurosensory (10011891)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear pain (10014020)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Middle ear effusion (10062545)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinnitus (10043882)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vertigo (10047340)	6	0.1	0.0	0.1	1	0.0	0.0	0.0	7	0.1	0.0	0.1	2	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Eye disorders (10015919)	At least one PT related to the corresponding SOC	9	0.1	0.0	0.2	4	0.0	0.0	0.1	10	0.1	0.0	0.2	5	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Asthenopia (10003552)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blepharospasm (10005159)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctival haemorrhage (10010719)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dark circles under eyes (10064729)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dry eye (10013774)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye pain (10015958)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	5	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye pruritus (10052140)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

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		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Primary System Organ Class (CODE)	Eye swelling (10015967)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eyelid oedema (10015993)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eyelids pruritus (10051627)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lacrimation increased (10023644)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ocular discomfort (10052143)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ocular hyperaemia (10030041)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Periorbital oedema (10034545)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Photopsia (10034962)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vision blurred (10047513)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Gastrointestinal disorders (10017947)	At least one PT related to the corresponding SOC	152	1.3	1.1	1.6	33	0.3	0.2	0.4	110	0.9	0.8	1.1	51	0.4	0.3	0.5	33	1.1	0.8	1.5	12	0.4	0.2	0.7	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Abdominal discomfort (10000059)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal distension (10000060)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal pain (10000081)	8	0.1	0.0	0.1	1	0.0	0.0	0.0	7	0.1	0.0	0.1	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal pain lower (10000084)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal pain upper (10000087)	8	0.1	0.0	0.1	6	0.1	0.0	0.1	14	0.1	0.1	0.2	10	0.1	0.0	0.2	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aphthous stomatitis (10002958)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cheilitis (10008417)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Colitis ulcerative (10009900)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Constipation (10010774)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diarrhoea (10012735)	18	0.2	0.1	0.3	6	0.1	0.0	0.1	20	0.2	0.1	0.3	13	0.1	0.1	0.2	6	0.2	0.1	0.4	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dry mouth (10013781)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	5	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dyspepsia (10013946)	5	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Faeces discoloured (10016100)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fatulence (10016766)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastritis (10017853)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal disorder (10017944)	5	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal pain (10017999)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glossitis (10018386)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glossodynia (10018388)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypoaesthesia oral (10057371)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip disorder (10048470)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

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Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Primary System Organ Class (CODE)	Lip swelling (10024570)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mouth ulceration (10028034)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Nausea (10028813)	91	0.8	0.6	1.0	14	0.1	0.1	0.2	61	0.5	0.4	0.7	14	0.1	0.1	0.2	18	0.6	0.4	0.9	6	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral mucosal blistering (10030995)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral pain (10031009)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Paraesthesia oral (10057372)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Periodontal disease (10034536)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Swollen tongue (10042727)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue coated (10043945)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue disorder (10043951)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue pruritus (10070072)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue ulceration (10043991)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Toothache (10044055)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
General disorders and administration site conditions (10018065)	Vomiting (10047700)	18	0.2	0.1	0.3	1	0.0	0.0	0.0	10	0.1	0.0	0.2	6	0.0	0.0	0.1	4	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	At least one PT related to the corresponding SOC	3141	27.7	26.9	28.5	223	2.0	1.7	2.2	2622	22.2	21.4	22.9	282	2.3	2.1	2.6	569	18.8	17.4	20.3	52	1.8	1.4	2.4	21	18.6	11.9	27.0	5	3.7	1.2	8.4
	Administration site erythema (10074796)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Administration site pain (10058049)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Administration site reaction (10001315)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Asthenia (10003549)	33	0.3	0.2	0.4	3	0.0	0.0	0.1	23	0.2	0.1	0.3	8	0.1	0.0	0.1	5	0.2	0.1	0.4	1	0.0	0.0	0.2	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Axillary pain (10048750)	5	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chest discomfort (10008469)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chest pain (10008479)	5	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chills (10008531)	287	2.5	2.2	2.8	10	0.1	0.0	0.2	206	1.7	1.5	2.0	11	0.1	0.0	0.2	38	1.3	0.9	1.7	2	0.1	0.0	0.3	4	3.5	1.0	8.8	0	0.0	0.0	2.7
	Discomfort (10013082)	4	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Face oedema (10016029)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Facial pain (10016059)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fatigue (10016256)	263	2.3	2.0	2.6	31	0.3	0.2	0.4	183	1.5	1.3	1.8	44	0.4	0.3	0.5	32	1.1	0.7	1.5	4	0.1	0.0	0.4	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Feeling abnormal (10016322)	6	0.1	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling cold (10016326)	30	0.3	0.2	0.4	2	0.0	0.0	0.1	17	0.1	0.1	0.2	5	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling hot (10016334)	27	0.2	0.2	0.3	1	0.0	0.0	0.0	12	0.1	0.1	0.2	4	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling of body temperature change (10061458)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gait disturbance (10017577)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	General physical health deterioration (10049438)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Influenza like illness (10022004)	56	0.5	0.4	0.6	5	0.0	0.0	0.1	32	0.3	0.2	0.4	9	0.1	0.0	0.1	7	0.2	0.1	0.5	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site atrophy (10022048)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site bruising (10022052)	19	0.2	0.1	0.3	17	0.2	0.1	0.2	16	0.1	0.1	0.2	14	0.1	0.1	0.2	2	0.1	0.0	0.2	1	0.0	0.0	0.2	1	0.9	0.0	4.8	1	0.7	0.0	4.1
	Injection site coldness (10050082)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site discolouration (10051572)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site discomfort (10054266)	10	0.1	0.0	0.2	2	0.0	0.0	0.1	9	0.1	0.0	0.1	1	0.0	0.0	0.0	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site eczema (10066221)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site erythema (10022061)	812	7.2	6.7	7.6	14	0.1	0.1	0.2	697	5.9	5.5	6.3	23	0.2	0.1	0.3	137	4.5	3.8	5.3	1	0.0	0.0	0.2	4	3.5	1.0	8.8	0	0.0	0.0	2.7
	Injection site haematoma (10022066)	9	0.1	0.0	0.2	7	0.1	0.0	0.1	3	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site haemorrhage (10022067)	5	0.0	0.0	0.1	6	0.1	0.0	0.1	6	0.1	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site hyperaesthesia (10073418)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site hypersensitivity (10022071)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site hypoaesthesia (10074586)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site induration (10022075)	23	0.2	0.1	0.3	2	0.0	0.0	0.1	29	0.2	0.2	0.4	2	0.0	0.0	0.1	7	0.2	0.1	0.5	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site inflammation (10022078)	21	0.2	0.1	0.3	0	0.0	0.0	0.0	22	0.2	0.1	0.3	1	0.0	0.0	0.0	9	0.3	0.1	0.6	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site injury (10066083)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site irritation (10022079)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site joint pain (10049261)	25	0.2	0.1	0.3	1	0.0	0.0	0.0	22	0.2	0.1	0.3	3	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site lymphadenopathy (10057665)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Injection site macule (10067255)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site mass (10022081)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	6	0.1	0.0	0.1	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site movement impairment (10056250)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site nodule (10057880)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site oedema (10022085)	14	0.1	0.1	0.2	0	0.0	0.0	0.0	21	0.2	0.1	0.3	0	0.0	0.0	0.0	7	0.2	0.1	0.5	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site pain (10022086)	2121	18.7	18.0	19.4	105	0.9	0.8	1.1	1849	15.6	15.0	16.3	118	1.0	0.8	1.2	396	13.1	11.9	14.3	34	1.2	0.8	1.7	12	10.6	5.6	17.8	3	2.2	0.5	6.4
	Injection site papule (10066044)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site paraesthesia (10022088)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site pruritus (10022093)	168	1.5	1.3	1.7	13	0.1	0.1	0.2	134	1.1	1.0	1.3	17	0.1	0.1	0.2	38	1.3	0.9	1.7	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site rash (10022094)	32	0.3	0.2	0.4	1	0.0	0.0	0.0	24	0.2	0.1	0.3	3	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site reaction (10022095)	30	0.3	0.2	0.4	4	0.0	0.0	0.1	30	0.3	0.2	0.4	7	0.1	0.0	0.1	4	0.1	0.0	0.3	1	0.0	0.0	0.2	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Injection site swelling (10053425)	585	5.2	4.8	5.6	8	0.1	0.0	0.1	489	4.1	3.8	4.5	8	0.1	0.0	0.1	111	3.7	3.0	4.4	6	0.2	0.1	0.5	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Injection site ulcer (10022105)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site urticaria (10022107)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	5	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site vesicles (10022111)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site warmth (10022112)	68	0.6	0.5	0.8	0	0.0	0.0	0.0	75	0.6	0.5	0.8	4	0.0	0.0	0.1	14	0.5	0.3	0.8	0	0.0	0.0	0.1	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Local swelling (10024770)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Malaise (10025482)	120	1.1	0.9	1.3	10	0.1	0.0	0.2	89	0.8	0.6	0.9	10	0.1	0.0	0.2	20	0.7	0.4	1.0	0	0.0	0.0	0.1	1	0.9	0.0	4.8	1	0.7	0.0	4.1
	Nodule (10054107)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oedema (10030095)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oedema peripheral (10030124)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Pain (10033371)	99	0.9	0.7	1.1	2	0.0	0.0	0.1	59	0.5	0.4	0.6	8	0.1	0.0	0.1	17	0.6	0.3	0.9	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Peripheral swelling (10048959)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyrexia (10037660)	647	5.7	5.3	6.1	12	0.1	0.1	0.2	381	3.2	2.9	3.6	14	0.1	0.1	0.2	58	1.9	1.5	2.5	3	0.1	0.0	0.3	3	2.7	0.6	7.6	0	0.0	0.0	2.7
	Reactogenicity event (10065109)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sluggishness (10041052)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Swelling (10042674)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Temperature intolerance (10057040)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tenderness (10043224)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thirst (10043458)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site coldness (10076157)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site discolouration (10069474)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site erythema (10059079)	16	0.1	0.1	0.2	0	0.0	0.0	0.0	22	0.2	0.1	0.3	1	0.0	0.0	0.0	7	0.2	0.1	0.5	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site haematoma (10069472)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site inflammation (10068878)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site irritation (10069479)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site pain (10068879)	35	0.3	0.2	0.4	0	0.0	0.0	0.0	27	0.2	0.2	0.3	5	0.0	0.0	0.1	5	0.2	0.1	0.4	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Vaccination site pruritus (10068881)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site reaction (10059080)	7	0.1	0.0	0.1	0	0.0	0.0	0.0	11	0.1	0.0	0.2	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site swelling (10069620)	11	0.1	0.0	0.2	0	0.0	0.0	0.0	9	0.1	0.0	0.1	0	0.0	0.0	0.0	4	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site warmth (10069624)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Immune system disorders (10021428)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anaphylactic reaction (10002198)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypersensitivity (10020751)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Multiple allergies (10028164)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	67	0.6	0.5	0.7	45	0.4	0.3	0.5	72	0.6	0.5	0.8	25	0.2	0.1	0.3	7	0.2	0.1	0.5	7	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchitis (10006451)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Candida infection (10074170)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cystitis (10011781)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erysipelas (10015145)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastroenteritis (10017888)	0	0.0	0.0	0.0	5	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Herpes simplex (10019948)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Herpes zoster oticus (10063491)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infection (10021789)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Influenza (10022000)	10	0.1	0.0	0.2	2	0.0	0.0	0.1	7	0.1	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site cellulitis (10050057)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	5	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site infection (10022076)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lower respiratory tract infection (10024968)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasopharyngitis (10028810)	35	0.3	0.2	0.4	16	0.1	0.1	0.2	31	0.3	0.2	0.4	15	0.1	0.1	0.2	3	0.1	0.0	0.3	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral herpes (10067152)	7	0.1	0.0	0.1	7	0.1	0.0	0.1	8	0.1	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pharyngitis (10034835)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory tract infection (10062352)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory tract infection viral (10062106)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinitis (10039083)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Upper respiratory tract infection (10046306)	5	0.0	0.0	0.1	7	0.1	0.0	0.1	11	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urinary tract infection (10046571)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Viral infection (10047461)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Viral rash (10047476)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Injury, poisoning and procedural complications (10022117)	At least one PT related to the corresponding SOC	4	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Contusion (10050584)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epicondylitis (10014971)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination complication (10046861)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Investigations (10022891)	At least one PT related to the corresponding SOC	56	0.5	0.4	0.6	3	0.0	0.0	0.1	56	0.5	0.4	0.6	2	0.0	0.0	0.1	7	0.2	0.1	0.5	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood glucose increased (10005557)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood pressure increased (10005750)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Body temperature decreased (10005910)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Body temperature fluctuation (10063488)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Body temperature increased (10005911)	55	0.5	0.4	0.6	2	0.0	0.0	0.1	51	0.4	0.3	0.6	1	0.0	0.0	0.0	7	0.2	0.1	0.5	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Grip strength decreased (10062556)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Heart rate increased (10019303)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Heart rate irregular (10019304)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	At least one PT related to the corresponding SOC	6	0.1	0.0	0.1	0	0.0	0.0	0.0	13	0.1	0.1	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Metabolism and nutrition disorders (10027433)	Decreased appetite (10061428)	6	0.1	0.0	0.1	0	0.0	0.0	0.0	11	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dehydration (10012174)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypercalcaemia (10020583)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Polydipsia (10036067)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	At least one PT related to the corresponding SOC	407	3.6	3.3	3.9	38	0.3	0.2	0.5	273	2.3	2.0	2.6	66	0.5	0.4	0.7	60	2.0	1.5	2.5	10	0.4	0.2	0.7	3	2.7	0.6	7.6	0	0.0	0.0	2.7
Musculoskeletal and connective tissue disorders (10028395)	Arthralgia (10003239)	78	0.7	0.5	0.9	14	0.1	0.1	0.2	39	0.3	0.2	0.5	10	0.1	0.0	0.2	9	0.3	0.1	0.6	2	0.1	0.0	0.3	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Arthritis (10003246)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Axillary mass (10049021)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Back pain (10003988)	27	0.2	0.2	0.3	2	0.0	0.0	0.1	11	0.1	0.0	0.2	13	0.1	0.1	0.2	5	0.2	0.1	0.4	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bone disorder (10005956)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bone pain (10006002)	4	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bone swelling (10053631)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fibromyalgia (10048439)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Flank pain (10016750)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint stiffness (10023230)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint swelling (10023232)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Limb discomfort (10061224)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mobility decreased (10048334)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle fatigue (10049565)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle rigidity (10028330)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle spasms (10028334)	5	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle tightness (10049816)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle twitching (10028347)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscular weakness (10028372)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Musculoskeletal	Musculoskeletal chest pain (10050819)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Musculoskeletal discomfort (10053156)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Musculoskeletal pain (10028391)	18	0.2	0.1	0.3	2	0.0	0.0	0.1	10	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Musculoskeletal stiffness (10052904)	8	0.1	0.0	0.1	1	0.0	0.0	0.0	5	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myalgia (10028411)	265	2.3	2.1	2.6	12	0.1	0.1	0.2	184	1.6	1.3	1.8	27	0.2	0.1	0.3	33	1.1	0.8	1.5	4	0.1	0.0	0.4	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Neck pain (10028836)	15	0.1	0.1	0.2	2	0.0	0.0	0.1	9	0.1	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteitis (10031149)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteoarthritis (10031161)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pain in extremity (10033425)	18	0.2	0.1	0.3	3	0.0	0.0	0.1	21	0.2	0.1	0.3	6	0.0	0.0	0.1	11	0.4	0.2	0.6	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Polymyalgia rheumatica (10036099)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rheumatoid arthritis (10039073)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Synovial cyst (10042858)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Synovitis (10042868)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Torticollis (10044074)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acrochordon (10000591)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	563	5.0	4.6	5.4	103	0.9	0.7	1.1	339	2.9	2.6	3.2	114	0.9	0.8	1.1	63	2.1	1.6	2.7	29	1.0	0.7	1.5	0	0.0	0.0	3.2	2	1.5	0.2	5.2
	Balance disorder (10049848)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Burning sensation (10006784)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Carpal tunnel syndrome (10007697)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebral infarction (10008118)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebrovascular accident (10008190)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervicobrachial syndrome (10008334)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Disturbance in attention (10013496)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dizziness (10013573)	56	0.5	0.4	0.6	13	0.1	0.1	0.2	44	0.4	0.3	0.5	27	0.2	0.1	0.3	12	0.4	0.2	0.7	7	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dizziness postural (10013578)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Dysgeusia (10013911)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Head discomfort (10019194)	5	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Headache (10019211)	480	4.2	3.9	4.6	84	0.7	0.6	0.9	272	2.3	2.0	2.6	66	0.5	0.4	0.7	47	1.6	1.1	2.1	15	0.5	0.3	0.9	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Hyperaesthesia (10020568)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypersomnia (10020765)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypoaesthesia (10020937)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypotonia (10021118)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lethargy (10024264)	7	0.1	0.0	0.1	1	0.0	0.0	0.0	11	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Loss of consciousness (10024855)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Memory impairment (10027175)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Migraine (10027599)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Mononeuritis (10027910)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Paraesthesia (10033775)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Poor quality sleep (10062519)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Presyncope (10036653)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Restless legs syndrome (10058920)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sciatica (10039674)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Somnolence (10041349)	12	0.1	0.1	0.2	1	0.0	0.0	0.0	16	0.1	0.1	0.2	4	0.0	0.0	0.1	4	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Syncope (10042772)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tension headache (10043269)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tremor (10044565)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Trigeminal neuralgia (10044652)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Psychiatric disorders (10037175)	At least one PT related to the corresponding SOC	33	0.3	0.2	0.4	9	0.1	0.0	0.2	20	0.2	0.1	0.3	3	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Agitation (10001497)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anxiety (10002855)	4	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aversion (10063659)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Depressed mood (10012374)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Depression (10012378)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Disorientation (10013395)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysphemia (10054964)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysphoria (10013954)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hallucination (10019063)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Insomnia (10022437)	17	0.1	0.1	0.2	7	0.1	0.0	0.1	12	0.1	0.1	0.2	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Irritability (10022998)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Libido decreased (10024419)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI							
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Listless (10024642)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Middle insomnia (10027590)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Nightmare (10029412)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Restlessness (10038743)	6	0.1	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Sleep disorder (10040984)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
Renal and urinary disorders (10038359)	At least one PT related to the corresponding SOC	4	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Dysuria (10013990)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Pollakiuria (10036018)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Polyuria (10036142)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Urinary incontinence (10046543)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
Reproductive system and breast disorders (10038604)	At least one PT related to the corresponding SOC	4	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Breast pain (10006298)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Erectile dysfunction (10061461)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Pelvic pain (10034263)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
Respiratory, thoracic and mediastinal disorders (10038738)	At least one PT related to the corresponding SOC	34	0.3	0.2	0.4	22	0.2	0.1	0.3	19	0.2	0.1	0.3	15	0.1	0.1	0.2	3	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cough (10011224)	7	0.1	0.0	0.1	5	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysphonia (10013952)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Dyspnoea (10013968)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epistaxis (10015090)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Nasal congestion (10028735)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Nasal obstruction (10028748)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Oropharyngeal discomfort (10068318)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Oropharyngeal pain (10068319)	15	0.1	0.1	0.2	13	0.1	0.1	0.2	10	0.1	0.0	0.2	5	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Paranasal sinus discomfort (10052438)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Productive cough (10036790)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Rhinorrhoea (10039101)	9	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Sneezing (10041232)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Throat irritation (10043521)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
	Vasomotor rhinitis (10047145)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Wheezing (10047924)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	
Skin and subcutaneous tissue disorders (10040785)	At least one PT related to the corresponding SOC	78	0.7	0.5	0.9	32	0.3	0.2	0.4	54	0.5	0.3	0.6	50	0.4	0.3	0.5	21	0.7	0.4	1.1	12	0.4	0.2	0.7	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Alopecia areata (10001761)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7	

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Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Blister (10005191)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cold sweat (10009866)	2	0.0	0.0	0.1	1	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatitis (10012431)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatitis allergic (10012434)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatitis contact (10012442)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatitis exfoliative (10012455)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ecchymosis (10014080)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eczema (10014184)	2	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erythema (10015150)	13	0.1	0.1	0.2	2	0.0	0.0	0.1	12	0.1	0.1	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erythema nodosum (10015226)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperhidrosis (10020642)	15	0.1	0.1	0.2	1	0.0	0.0	0.0	7	0.1	0.0	0.1	7	0.1	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypersensitivity vasculitis (10020764)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypohidrosis (10021013)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Night sweats (10029410)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Onychalgia (10064251)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pain of skin (10033474)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Papule (10033733)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Photosensitivity reaction (10034972)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pruritus (10037087)	19	0.2	0.1	0.3	10	0.1	0.0	0.2	11	0.1	0.0	0.2	17	0.1	0.1	0.2	11	0.4	0.2	0.6	5	0.2	0.1	0.4	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Pruritus generalised (10052576)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	7	0.1	0.0	0.1	4	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Psoriasis (10037153)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash (10037844)	13	0.1	0.1	0.2	6	0.1	0.0	0.1	8	0.1	0.0	0.1	13	0.1	0.1	0.2	4	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash generalised (10037858)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash macular (10037867)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash pruritic (10037884)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin burning sensation (10054786)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin exfoliation (10040844)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin lesion (10040882)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin swelling (10053262)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin warm (10040952)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urticaria (10046735)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Surgical and medical procedures (10042613)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth extraction (10062132)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

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Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	16	0.1	0.1	0.2	3	0.0	0.0	0.1	9	0.1	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Angiopathy (10059245)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Behcet's syndrome (10004213)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood pressure fluctuation (10005746)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Flushing (10016825)	4	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hot flush (10060800)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperaemia (10020565)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertension (10020772)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypotension (10021097)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral coldness (10034568)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Varicose vein (10046996)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of administered doses

n/% = number/percentage of doses with the symptom

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

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Report Final

Table 14.3.1.29 Global Summary of unsolicited signs and symptoms reported with causal relationship to vaccination, within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	2223	386	1962	420	449	91	16	6	4650	903
Number of doses followed by at least one unsolicited symptom	3399	431	2857	470	613	105	24	6	6893	1012
Number of unsolicited symptoms classified by MedDRA Preferred Term*	7219	598	5640	721	1173	149	41	8	14073	1476
Number of unsolicited symptoms reported**	7291	614	5683	735	1186	153	41	8	14201	1510

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

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Table 14.3.1.30 Percentage of subjects reporting the occurrence of grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

		Non-Frail						Pre-Frail						Frail						Unknown					
		HZ/su N = 5784			Placebo N = 5734			HZ/su N = 6071			Placebo N = 6219			HZ/su N = 1573			Placebo N = 1464			HZ/su N = 59			Placebo N = 72		
		95% CI			95% CI			95% CI			95% CI			95% CI			95% CI			95% CI			95% CI		
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		252	4.4	3.8	4.9	18	0.3	0.2	0.5	207	3.4	3.0	3.9	26	0.4	0.3	0.6	69	4.4	3.4	5.5	8	0.5	0.2	1.1
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Lymphadenopathy (10025197)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
Cardiac disorders (10007541)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3
	Acute myocardial infarction (10000891)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Arrhythmia (10003119)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3
	Palpitations (10033557)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3
	Tachycardia (10043071)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
Ear and labyrinth disorders (10013993)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3
	Deafness neurosensory (10011891)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Tinnitus (10043882)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3
Eye disorders (10015919)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3
	Eye pruritus (10052140)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3
	Ocular hyperaemia (10030041)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
Gastrointestinal disorders (10017947)	At least one PT related to the corresponding SOC	19	0.3	0.2	0.5	3	0.1	0.0	0.2	14	0.2	0.1	0.4	3	0.0	0.0	0.1	5	0.3	0.1	0.7	2	0.1	0.0	0.5
	Abdominal pain (10000081)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3
	Abdominal pain upper (10000087)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Colitis ulcerative (10009900)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Diarrhoea (10012735)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.0	0.0	0.3
	Dry mouth (10013781)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Glossitis (10018386)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Nausea (10028813)	10	0.2	0.1	0.3	0	0.0	0.0	0.1	7	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.2	0.0	0.6	1	0.1	0.0	0.4
	Swollen tongue (10042727)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Tongue coated (10043945)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Tongue ulceration (10043991)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Toothache (10044055)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Vomiting (10047700)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3

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		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
General disorders and administration site conditions (10018065)	At least one PT related to the corresponding SOC	209	3.6	3.1	4.1	6	0.1	0.0	0.2	158	2.6	2.2	3.0	14	0.2	0.1	0.4	52	3.3	2.5	4.3	1	0.1	0.0	0.4	2	3.4	0.4	11.7	1	1.4	0.0	7.5
	Asthenia (10003549)	6	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chest pain (10008479)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chills (10008531)	38	0.7	0.5	0.9	0	0.0	0.0	0.1	30	0.5	0.3	0.7	2	0.0	0.0	0.1	7	0.4	0.2	0.9	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Face oedema (10016029)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fatigue (10016256)	27	0.5	0.3	0.7	0	0.0	0.0	0.1	20	0.3	0.2	0.5	5	0.1	0.0	0.2	5	0.3	0.1	0.7	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeling abnormal (10016322)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeling cold (10016326)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeling hot (10016334)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gait disturbance (10017577)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Influenza like illness (10022004)	8	0.1	0.1	0.3	0	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site bruising (10022052)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Injection site erythema (10022061)	21	0.4	0.2	0.6	0	0.0	0.0	0.1	23	0.4	0.2	0.6	0	0.0	0.0	0.1	10	0.6	0.3	1.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site haemorrhage (10022067)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site hypersensitivity (10022071)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site hypoaesthesia (10074586)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site induration (10022075)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site inflammation (10022078)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site joint pain (10049261)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site movement impairment (10056250)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site nodule (10057880)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site oedema (10022085)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site pain (10022086)	80	1.4	1.1	1.7	2	0.0	0.0	0.1	74	1.2	1.0	1.5	2	0.0	0.0	0.1	39	2.5	1.8	3.4	0	0.0	0.0	0.3	2	3.4	0.4	11.7	0	0.0	0.0	5.0
	Injection site paraesthesia (10022088)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site pruritus (10022093)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site reaction (10022095)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site swelling (10053425)	16	0.3	0.2	0.4	0	0.0	0.0	0.1	16	0.3	0.2	0.4	0	0.0	0.0	0.1	7	0.4	0.2	0.9	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site warmth (10022112)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Malaise (10025482)	11	0.2	0.1	0.3	2	0.0	0.0	0.1	6	0.1	0.0	0.2	0	0.0	0.0	0.1	4	0.3	0.1	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oedema peripheral (10030124)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pain (10033371)	12	0.2	0.1	0.4	0	0.0	0.0	0.1	6	0.1	0.0	0.2	0	0.0	0.0	0.1	5	0.3	0.1	0.7	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyrexia (10037660)	74	1.3	1.0	1.6	1	0.0	0.0	0.1	35	0.6	0.4	0.8	1	0.0	0.0	0.1	6	0.4	0.1	0.8	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Reactogenicity event (10065109)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site pain (10068879)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Immune system disorders (10021428)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypersensitivity (10020751)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

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		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219			
		95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	8	0.1	0.1	0.3	3	0.1	0.0	0.2	11	0.2	0.1	0.3	0	0.0	0.0	0.1
	Bronchitis (10006451)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Candida infection (10074170)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Erysipelas (10015145)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Gastroenteritis (10017888)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Influenza (10022000)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Lower respiratory tract infection (10024968)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Nasopharyngitis (10028810)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.1
	Respiratory tract infection (10062352)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Respiratory tract infection viral (10062106)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Upper respiratory tract infection (10046306)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Viral infection (10047461)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
Injury, poisoning and procedural complications (10022117)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Vaccination complication (10046861)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
Investigations (10022891)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2
	Blood pressure increased (10005750)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Body temperature fluctuation (10063488)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Body temperature increased (10005911)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
Metabolism and nutrition disorders (10027433)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Decreased appetite (10061428)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
Musculoskeletal and connective tissue disorders (10028395)	At least one PT related to the corresponding SOC	39	0.7	0.5	0.9	2	0.0	0.0	0.1	34	0.6	0.4	0.8	4	0.1	0.0	0.2
	Arthralgia (10003239)	6	0.1	0.0	0.2	0	0.0	0.0	0.1	7	0.1	0.0	0.2	1	0.0	0.0	0.1
	Back pain (10003988)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2
	Bone disorder (10005956)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Bone pain (10006002)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Joint swelling (10023232)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Muscular weakness (10028372)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Musculoskeletal chest pain (10050819)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Musculoskeletal pain (10028391)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Myalgia (10028411)	31	0.5	0.4	0.8	1	0.0	0.0	0.1	18	0.3	0.2	0.5	2	0.0	0.0	0.1
	Neck pain (10028836)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Osteoarthritis (10031161)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2
	Pain in extremity (10033425)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.2	0.0	0.6
	Rheumatoid arthritis (10039073)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2

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Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	46	0.8	0.6	1.1	4	0.1	0.0	0.2	38	0.6	0.4	0.9	7	0.1	0.0	0.2
	Burning sensation (10006784)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Cerebral infarction (10008118)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Dizziness (10013573)	7	0.1	0.0	0.2	3	0.1	0.0	0.2	7	0.1	0.0	0.2	0	0.0	0.0	0.1
	Headache (10019211)	35	0.6	0.4	0.8	0	0.0	0.0	0.1	23	0.4	0.2	0.6	3	0.0	0.0	0.1
	Hyperaesthesia (10020568)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Lethargy (10024264)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1
	Loss of consciousness (10024855)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Migraine (10027599)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Presyncope (10036653)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Somnolence (10041349)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Syncope (10042772)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Tremor (10044565)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
Psychiatric disorders (10037175)	At least one PT related to the corresponding SOC	8	0.1	0.1	0.3	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Anxiety (10002855)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Disorientation (10013395)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Insomnia (10022437)	4	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Libido decreased (10024419)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Nightmare (10029412)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
Reproductive system and breast disorders (10038604)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Erectile dysfunction (10061461)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
Respiratory, thoracic and mediastinal disorders (10038738)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Cough (10011224)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Nasal congestion (10028735)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
Skin and subcutaneous tissue disorders (10040785)	At least one PT related to the corresponding SOC	6	0.1	0.0	0.2	1	0.0	0.0	0.1	8	0.1	0.1	0.3	1	0.0	0.0	0.1
	Blister (10005191)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Cold sweat (10009866)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Dermatitis (10012431)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Ecchymosis (10014080)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Eczema (10014184)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Erythema (10015150)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1
	Hyperhidrosis (10020642)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1
	Photosensitivity reaction (10034972)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Pruritus (10037087)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.2	0.0	0.6

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Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Psoriasis (10037153)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Rash (10037844)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5
	Rash generalised (10037858)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Rash pruritic (10037884)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Urticaria (10046735)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
Surgical and medical procedures (10042613)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Tooth extraction (10062132)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Hypotension (10021097)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects reporting the symptom at least once

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 14.3.1.31 Percentage of doses with grade 3 unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		272	2.4	2.1	2.7	18	0.2	0.1	0.3	223	1.9	1.6	2.1	26	0.2	0.1	0.3	78	2.6	2.0	3.2	8	0.3	0.1	0.6	2	1.8	0.2	6.2	1	0.7	0.0	4.1
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymphadenopathy (10025197)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Cardiac disorders (10007541)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute myocardial infarction (10000891)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arrhythmia (10003119)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Palpitations (10033557)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tachycardia (10043071)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Ear and labyrinth disorders (10013993)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Deafness neurosensory (10011891)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinnitus (10043882)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Eye disorders (10015919)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye pruritus (10052140)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ocular hyperaemia (10030041)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Gastrointestinal disorders (10017947)	At least one PT related to the corresponding SOC	19	0.2	0.1	0.3	3	0.0	0.0	0.1	14	0.1	0.1	0.2	3	0.0	0.0	0.1	5	0.2	0.1	0.4	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal pain (10000081)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal pain upper (10000087)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Colitis ulcerative (10009900)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diarrhoea (10012735)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dry mouth (10013781)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glossitis (10018386)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nausea (10028813)	10	0.1	0.0	0.2	0	0.0	0.0	0.0	7	0.1	0.0	0.1	0	0.0	0.0	0.0	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Swollen tongue (10042727)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue coated (10043945)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue ulceration (10043991)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Toothache (10044055)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vomiting (10047700)	5	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
General disorders and administration site conditions (10018065)	At least one PT related to the corresponding SOC	223	2.0	1.7	2.2	6	0.1	0.0	0.1	167	1.4	1.2	1.6	14	0.1	0.1	0.2	61	2.0	1.5	2.6	1	0.0	0.0	0.2	2	1.8	0.2	6.2	1	0.7	0.0	4.1
	Asthenia (10003549)	6	0.1	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chest pain (10008479)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chills (10008531)	38	0.3	0.2	0.5	0	0.0	0.0	0.0	32	0.3	0.2	0.4	2	0.0	0.0	0.1	7	0.2	0.1	0.5	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Face oedema (10016029)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fatigue (10016256)	27	0.2	0.2	0.3	0	0.0	0.0	0.0	22	0.2	0.1	0.3	5	0.0	0.0	0.1	6	0.2	0.1	0.4	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling abnormal (10016322)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling cold (10016326)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling hot (10016334)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gait disturbance (10017577)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Influenza like illness (10022004)	8	0.1	0.0	0.1	0	0.0	0.0	0.0	6	0.1	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site bruising (10022052)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Injection site erythema (10022061)	21	0.2	0.1	0.3	0	0.0	0.0	0.0	24	0.2	0.1	0.3	0	0.0	0.0	0.0	11	0.4	0.2	0.6	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site haemorrhage (10022067)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site hypersensitivity (10022071)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site hypoaesthesia (10074586)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site induration (10022075)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site inflammation (10022078)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site joint pain (10049261)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site movement impairment (10056250)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site nodule (10057880)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site oedema (10022085)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site pain (10022086)	82	0.7	0.6	0.9	2	0.0	0.0	0.1	77	0.7	0.5	0.8	2	0.0	0.0	0.1	43	1.4	1.0	1.9	0	0.0	0.0	0.1	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Injection site paraesthesia (10022088)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site pruritus (10022093)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site reaction (10022095)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site swelling (10053425)	16	0.1	0.1	0.2	0	0.0	0.0	0.0	16	0.1	0.1	0.2	0	0.0	0.0	0.0	8	0.3	0.1	0.5	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site warmth (10022112)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Malaise (10025482)	11	0.1	0.0	0.2	2	0.0	0.0	0.1	6	0.1	0.0	0.1	0	0.0	0.0	0.0	4	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oedema peripheral (10030124)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pain (10033371)	12	0.1	0.1	0.2	0	0.0	0.0	0.0	6	0.1	0.0	0.1	0	0.0	0.0	0.0	5	0.2	0.1	0.4	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyrexia (10037660)	79	0.7	0.6	0.9	1	0.0	0.0	0.0	35	0.3	0.2	0.4	1	0.0	0.0	0.0	6	0.2	0.1	0.4	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Reactogenicity event (10065109)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site pain (10068879)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Immune system disorders (10021428)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypersensitivity (10020751)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 11347		Placebo N = 11303		HZ/su N = 11821		Placebo N = 12204		HZ/su N = 3024		Placebo N = 2816		HZ/su N = 113		Placebo N = 135	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	8	0.1	0.0	0.1	3	0.0	0.0	0.1	11	0.1	0.0	0.2	0	0.0	0.0	0.2
	Bronchitis (10006451)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1
	Candida infection (10074170)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1
	Erysipelas (10015145)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1
	Gastroenteritis (10017888)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1
	Influenza (10022000)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1
	Lower respiratory tract infection (10024968)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2
	Nasopharyngitis (10028810)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	5	0.0	0.0	0.1	1	0.0	0.0	0.2
	Respiratory tract infection (10062352)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1
	Respiratory tract infection viral (10062106)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1
	Upper respiratory tract infection (10046306)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1
	Viral infection (10047461)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1
Injury, poisoning and procedural complications (10022117)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2
	Vaccination complication (10046861)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1
Investigations (10022891)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Blood pressure increased (10005750)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1
	Body temperature fluctuation (10063488)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1
	Body temperature increased (10005911)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1
Metabolism and nutrition disorders (10027433)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1
	Decreased appetite (10061428)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1
Musculoskeletal and connective tissue disorders (10028395)	At least one PT related to the corresponding SOC	41	0.4	0.3	0.5	2	0.0	0.0	0.1	35	0.3	0.2	0.4	4	0.0	0.0	0.1
	Arthralgia (10003239)	6	0.1	0.0	0.1	0	0.0	0.0	0.0	7	0.1	0.0	0.1	1	0.0	0.0	0.0
	Back pain (10003988)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0
	Bone disorder (10005956)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0
	Bone pain (10006002)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0
	Joint swelling (10023232)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0
	Muscular weakness (10028372)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0
	Musculoskeletal chest pain (10050819)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0
	Musculoskeletal pain (10028391)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0
	Myalgia (10028411)	33	0.3	0.2	0.4	1	0.0	0.0	0.0	18	0.2	0.1	0.2	8	0.3	0.1	0.5
	Neck pain (10028836)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0
	Osteoarthritis (10031161)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0
	Pain in extremity (10033425)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0
	Rheumatoid arthritis (10039073)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0

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		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	50	0.4	0.3	0.6	4	0.0	0.0	0.1	39	0.3	0.2	0.5	7	0.1	0.0	0.1	9	0.3	0.1	0.6	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Burning sensation (10006784)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebral infarction (10008118)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dizziness (10013573)	7	0.1	0.0	0.1	3	0.0	0.0	0.1	7	0.1	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Headache (10019211)	38	0.3	0.2	0.5	0	0.0	0.0	0.0	24	0.2	0.1	0.3	3	0.0	0.0	0.1	6	0.2	0.1	0.4	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperaesthesia (10020568)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lethargy (10024264)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Loss of consciousness (10024855)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Migraine (10027599)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Presyncope (10036653)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Somnolence (10041349)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Syncope (10042772)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tremor (10044565)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Psychiatric disorders (10037175)	At least one PT related to the corresponding SOC	8	0.1	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anxiety (10002855)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Disorientation (10013395)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Insomnia (10022437)	4	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Libido decreased (10024419)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nightmare (10029412)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Reproductive system and breast disorders (10038604)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erectile dysfunction (10061461)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Respiratory, thoracic and mediastinal disorders (10038738)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cough (10011224)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal congestion (10028735)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Skin and subcutaneous tissue disorders (10040785)	At least one PT related to the corresponding SOC	6	0.1	0.0	0.1	1	0.0	0.0	0.0	8	0.1	0.0	0.1	1	0.0	0.0	0.0	4	0.1	0.0	0.3	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blister (10005191)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cold sweat (10009866)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatitis (10012431)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ecchymosis (10014080)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eczema (10014184)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erythema (10015150)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperhidrosis (10020642)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Photosensitivity reaction (10034972)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pruritus (10037087)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

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		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Psoriasis (10037153)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash (10037844)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash generalised (10037858)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash pruritic (10037884)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urticaria (10046735)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Surgical and medical procedures (10042613)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth extraction (10062132)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypotension (10021097)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of administered doses

n/% = number/percentage of doses with the symptom

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 14.3.1.32 Global Summary of grade 3 unsolicited signs and symptoms reported with causal relationship to vaccination, within the 30-day (Days 0-29) post-vaccination period by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	252	18	207	26	69	8	2	1	530	53
Number of doses followed by at least one unsolicited symptom	272	18	223	26	78	8	2	1	575	53
Number of unsolicited symptoms classified by MedDRA Preferred Term*	464	25	367	34	141	9	4	1	976	69
Number of unsolicited symptoms reported**	465	25	367	34	141	9	4	1	977	69

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

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Table 14.3.1.33 Percentage of subjects reporting the occurrence of unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with medically attended visit, from first vaccination up to month 8 post first vaccination by frailty status (Total Vaccinated Cohort)

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	At least one symptom	1872	32.4	31.2	33.6	1957	34.1	32.9	35.4	2590	42.7	41.4	43.9	2680	43.1	41.9	44.3	817	51.9	49.4	54.4	782	53.4	50.8	56.0	20	33.9	22.1	47.4	26	36.1	25.1	48.3
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	17	0.3	0.2	0.5	11	0.2	0.1	0.3	33	0.5	0.4	0.8	37	0.6	0.4	0.8	17	1.1	0.6	1.7	22	1.5	0.9	2.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anaemia (10002034)	11	0.2	0.1	0.3	3	0.1	0.0	0.2	14	0.2	0.1	0.4	14	0.2	0.1	0.4	9	0.6	0.3	1.1	14	1.0	0.5	1.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anaemia megaloblastic (10002065)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anaemia vitamin b12 deficiency (10002080)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coagulopathy (10009802)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Disseminated intravascular coagulation (10013442)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eosinophilia (10014950)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhagic anaemia (10052293)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Heparin-induced thrombocytopenia (10062506)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hilar lymphadenopathy (10020094)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypersplenism (10020769)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypochromic anaemia (10020969)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Immune thrombocytopenic purpura (10074667)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Increased tendency to bruise (10021688)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Iron deficiency anaemia (10022972)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.2	8	0.1	0.1	0.3	5	0.3	0.1	0.7	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Leukopenia (10024384)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymphadenitis (10025188)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymphadenopathy (10025197)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Macrocytosis (10025382)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Microcytic anaemia (10027538)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Nephrogenic anaemia (10058116)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Normochromic normocytic anaemia (10029783)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Splenic cyst (10051169)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Splenic infarction (10041648)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombocytopenia (10043554)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombocytosis (10043563)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Cardiac disorders (10007541)	At least one PT related to the corresponding SOC	68	1.2	0.9	1.5	57	1.0	0.8	1.3	151	2.5	2.1	2.9	157	2.5	2.1	2.9	71	4.5	3.5	5.7	93	6.4	5.2	7.7	2	3.4	0.4	11.7	1	1.4	0.0	7.5
	Acute coronary syndrome (10051592)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute myocardial infarction (10000891)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	6	0.1	0.0	0.2	10	0.2	0.1	0.3	4	0.3	0.1	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Angina pectoris (10002383)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	5	0.1	0.0	0.2	10	0.2	0.1	0.3	8	0.5	0.2	1.0	10	0.7	0.3	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Angina unstable (10002388)	4	0.1	0.0	0.2	0	0.0	0.0	0.1	5	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic valve disease (10061589)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic valve incompetence (10002915)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic valve sclerosis (10002917)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic valve stenosis (10002918)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arrhythmia (10003119)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	22	0.4	0.2	0.5	14	0.2	0.1	0.4	4	0.3	0.1	0.6	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arrhythmia supraventricular (10003130)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arteriosclerosis coronary artery (10003211)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrial fibrillation (10003658)	10	0.2	0.1	0.3	9	0.2	0.1	0.3	31	0.5	0.3	0.7	28	0.5	0.3	0.7	12	0.8	0.4	1.3	17	1.2	0.7	1.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrial flutter (10003662)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.1	0.0	0.5	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrioventricular block (10003671)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Atrioventricular block complete (10003673)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrioventricular block first degree (10003674)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrioventricular block second degree (10003677)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bradycardia (10049765)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bradycardia (10006093)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	4	0.1	0.0	0.2	6	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bundle branch block right (10006582)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Cardiac aneurysm (10007513)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac arrest (10007515)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac discomfort (10054211)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac disorder (10061024)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Cardiac failure (10007554)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	13	0.2	0.1	0.4	16	0.3	0.1	0.4	10	0.6	0.3	1.2	13	0.9	0.5	1.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac failure acute (10007556)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac failure chronic (10007558)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac failure congestive (10007559)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	11	0.2	0.1	0.3	11	0.7	0.3	1.2	11	0.8	0.4	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac flutter (10052840)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac valve disease (10061406)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardio-respiratory arrest (10007617)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiogenic shock (10007625)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiomegaly (10007632)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiomyopathy (10007636)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiovascular disorder (10007649)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Chronotropic incompetence (10068627)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Congestive cardiomyopathy (10056370)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cor pulmonale (10010968)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coronary artery disease (10011078)	3	0.1	0.0	0.2	6	0.1	0.0	0.2	13	0.2	0.1	0.4	10	0.2	0.1	0.3	13	0.8	0.4	1.4	11	0.8	0.4	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coronary artery occlusion (10011086)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coronary artery stenosis (10011089)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diastolic dysfunction (10052337)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Extrasystoles (10015856)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Heart valve incompetence (10067660)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertensive heart disease (10020823)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intracardiac thrombus (10048620)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Ischaemic cardiomyopathy (10048858)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Left ventricular dysfunction (10049694)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Left ventricular failure (10024119)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Left ventricular hypertrophy (10049773)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mitral valve disease (10061532)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mitral valve incompetence (10027727)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mitral valve prolapse (10027730)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myocardial infarction (10028596)	2	0.0	0.0	0.1	6	0.1	0.0	0.2	9	0.1	0.1	0.3	9	0.1	0.1	0.3	8	0.5	0.2	1.0	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myocardial ischaemia (10028600)	5	0.1	0.0	0.2	3	0.1	0.0	0.2	11	0.2	0.1	0.3	14	0.2	0.1	0.4	4	0.3	0.1	0.6	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myocarditis (10028606)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Palpitations (10033557)	10	0.2	0.1	0.3	3	0.1	0.0	0.2	5	0.1	0.0	0.2	8	0.1	0.1	0.3	2	0.1	0.0	0.5	2	0.1	0.0	0.5	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Pericardial haemorrhage (10034476)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pericarditis (10034484)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Right ventricular failure (10039163)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinus bradycardia (10040741)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinus node dysfunction (10075889)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Supraventricular extrasystoles (10042602)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Supraventricular tachycardia (10042604)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tachyarrhythmia (10049447)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tachycardia (10043071)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	5	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tachycardia paroxysmal (10043079)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tricuspid valve incompetence (10044640)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ventricular arrhythmia (10047281)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ventricular extrasystoles (10047289)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Ventricular fibrillation (10047290)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ventricular tachycardia (10047302)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Congenital, familial and genetic disorders (10010331)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Birth mark (10004950)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Congenital cystic kidney disease (10010428)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Corneal dystrophy (10011005)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertrophic cardiomyopathy (10020871)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lipidosis (10024585)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malformation venous (10025532)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Phimosis (10034878)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spina bifida occulta (10041525)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thyroglossal cyst (10051320)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Ear and labyrinth disorders (10013993)	At least one PT related to the corresponding SOC	44	0.8	0.6	1.0	54	0.9	0.7	1.2	101	1.7	1.4	2.0	102	1.6	1.3	2.0	23	1.5	0.9	2.2	31	2.1	1.4	3.0	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Cerumen impaction (10050337)	4	0.1	0.0	0.2	7	0.1	0.0	0.3	20	0.3	0.2	0.5	8	0.1	0.1	0.3	4	0.3	0.1	0.6	5	0.3	0.1	0.8	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Cupulolithiasis (10056454)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Deafness (10011878)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.1	0.0	0.2	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Deafness bilateral (10052556)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Deafness neurosensory (10011891)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Deafness unilateral (10048812)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ear discomfort (10052137)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ear disorder (10014004)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ear haemorrhage (10014009)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ear pain (10014020)	1	0.0	0.0	0.1	4	0.1	0.0	0.2	8	0.1	0.1	0.3	8	0.1	0.1	0.3	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ear pruritus (10052138)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ear swelling (10014025)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eustachian tube disorder (10061462)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eustachian tube obstruction (10015544)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eustachian tube stenosis (10067764)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

22-OCT-2019

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CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hearing impaired (10019245)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypoacusis (10048865)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	8	0.1	0.1	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Inner ear disorder (10061524)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meniere's disease (10027183)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Middle ear effusion (10062545)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Middle ear inflammation (10065838)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mixed deafness (10027757)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Motion sickness (10027990)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neurosensory hypoacusis (10067587)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Presbycusis (10036626)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sudden hearing loss (10061373)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinnitus (10043882)	5	0.1	0.0	0.2	10	0.2	0.1	0.3	10	0.2	0.1	0.3	14	0.2	0.1	0.4	6	0.4	0.1	0.8	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tympanic membrane perforation (10045210)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vertigo (10047340)	17	0.3	0.2	0.5	18	0.3	0.2	0.5	43	0.7	0.5	1.0	42	0.7	0.5	0.9	8	0.5	0.2	1.0	12	0.8	0.4	1.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vertigo positional (10047348)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	2	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vestibular disorder (10047386)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Endocrine disorders (10014698)	At least one PT related to the corresponding SOC	16	0.3	0.2	0.4	15	0.3	0.1	0.4	19	0.3	0.2	0.5	21	0.3	0.2	0.5	7	0.4	0.2	0.9	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Androgen deficiency (10002261)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Autoimmune thyroiditis (10049046)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Basedow's disease (10004161)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetes insipidus (10012599)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Goitre (10018498)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperparathyroidism (10020705)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperthyroidism (10020850)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypogonadism (10058359)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypopituitarism (10021067)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypothyroidism (10021114)	11	0.2	0.1	0.3	9	0.2	0.1	0.3	12	0.2	0.1	0.3	12	0.2	0.1	0.3	5	0.3	0.1	0.7	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Primary hyperaldosteronism (10036692)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thyroid cyst (10043706)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thyroiditis (10043778)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thyroiditis subacute (10043784)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Eye disorders (10015919)	At least one PT related to the corresponding SOC	86	1.5	1.2	1.8	82	1.4	1.1	1.8	119	2.0	1.6	2.3	136	2.2	1.8	2.6	47	3.0	2.2	4.0	33	2.3	1.6	3.2	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Acquired corneal dystrophy (10065058)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Age-related macular degeneration (10064930)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Amaurosis (10001902)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Asthenopia (10003552)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	6	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blepharitis (10005148)	1	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.0	0.0	0.1	8	0.1	0.1	0.3	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blepharitis allergic (10005149)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cataract (10007739)	18	0.3	0.2	0.5	23	0.4	0.3	0.6	28	0.5	0.3	0.7	40	0.6	0.5	0.9	14	0.9	0.5	1.5	14	1.0	0.5	1.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cataract nuclear (10007759)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chalazion (10008388)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chorioretinal atrophy (10008762)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chorioretinopathy (10063118)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Choroidal effusion (10063970)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Conjunctival degeneration (10010705)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Conjunctival haemorrhage (10010719)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	6	0.1	0.0	0.2	10	0.2	0.1	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Conjunctival hyperaemia (10051625)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Conjunctivitis allergic (10010744)	3	0.1	0.0	0.2	4	0.1	0.0	0.2	8	0.1	0.1	0.3	6	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Corneal erosion (10011013)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Corneal irritation (10056476)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dacryostenosis acquired (10053990)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic retinopathy (10012689)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diplopia (10013036)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dry age-related macular degeneration (10075567)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dry eye (10013774)	11	0.2	0.1	0.3	3	0.1	0.0	0.2	6	0.1	0.0	0.2	15	0.2	0.1	0.4	4	0.3	0.1	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eczema eyelids (10014194)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Enophthalmos (10014853)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Entropion (10061842)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Episcleritis (10015084)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erythema of eyelid (10015237)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye allergy (10015907)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye discharge (10015915)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Eye disorder (10015916)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye haemorrhage (10015926)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye inflammation (10015943)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye irritation (10015946)	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye pain (10015958)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye pruritus (10052140)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye swelling (10015967)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eyelid cyst (10063692)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eyelid dermatochalasis (10075309)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eyelid disorder (10061130)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eyelid oedema (10015993)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Eyelid ptosis (10015995)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Foreign body sensation in eyes (10051116)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glaucoma (10018304)	4	0.1	0.0	0.2	4	0.1	0.0	0.2	7	0.1	0.0	0.2	10	0.2	0.1	0.3	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Iridocyclitis (10022941)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Keratitis (10023332)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lacrimal disorder (10061525)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lacrimation decreased (10023642)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lacrimation increased (10023644)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lens dislocation (10024203)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Macular cyst (10025407)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Macular degeneration (10025409)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	7	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Macular fibrosis (10071392)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Macular hole (10051058)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Macular oedema (10025415)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Macular scar (10063185)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Maculopathy (10025425)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myopia (10028651)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Narrow anterior chamber angle (10068960)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neovascular age-related macular degeneration (10071129)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ocular discomfort (10052143)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ocular hyperaemia (10030041)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Ocular hypertension (10030043)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ocular myasthenia (10049168)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ocular vascular disorder (10052896)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Open angle glaucoma (10030348)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ophthalmic vein thrombosis (10074349)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Optic ischaemic neuropathy (10030924)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Panophthalmitis (10033683)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Parophthalmia (10059407)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Photopsia (10034962)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Posterior capsule opacification (10036346)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Presbyopia (10036628)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinal artery thrombosis (10038831)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinal degeneration (10038845)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinal detachment (10038848)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinal disorder (10038853)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinal haemorrhage (10038867)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinal tear (10038897)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinal vein occlusion (10038907)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinopathy (10038923)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinopathy hypertensive (10038926)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Trichiasis (10044604)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ulcerative keratitis (10064996)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Uveitis (10046851)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vision blurred (10047513)	4	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Visual acuity reduced (10047531)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Visual impairment (10047571)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vitreous degeneration (10047649)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vitreous detachment (10047650)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vitreous floaters (10047654)	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Vitreous haemorrhage (10047655)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vitreous opacities (10047658)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Xerophthalmia (10048221)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	At least one PT related to the corresponding SOC	223	3.9	3.4	4.4	268	4.7	4.1	5.3	379	6.2	5.6	6.9	390	6.3	5.7	6.9	118	7.5	6.2	8.9	132	9.0	7.6	10.6	3	5.1	1.1	14.1	3	4.2	0.9	11.7
Gastrointestinal disorders (10017947)	Abdominal discomfort (10000059)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.1	0.0	0.2	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal distension (10000060)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal hernia (10060954)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal mass (10000077)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal pain (10000081)	10	0.2	0.1	0.3	12	0.2	0.1	0.4	23	0.4	0.2	0.6	18	0.3	0.2	0.5	9	0.6	0.3	1.1	11	0.8	0.4	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal pain lower (10000084)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	4	0.3	0.1	0.7	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Abdominal pain upper (10000087)	12	0.2	0.1	0.4	23	0.4	0.3	0.6	25	0.4	0.3	0.6	26	0.4	0.3	0.6	9	0.6	0.3	1.1	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal strangulated hernia (10053203)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acid peptic disease (10075494)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aerophagia (10052813)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal fissure (10002153)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal fistula (10002156)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal haemorrhage (10049555)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal inflammation (10050247)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal polyp (10002168)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal prolapse (10065360)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal pruritus (10068172)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aphthous stomatitis (10002958)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ascites (10003445)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Barrett's oesophagus (10004137)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Change of bowel habit (10008399)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cheilitis (10008417)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic gastritis (10008882)	5	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coeliac disease (10009839)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colitis (10009887)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colitis ischaemic (10009895)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colitis microscopic (10056979)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Colitis ulcerative (10009900)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Constipation (10010774)	8	0.1	0.1	0.3	13	0.2	0.1	0.4	33	0.5	0.4	0.8	28	0.5	0.3	0.7	13	0.8	0.4	1.4	15	1.0	0.6	1.7	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Crohn's disease (10011401)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dental alveolar anomaly (10012316)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dental caries (10012318)	5	0.1	0.0	0.2	8	0.1	0.1	0.3	5	0.1	0.0	0.2	8	0.1	0.1	0.3	1	0.1	0.0	0.4	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Dental necrosis (10012327)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diaphragmatic hernia (10012713)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diarrhoea (10012735)	18	0.3	0.2	0.5	29	0.5	0.3	0.7	36	0.6	0.4	0.8	44	0.7	0.5	0.9	12	0.8	0.4	1.3	17	1.2	0.7	1.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diverticular perforation (10061820)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diverticulum (10013554)	7	0.1	0.0	0.2	2	0.0	0.0	0.1	5	0.1	0.0	0.2	5	0.1	0.0	0.2	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diverticulum intestinal (10013559)	0	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	6	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dry mouth (10013781)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Duodenal ulcer (10013836)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dyspepsia (10013946)	14	0.2	0.1	0.4	8	0.1	0.1	0.3	20	0.3	0.2	0.5	28	0.5	0.3	0.7	5	0.3	0.1	0.7	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysphagia (10013950)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Enteritis (10014866)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Enterovesical fistula (10062570)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epigastric discomfort (10053155)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erosive oesophagitis (10063655)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Faecal incontinence (10016092)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Faecaloma (10056325)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Faeces discoloured (10016100)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Faeces pale (10016102)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Flatulence (10016766)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Food poisoning (10016952)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Functional gastrointestinal disorder (10071275)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric dilatation (10017779)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric disorder (10056819)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric polyps (10017817)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric ulcer (10017822)	3	0.1	0.0	0.2	4	0.1	0.0	0.2	7	0.1	0.0	0.2	5	0.1	0.0	0.2	6	0.4	0.1	0.8	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric ulcer haemorrhage (10017826)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastritis (10017853)	9	0.2	0.1	0.3	18	0.3	0.2	0.5	39	0.6	0.5	0.9	30	0.5	0.3	0.7	4	0.3	0.1	0.6	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastritis alcoholic (10017856)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Gastritis erosive (10017865)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastritis haemorrhagic (10017866)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastroduodenitis (10048714)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal angiodysplasia (10017928)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal disorder (10017944)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Gastrointestinal haemorrhage (10017955)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal motility disorder (10061173)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal sounds abnormal (10067715)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastroesophageal heterotopia (10051335)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastroesophageal reflux disease (10017885)	17	0.3	0.2	0.5	22	0.4	0.2	0.6	23	0.4	0.2	0.6	29	0.5	0.3	0.7	9	0.6	0.3	1.1	7	0.5	0.2	1.0	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Gastroesophageal sphincter insufficiency (10062879)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gingival bleeding (10018276)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gingival blister (10049304)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gingival disorder (10018280)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gingival pain (10018286)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gingival swelling (10018291)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glossitis (10018386)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glossodynia (10018388)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haematemesis (10018830)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haematochezia (10018836)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhoidal haemorrhage (10054787)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhoids (10019022)	12	0.2	0.1	0.4	23	0.4	0.3	0.6	26	0.4	0.3	0.6	22	0.4	0.2	0.5	8	0.5	0.2	1.0	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhoids thrombosed (10019023)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hiatus hernia (10020028)	6	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.0	0.0	0.1	8	0.1	0.1	0.3	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypoesthesia oral (10057371)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ileus (10021328)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Impaired gastric emptying (10021518)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Incarcerated umbilical hernia (10064492)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Inguinal hernia (10022016)	7	0.1	0.0	0.2	6	0.1	0.0	0.2	8	0.1	0.1	0.3	11	0.2	0.1	0.3	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal cyst (10062023)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal haemorrhage (10059175)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal mass (10059017)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal obstruction (10022687)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal perforation (10022694)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal polyp (10048616)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal prolapse (10056990)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Irritable bowel syndrome (10023003)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.1	0.0	0.2	5	0.1	0.0	0.2	3	0.2	0.0	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Large intestine perforation (10023804)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Large intestine polyp (10051589)	8	0.1	0.1	0.3	8	0.1	0.1	0.3	6	0.1	0.0	0.2	13	0.2	0.1	0.4	2	0.1	0.0	0.5	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip blister (10049307)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip oedema (10024558)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip pain (10024561)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip swelling (10024570)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip ulceration (10024572)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Loose tooth (10065612)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lumbar hernia (10024995)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mallory-weiss syndrome (10026712)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Melanosis coli (10027158)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mesenteritis (10069665)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mouth cyst (10028020)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mouth haemorrhage (10028024)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mouth ulceration (10028034)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	6	0.1	0.0	0.2	11	0.2	0.1	0.3	2	0.1	0.0	0.5	4	0.3	0.1	0.7	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Nausea (10028813)	12	0.2	0.1	0.4	9	0.2	0.1	0.3	7	0.1	0.0	0.2	18	0.3	0.2	0.5	5	0.3	0.1	0.7	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Noninfective gingivitis (10074863)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Noninfective sialadenitis (10075243)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Odynophagia (10030094)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal discomfort (10053634)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Oesophageal disorder (10061318)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal haemorrhage (10030172)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal spasm (10030184)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal ulcer (10030201)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal ulcer haemorrhage (10030202)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophagitis (10030216)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.2	4	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral disorder (10067621)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral lichen planus (10030983)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral mucosal blistering (10030995)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral mucosal erythema (10067418)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral pain (10031009)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Palatal oedema (10056998)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatic cyst (10033615)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatic disorder (10033616)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatic steatosis (10072787)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatitis (10033645)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatitis acute (10033647)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.3	0.1	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Parotid duct obstruction (10034021)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peptic ulcer (10034341)	1	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	7	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peptic ulcer haemorrhage (10034344)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Periodontal disease (10034536)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peritoneal cyst (10051942)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Portal hypertensive gastropathy (10050897)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Proctalgia (10036772)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Proctitis (10036774)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Proctitis ulcerative (10036783)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal haemorrhage (10038063)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	7	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal polyp (10038074)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal prolapse (10038077)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Reflux gastritis (10057969)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retching (10038776)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Retroperitoneal haemorrhage (10038980)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Salivary gland calculus (10039394)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Salivary gland cyst (10052248)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Salivary gland mucocoele (10060870)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Salivary hypersecretion (10039424)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Small intestinal obstruction (10041101)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Stomatitis (10042128)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Subileus (10050396)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Swollen tongue (10042727)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombosis mesenteric vessel (10043626)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue blistering (10043942)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue disorder (10043951)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue eruption (10052002)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue geographic (10043957)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue oedema (10043967)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue pruritus (10070072)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue ulceration (10043991)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth deposit (10044029)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth disorder (10044034)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth erosion (10044038)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth impacted (10044042)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Toothache (10044055)	22	0.4	0.2	0.6	27	0.5	0.3	0.7	23	0.4	0.2	0.6	21	0.3	0.2	0.5	2	0.1	0.0	0.5	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Umbilical hernia (10045458)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Upper gastrointestinal haemorrhage (10046274)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vomiting (10047700)	7	0.1	0.0	0.2	7	0.1	0.0	0.3	5	0.1	0.0	0.2	11	0.2	0.1	0.3	7	0.4	0.2	0.9	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
General disorders and administration site conditions (10018065)	At least one PT related to the corresponding SOC	133	2.3	1.9	2.7	78	1.4	1.1	1.7	194	3.2	2.8	3.7	155	2.5	2.1	2.9	72	4.6	3.6	5.7	58	4.0	3.0	5.1	0	0.0	0.0	6.1	3	4.2	0.9	11.7
	Abasia (10049460)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Administration site erythema (10074796)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Administration site pain (10058049)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Adverse drug reaction (10061623)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Asthenia (10003549)	5	0.1	0.0	0.2	4	0.1	0.0	0.2	10	0.2	0.1	0.3	10	0.2	0.1	0.3	6	0.4	0.1	0.8	5	0.3	0.1	0.8	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Axillary pain (10048750)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Calcinosis (10006938)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chest discomfort (10008469)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chest pain (10008479)	22	0.4	0.2	0.6	13	0.2	0.1	0.4	33	0.5	0.4	0.8	40	0.6	0.5	0.9	9	0.6	0.3	1.1	10	0.7	0.3	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chills (10008531)	4	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic fatigue syndrome (10008874)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cyst (10011732)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	4	0.1	0.0	0.2	7	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Death (10011906)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Device battery issue (10071172)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Device breakage (10012575)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Device malfunction (10063829)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Device occlusion (10064685)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Discomfort (10013082)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Drug intolerance (10061822)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Drug withdrawal syndrome (10013754)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Face oedema (10016029)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Facial pain (10016059)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fatigue (10016256)	11	0.2	0.1	0.3	2	0.0	0.0	0.1	14	0.2	0.1	0.4	18	0.3	0.2	0.5	3	0.2	0.0	0.6	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeling abnormal (10016322)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeling cold (10016326)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeling hot (10016334)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gait disturbance (10017577)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	General physical health deterioration (10049438)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Generalised oedema (10018092)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hernia (10019909)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ill-defined disorder (10061520)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Incarcerated hernia (10021610)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Inflammation (10061218)	4	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Inflammatory pain (10065390)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Influenza like illness (10022004)	11	0.2	0.1	0.3	8	0.1	0.1	0.3	7	0.1	0.0	0.2	8	0.1	0.1	0.3	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site erythema (10022061)	9	0.2	0.1	0.3	0	0.0	0.0	0.1	14	0.2	0.1	0.4	0	0.0	0.0	0.1	5	0.3	0.1	0.7	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Injection site haematoma (10022066)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site haemorrhage (10022067)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site hypersensitivity (10022071)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site induration (10022075)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site inflammation (10022078)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site joint pain (10049261)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site mass (10022081)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site nodule (10057880)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site oedema (10022085)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site pain (10022086)	20	0.3	0.2	0.5	1	0.0	0.0	0.1	26	0.4	0.3	0.6	0	0.0	0.0	0.1	7	0.4	0.2	0.9	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site pruritus (10022093)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site rash (10022094)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site swelling (10053425)	9	0.2	0.1	0.3	0	0.0	0.0	0.1	8	0.1	0.1	0.3	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site urticaria (10022107)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site warmth (10022112)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injury associated with device (10069803)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Local swelling (10024770)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malaise (10025482)	2	0.0	0.0	0.1	5	0.1	0.0	0.2	6	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Medical device complication (10057281)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metaplasia (10054949)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mucous membrane disorder (10028133)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Multi-organ failure (10028154)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nodule (10054107)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Non-cardiac chest pain (10062501)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oedema (10030095)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oedema peripheral (10030124)	7	0.1	0.0	0.2	2	0.0	0.0	0.1	20	0.3	0.2	0.5	20	0.3	0.2	0.5	10	0.6	0.3	1.2	9	0.6	0.3	1.2	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Organ failure (10053159)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pain (10033371)	6	0.1	0.0	0.2	4	0.1	0.0	0.2	10	0.2	0.1	0.3	4	0.1	0.0	0.2	5	0.3	0.1	0.7	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pelvic mass (10034260)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Peripheral swelling (10048959)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.1	0.0	0.5	6	0.4	0.2	0.9	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Polyp (10061529)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyrexia (10037660)	27	0.5	0.3	0.7	12	0.2	0.1	0.4	23	0.4	0.2	0.6	16	0.3	0.1	0.4	12	0.8	0.4	1.3	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Strangulated hernia (10042166)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sudden death (10042434)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Swelling (10042674)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Systemic inflammatory response syndrome (10051379)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thirst (10043458)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombosis in device (10062546)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ulcer haemorrhage (10061577)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site erythema (10059079)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site pain (10068879)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site reaction (10059080)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination site swelling (10069620)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Xerosis (10048222)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Hepatobiliary disorders (10019805)	At least one PT related to the corresponding SOC	15	0.3	0.1	0.4	20	0.3	0.2	0.5	27	0.4	0.3	0.6	47	0.8	0.6	1.0	9	0.6	0.3	1.1	15	1.0	0.6	1.7	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Bile duct obstruction (10056375)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bile duct stenosis (10051341)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bile duct stone (10004637)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Biliary colic (10004663)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Biliary dilatation (10057202)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Biliary tract disorder (10061008)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholangitis (10008604)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholangitis acute (10008605)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholecystitis (10008612)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	5	0.1	0.0	0.2	6	0.1	0.0	0.2	1	0.1	0.0	0.4	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholecystitis acute (10008614)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholecystitis chronic (10008617)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholelithiasis (10008629)	3	0.1	0.0	0.2	9	0.2	0.1	0.3	5	0.1	0.0	0.2	20	0.3	0.2	0.5	7	0.4	0.2	0.9	6	0.4	0.2	0.9	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Chronic hepatitis (10008909)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cirrhosis alcoholic (10009208)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gallbladder disorder (10017626)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gallbladder polyp (10049704)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic cirrhosis (10019641)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic cyst (10019646)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hepatic function abnormal (10019670)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic lesion (10061998)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic steatosis (10019708)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatitis (10019717)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatotoxicity (10019851)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperbilirubinaemia (10020578)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertransaminasaemia (10068237)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Jaundice cholestatic (10023129)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Liver disorder (10024670)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Immune system disorders (10021428)	At least one PT related to the corresponding SOC	10	0.2	0.1	0.3	21	0.4	0.2	0.6	20	0.3	0.2	0.5	19	0.3	0.2	0.5	7	0.4	0.2	0.9	6	0.4	0.2	0.9	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Allergy to arthropod bite (10058285)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Allergy to arthropod sting (10058284)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Allergy to plants (10054928)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Amyloidosis (10002022)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anaphylactic reaction (10002198)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Atopy (10003645)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Contrast media allergy (10066973)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Drug hypersensitivity (10013700)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Food allergy (10016946)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypersensitivity (10020751)	2	0.0	0.0	0.1	11	0.2	0.1	0.3	10	0.2	0.1	0.3	8	0.1	0.1	0.3	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Milk allergy (10027633)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Multiple allergies (10028164)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mycotic allergy (10052758)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sarcoidosis (10039486)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Seasonal allergy (10048908)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	7	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	815	14.1	13.2	15.0	830	14.5	13.6	15.4	1073	17.7	16.7	18.7	1102	17.7	16.8	18.7	336	21.4	19.4	23.5	354	24.2	22.0	26.5	7	11.9	4.9	22.9	7	9.7	4.0	19.0
	Abdominal abscess (10060921)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal infection (10056519)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal wall abscess (10000099)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abscess (10000269)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Abscess jaw (10053573)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abscess limb (10050473)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abscess oral (10000311)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acarodermatitis (10063409)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute sinusitis (10001076)	1	0.0	0.0	0.1	4	0.1	0.0	0.2	5	0.1	0.0	0.2	5	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute tonsillitis (10001093)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Alcaligenes infection (10068911)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Alveolar osteitis (10066995)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	American trypanosomiasis (10001935)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal abscess (10048946)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anorectal cellulitis (10002643)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Appendiceal abscess (10049764)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Appendicitis (10003011)	0	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Appendicitis perforated (10003012)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arteriosclerotic gangrene (10003222)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthritis bacterial (10053555)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthritis infective (10060968)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bacteraemia (10003997)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bacterial infection (10060945)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bacteriuria (10004056)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Balanitis candida (10004074)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Biliary tract infection (10061695)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blastocystis infection (10005092)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Body tinea (10005913)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Borrelia infection (10061591)	7	0.1	0.0	0.2	10	0.2	0.1	0.3	1	0.0	0.0	0.1	6	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast abscess (10006171)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchiolitis (10006448)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchitis (10006451)	55	1.0	0.7	1.2	68	1.2	0.9	1.5	139	2.3	1.9	2.7	122	2.0	1.6	2.3	47	3.0	2.2	4.0	46	3.1	2.3	4.2	0	0.0	0.0	6.1	2	2.8	0.3	9.7
	Bronchitis bacterial (10061736)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchitis viral (10053160)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchopneumonia (10006469)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Candida infection (10074170)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	6	0.1	0.0	0.2	5	0.3	0.1	0.7	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Candida sepsis (10053166)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carbuncle (10007247)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Catheter site infection (10056520)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Cellulitis (10007882)	9	0.2	0.1	0.3	10	0.2	0.1	0.3	17	0.3	0.2	0.4	25	0.4	0.3	0.6	5	0.3	0.1	0.7	18	1.2	0.7	1.9	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Cellulitis orbital (10007918)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervicitis (10008323)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholecystitis infective (10062631)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chorioretinitis (10008769)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic hepatitis b (10008910)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic sinusitis (10009137)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Clostridium difficile colitis (10009657)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Clostridium difficile infection (10054236)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Conjunctivitis (10010741)	16	0.3	0.2	0.4	16	0.3	0.2	0.5	24	0.4	0.3	0.6	46	0.7	0.5	1.0	19	1.2	0.7	1.9	16	1.1	0.6	1.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cutaneous tuberculosis (10011684)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cystitis (10011781)	30	0.5	0.4	0.7	28	0.5	0.3	0.7	45	0.7	0.5	1.0	44	0.7	0.5	0.9	10	0.6	0.3	1.2	10	0.7	0.3	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cystitis klebsiella (10011797)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dacryocanaliculitis (10011843)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dacryocystitis (10011844)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dengue fever (10012310)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dental fistula (10065268)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatophytosis (10012504)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Device related infection (10064687)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic foot infection (10060803)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic gangrene (10012665)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diarrhoea infectious (10012742)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diverticulitis (10013538)	6	0.1	0.0	0.2	8	0.1	0.1	0.3	7	0.1	0.0	0.2	8	0.1	0.1	0.3	6	0.4	0.1	0.8	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ear infection (10014011)	10	0.2	0.1	0.3	17	0.3	0.2	0.5	20	0.3	0.2	0.5	12	0.2	0.1	0.3	7	0.4	0.2	0.9	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eczema impetiginous (10051890)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eczema infected (10014199)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Empyema (10014568)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Encephalitis viral (10014612)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Encephalomyelitis (10014619)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Endocarditis (10014665)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Endometritis (10014791)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Endophthalmitis (10014801)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Enteritis infectious (10058839)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Enterobiasis (10014881)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epididymitis (10015000)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erysipelas (10015145)	0	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	5	0.1	0.0	0.2	6	0.4	0.1	0.8	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erythema infectiosum (10015214)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erythema migrans (10062488)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Escherichia infection (10061126)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Escherichia sepsis (10015296)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Escherichia urinary tract infection (10052238)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	External ear cellulitis (10015729)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Extrapulmonary tuberculosis (10064445)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye infection (10015929)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye infection bacterial (10015930)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eyelid infection (10015988)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Folliculitis (10016936)	10	0.2	0.1	0.3	5	0.1	0.0	0.2	8	0.1	0.1	0.3	8	0.1	0.1	0.3	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fungal infection (10017533)	5	0.1	0.0	0.2	5	0.1	0.0	0.2	7	0.1	0.0	0.2	5	0.1	0.0	0.2	1	0.1	0.0	0.4	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fungal skin infection (10017543)	3	0.1	0.0	0.2	6	0.1	0.0	0.2	7	0.1	0.0	0.2	5	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Furuncle (10017553)	1	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gangrene (10017711)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric infection (10056663)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastritis viral (10051791)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastroenteritis (10017888)	28	0.5	0.3	0.7	28	0.5	0.3	0.7	39	0.6	0.5	0.9	38	0.6	0.4	0.8	10	0.6	0.3	1.2	12	0.8	0.4	1.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastroenteritis clostridial (10017898)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastroenteritis salmonella (10017914)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastroenteritis viral (10017918)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal fungal infection (10049479)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Genital abscess (10062316)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Genital candidiasis (10018143)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Genital herpes (10018150)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Genital infection (10048461)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Genital infection fungal (10061180)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gingival abscess (10052359)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gingivitis (10018292)	9	0.2	0.1	0.3	14	0.2	0.1	0.4	3	0.0	0.0	0.1	8	0.1	0.1	0.3	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gonorrhoea (10018612)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Graft infection (10056559)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Groin abscess (10050269)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Groin infection (10050821)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	H1n1 influenza (10069767)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haematoma infection (10051564)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhoid infection (10051541)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Helicobacter gastritis (10054272)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Helicobacter infection (10054263)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic infection (10056522)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatitis a (10019719)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatitis b (10019731)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Herpangina (10019936)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Herpes simplex (10019948)	6	0.1	0.0	0.2	8	0.1	0.1	0.3	7	0.1	0.0	0.2	4	0.1	0.0	0.2	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Herpes zoster (10019974)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Herpes zoster disseminated (10065038)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Herpes zoster oticus (10063491)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hordeolum (10020377)	2	0.0	0.0	0.1	6	0.1	0.0	0.2	4	0.1	0.0	0.2	4	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Impetigo (10021531)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infected bites (10021769)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infected cyst (10058015)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infected dermal cyst (10071367)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infected skin ulcer (10021784)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infected varicose vein (10057258)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infection (10021789)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infection parasitic (10021857)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infectious colitis (10021905)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Infective exacerbation of chronic obstructive airways disease (10056971)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infective glossitis (10070963)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Influenza (10022000)	24	0.4	0.3	0.6	21	0.4	0.2	0.6	14	0.2	0.1	0.4	29	0.5	0.3	0.7	6	0.4	0.1	0.8	10	0.7	0.3	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site cellulitis (10050057)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injection site infection (10022076)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal gangrene (10022651)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Kidney infection (10023424)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Klebsiella bacteraemia (10058856)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Klebsiella sepsis (10054160)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Labyrinthitis (10023567)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	8	0.1	0.1	0.3	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Laryngitis (10023874)	6	0.1	0.0	0.2	8	0.1	0.1	0.3	9	0.1	0.1	0.3	7	0.1	0.0	0.2	4	0.3	0.1	0.6	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Liver abscess (10024652)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lobar pneumonia (10024738)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Localised infection (10024774)	5	0.1	0.0	0.2	6	0.1	0.0	0.2	9	0.1	0.1	0.3	8	0.1	0.1	0.3	4	0.3	0.1	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Lower respiratory tract infection (10024968)	12	0.2	0.1	0.4	15	0.3	0.1	0.4	34	0.6	0.4	0.8	34	0.5	0.4	0.8	22	1.4	0.9	2.1	17	1.2	0.7	1.9	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Lung abscess (10025028)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung infection (10061229)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lyme disease (10025169)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymph node tuberculosis (10025183)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymphangitis (10025226)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mastitis (10026883)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mastoiditis (10026900)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meningitis (10027199)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meningitis pneumococcal (10027253)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nail infection (10061304)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal abscess (10028720)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal herpes (10074936)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasopharyngitis (10028810)	167	2.9	2.5	3.4	200	3.5	3.0	4.0	207	3.4	3.0	3.9	220	3.5	3.1	4.0	49	3.1	2.3	4.1	41	2.8	2.0	3.8	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Neuroborreliosis (10052057)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neutropenic sepsis (10049151)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal candidiasis (10030154)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Omphalitis (10030306)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Onychomycosis (10030338)	14	0.2	0.1	0.4	13	0.2	0.1	0.4	17	0.3	0.2	0.4	23	0.4	0.2	0.6	4	0.3	0.1	0.6	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ophthalmic herpes simplex (10073938)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ophthalmic herpes zoster (10030865)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral candidiasis (10030963)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral fungal infection (10061324)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral herpes (10067152)	10	0.2	0.1	0.3	9	0.2	0.1	0.3	9	0.1	0.1	0.3	9	0.1	0.1	0.3	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral infection (10048685)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Orchitis (10031064)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oropharyngeal candidiasis (10050346)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteomyelitis (10031252)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Otitis externa (10033072)	6	0.1	0.0	0.2	8	0.1	0.1	0.3	14	0.2	0.1	0.4	15	0.2	0.1	0.4	1	0.1	0.0	0.4	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Otitis externa fungal (10052557)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Otitis media (10033078)	8	0.1	0.1	0.3	7	0.1	0.0	0.3	8	0.1	0.1	0.3	10	0.2	0.1	0.3	1	0.1	0.0	0.4	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Otitis media acute (10033079)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Otitis media chronic (10033081)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Otosalpingitis (10033102)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Overgrowth bacterial (10033302)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Parasitic gastroenteritis (10067720)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Paronychia (10034016)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	5	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Parotitis (10034038)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pasteurella infection (10034106)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pelvic abscess (10034236)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Perichondritis (10062067)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Periodontitis (10034539)	5	0.1	0.0	0.2	4	0.1	0.0	0.2	9	0.1	0.1	0.3	6	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Periorbital cellulitis (10057182)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peritonitis (10034674)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peritonsillar abscess (10034686)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pertussis (10034738)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pharyngitis (10034835)	42	0.7	0.5	1.0	33	0.6	0.4	0.8	53	0.9	0.7	1.1	67	1.1	0.8	1.4	10	0.6	0.3	1.2	10	0.7	0.3	1.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Pharyngitis bacterial (10057869)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pharyngitis streptococcal (10034839)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pharyngotonsillitis (10049140)	7	0.1	0.0	0.2	6	0.1	0.0	0.2	2	0.0	0.0	0.1	6	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pilonidal cyst (10035043)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Pneumonia (10035664)	30	0.5	0.4	0.7	18	0.3	0.2	0.5	44	0.7	0.5	1.0	39	0.6	0.4	0.9	18	1.1	0.7	1.8	25	1.7	1.1	2.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumonia bacterial (10060946)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumonia chlamydial (10035673)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumonia klebsiella (10035717)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumonia pneumococcal (10035728)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumonia viral (10035737)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post procedural infection (10067268)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	6	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Postoperative wound infection (10036410)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostate infection (10050662)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pseudomembranous colitis (10037128)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Psittacosis (10037151)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Psoas abscess (10056517)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary tuberculosis (10037440)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulpitis dental (10037464)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	6	0.1	0.0	0.2	4	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Purulence (10061926)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Purulent discharge (10037569)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyelonephritis (10037596)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	6	0.1	0.0	0.2	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyelonephritis acute (10037597)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyelonephritis chronic (10037601)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyoderma (10037632)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyuria (10037686)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash pustular (10037888)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal abscess (10038351)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Respiratory tract infection (10062352)	16	0.3	0.2	0.4	8	0.1	0.1	0.3	24	0.4	0.3	0.6	20	0.3	0.2	0.5	10	0.6	0.3	1.2	5	0.3	0.1	0.8	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Respiratory tract infection viral (10062106)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinitis (10038910)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinitis (10039083)	12	0.2	0.1	0.4	16	0.3	0.2	0.5	10	0.2	0.1	0.3	12	0.2	0.1	0.3	4	0.3	0.1	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinolaryngitis (10057442)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinotracheitis (10051497)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinovirus infection (10061494)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Root canal infection (10075136)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rotavirus infection (10067470)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Salmonellosis (10039447)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Salpingitis (10039453)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Scrotal abscess (10049571)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sepsis (10040047)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Septic shock (10040070)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Shigella infection (10054178)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sialoadenitis (10040628)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinobronchitis (10048979)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinusitis (10040753)	51	0.9	0.7	1.2	57	1.0	0.8	1.3	56	0.9	0.7	1.2	46	0.7	0.5	1.0	15	1.0	0.5	1.6	18	1.2	0.7	1.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinusitis bacterial (10060841)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin bacterial infection (10052891)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin candida (10054152)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin infection (10040872)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	6	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Soft tissue infection (10062255)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Staphylococcal infection (10058080)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Streptococcal infection (10061372)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Streptococcal sepsis (10048960)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Subcutaneous abscess (10042343)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	2	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Syphilis (10062120)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Testicular abscess (10064724)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinea capitis (10043866)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinea cruris (10043868)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinea infection (10060889)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinea manuum (10067197)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinea pedis (10043873)	9	0.2	0.1	0.3	8	0.1	0.1	0.3	8	0.1	0.1	0.3	8	0.1	0.1	0.3	4	0.3	0.1	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tinea versicolour (10056131)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tonsillitis (10044008)	13	0.2	0.1	0.4	6	0.1	0.0	0.2	4	0.1	0.0	0.2	9	0.1	0.1	0.3	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tonsillitis bacterial (10065235)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tonsillitis streptococcal (10044013)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth abscess (10044016)	14	0.2	0.1	0.4	15	0.3	0.1	0.4	11	0.2	0.1	0.3	11	0.2	0.1	0.3	4	0.3	0.1	0.6	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth infection (10048762)	18	0.3	0.2	0.5	6	0.1	0.0	0.2	5	0.1	0.0	0.2	6	0.1	0.0	0.2	2	0.1	0.0	0.5	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Toxoplasmosis (10044272)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Tracheitis (10044302)	6	0.1	0.0	0.2	4	0.1	0.0	0.2	5	0.1	0.0	0.2	5	0.1	0.0	0.2	5	0.3	0.1	0.7	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tracheobronchitis (10044314)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tuberculosis (10044755)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Upper respiratory tract infection (10046306)	101	1.7	1.4	2.1	88	1.5	1.2	1.9	131	2.2	1.8	2.6	117	1.9	1.6	2.3	42	2.7	1.9	3.6	33	2.3	1.6	3.2	0	0.0	0.0	6.1	2	2.8	0.3	9.7
	Upper respiratory tract infection bacterial (10057868)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urethritis (10046480)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Urinary tract infection (10046571)	73	1.3	1.0	1.6	77	1.3	1.1	1.7	120	2.0	1.6	2.4	100	1.6	1.3	2.0	48	3.1	2.3	4.0	41	2.8	2.0	3.8	2	3.4	0.4	11.7	1	1.4	0.0	7.5
	Urinary tract infection bacterial (10054088)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urinary tract infection staphylococcal (10062280)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urosepsis (10048709)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaginal infection (10046914)	3	0.1	0.0	0.2	5	0.1	0.0	0.2	7	0.1	0.0	0.2	12	0.2	0.1	0.3	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vestibular neuritis (10047393)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Viral infection (10047461)	5	0.1	0.0	0.2	5	0.1	0.0	0.2	9	0.1	0.1	0.3	7	0.1	0.0	0.2	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Viral sinusitis (10051513)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.2	4	0.1	0.0	0.2	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Visceral leishmaniasis (10047505)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vulvitis (10047780)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vulvovaginal candidiasis (10047784)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vulvovaginal mycotic infection (10064899)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vulvovaginitis (10047794)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wound infection (10048038)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	10	0.2	0.1	0.3	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Wound infection pseudomonas (10059444)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wound infection staphylococcal (10059442)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Injury, poisoning and procedural complications (10022117)	At least one PT related to the corresponding SOC	189	3.3	2.8	3.8	208	3.6	3.2	4.1	310	5.1	4.6	5.7	293	4.7	4.2	5.3	107	6.8	5.6	8.2	104	7.1	5.8	8.5	5	8.5	2.8	18.7	3	4.2	0.9	11.7
	Abdominal injury (10060924)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Accident (10000369)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Acetabulum fracture (10000397)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anaesthetic complication neurological (10002105)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aneurysm perforation (10075395)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Animal bite (10002515)	3	0.1	0.0	0.2	7	0.1	0.0	0.3	2	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ankle fracture (10002544)	9	0.2	0.1	0.3	6	0.1	0.0	0.2	5	0.1	0.0	0.2	6	0.1	0.0	0.2	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthropod bite (10003399)	11	0.2	0.1	0.3	11	0.2	0.1	0.3	17	0.3	0.2	0.4	10	0.2	0.1	0.3	3	0.2	0.0	0.6	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Arthropod sting (10003402)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Back injury (10003986)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bite (10004966)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bone contusion (10066251)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	3	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bone fissure (10064210)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast injury (10059391)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Burns first degree (10006797)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Burns second degree (10006802)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Burns third degree (10006803)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cartilage injury (10007710)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cataract operation complication (10057419)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervical vertebral fracture (10049946)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chemical poisoning (10008428)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chest injury (10061386)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chillblains (10008528)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Clavicle fracture (10009245)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Comminuted fracture (10052614)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Compression fracture (10010214)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Concussion (10010254)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	5	0.1	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Contrast media reaction (10010836)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Contusion (10050584)	13	0.2	0.1	0.4	22	0.4	0.2	0.6	44	0.7	0.5	1.0	37	0.6	0.4	0.8	18	1.1	0.7	1.8	13	0.9	0.5	1.5	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Corneal abrasion (10010984)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coronary artery reocclusion (10053261)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cranocerebral injury (10070976)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Crush injury (10061097)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Deafness traumatic (10011903)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Deep vein thrombosis postoperative (10066881)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epicondylitis (10014971)	4	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epiphyseal fracture (10053962)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Excoriation (10049796)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye contusion (10073354)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye injury (10061128)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye penetration (10015960)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eyelid injury (10069200)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Face injury (10050392)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Facial bones fracture (10016042)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fall (10016173)	7	0.1	0.0	0.2	11	0.2	0.1	0.3	19	0.3	0.2	0.5	16	0.3	0.1	0.4	12	0.8	0.4	1.3	13	0.9	0.5	1.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Femoral neck fracture (10016450)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Femur fracture (10016454)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	3	0.0	0.0	0.1	10	0.2	0.1	0.3	3	0.2	0.0	0.6	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Fibula fracture (10016667)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Foot fracture (10016970)	7	0.1	0.0	0.2	3	0.1	0.0	0.2	7	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Forearm fracture (10016997)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Foreign body (10070245)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Foreign body in eye (10017012)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fracture (10017076)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fractured coccyx (10049164)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fractured sacrum (10017308)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hair injury (10074924)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hand fracture (10019114)	5	0.1	0.0	0.2	3	0.1	0.0	0.2	3	0.0	0.0	0.1	6	0.1	0.0	0.2	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Head injury (10019196)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	7	0.1	0.0	0.2	6	0.1	0.0	0.2	4	0.3	0.1	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Heat stroke (10019345)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hip fracture (10020100)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Humerus fracture (10020462)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	6	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Incarcerated incisional hernia (10076387)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Incisional hernia (10021619)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Inflammation of wound (10054923)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injury (10022116)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	5	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Injury corneal (10022120)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Jaw fracture (10023149)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint dislocation (10023204)	3	0.1	0.0	0.2	4	0.1	0.0	0.2	7	0.1	0.0	0.2	4	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Joint injury (10060820)	4	0.1	0.0	0.2	4	0.1	0.0	0.2	7	0.1	0.0	0.2	5	0.1	0.0	0.2	1	0.1	0.0	0.4	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Kidney contusion (10023413)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Laceration (10023572)	11	0.2	0.1	0.3	11	0.2	0.1	0.3	12	0.2	0.1	0.3	15	0.2	0.1	0.4	3	0.2	0.0	0.6	7	0.5	0.2	1.0	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Laryngeal injury (10057441)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ligament injury (10061223)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ligament rupture (10065433)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ligament sprain (10024453)	20	0.3	0.2	0.5	25	0.4	0.3	0.6	22	0.4	0.2	0.5	22	0.4	0.2	0.5	4	0.3	0.1	0.6	5	0.3	0.1	0.8	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Limb crushing injury (10064031)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Limb injury (10061225)	10	0.2	0.1	0.3	12	0.2	0.1	0.4	17	0.3	0.2	0.4	11	0.2	0.1	0.3	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip injury (10055082)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lower limb fracture (10061599)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lumbar vertebral fracture (10049947)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meniscus injury (10072970)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	7	0.1	0.0	0.2	4	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Mouth injury (10049294)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Multiple fractures (10028200)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Multiple injuries (10028224)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle contusion (10070757)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle injury (10028314)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle rupture (10028331)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle strain (10050031)	7	0.1	0.0	0.2	5	0.1	0.0	0.2	11	0.2	0.1	0.3	7	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nerve root injury cervical (10029183)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Open fracture (10030527)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Optic nerve injury (10030938)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Overdose (10033295)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Patella fracture (10034122)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pelvic fracture (10061161)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Periorbital contusion (10062515)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Poisoning (10061355)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post procedural complication (10058046)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post procedural haematuria (10066225)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post procedural haemorrhage (10051077)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post procedural inflammation (10063101)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Post procedural pulmonary embolism (10063909)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post-traumatic neck syndrome (10071366)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post-traumatic pain (10065016)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Postoperative wound complication (10061468)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Procedural complication (10057765)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Procedural pain (10064882)	4	0.1	0.0	0.2	6	0.1	0.0	0.2	8	0.1	0.1	0.3	9	0.1	0.1	0.3	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pubis fracture (10070286)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Radius fracture (10037802)	4	0.1	0.0	0.2	10	0.2	0.1	0.3	8	0.1	0.1	0.3	11	0.2	0.1	0.3	5	0.3	0.1	0.7	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rib fracture (10039117)	4	0.1	0.0	0.2	10	0.2	0.1	0.3	10	0.2	0.1	0.3	6	0.1	0.0	0.2	3	0.2	0.0	0.6	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Road traffic accident (10039203)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Scapula fracture (10039579)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Seroma (10040102)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skeletal injury (10061363)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin abrasion (10064990)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin injury (10061364)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin wound (10072170)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skull fracture (10061365)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skull fractured base (10040960)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Snake bite (10041230)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Soft tissue injury (10041291)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Spinal column injury (10069689)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal compression fracture (10041541)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	5	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Spinal cord injury (10041552)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal cord injury cervical (10041554)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal cord injury lumbar (10041555)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal fracture (10041569)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sternal fracture (10042015)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Subcutaneous haematoma (10042345)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Subdural haematoma (10042361)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sunburn (10042496)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Synovial rupture (10042862)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tendon injury (10043242)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tendon rupture (10043248)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thermal burn (10053615)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thoracic vertebral fracture (10049948)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tibia fracture (10043827)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth fracture (10062544)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Toxicity to various agents (10070863)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Traumatic arthropathy (10044502)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Traumatic haematoma (10044522)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Traumatic intracranial haemorrhage (10061387)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ulna fracture (10045375)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Upper limb fracture (10061394)	5	0.1	0.0	0.2	3	0.1	0.0	0.2	5	0.1	0.0	0.2	7	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaccination complication (10046861)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vascular graft occlusion (10049060)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vascular injury (10047080)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vascular pseudoaneurysm (10048975)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vascular pseudoaneurysm ruptured (10053949)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wound (10052428)	7	0.1	0.0	0.2	3	0.1	0.0	0.2	14	0.2	0.1	0.4	12	0.2	0.1	0.3	6	0.4	0.1	0.8	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wound complication (10053692)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wound dehiscence (10048031)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wrist fracture (10048049)	6	0.1	0.0	0.2	8	0.1	0.1	0.3	5	0.1	0.0	0.2	8	0.1	0.1	0.3	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Investigations (10022891)	At least one PT related to the corresponding SOC	17	0.3	0.2	0.5	19	0.3	0.2	0.5	49	0.8	0.6	1.1	39	0.6	0.4	0.9	10	0.6	0.3	1.2	17	1.2	0.7	1.9	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Alanine aminotransferase increased (10001551)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Amylase increased (10002016)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anticoagulation drug level above therapeutic (10060320)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood alkaline phosphatase increased (10059570)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

22-OCT-2019

0835a07c1bad60fc585b66058de150c427ab0011

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Blood cholesterol increased (10005425)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood creatine phosphokinase increased (10005470)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood creatinine increased (10005483)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood folate decreased (10005527)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood glucose abnormal (10005554)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood glucose fluctuation (10049803)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood glucose increased (10005557)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.1	0.0	0.2	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood heavy metal increased (10061718)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood iron decreased (10005619)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood oestrogen decreased (10005687)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood potassium decreased (10005724)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood potassium increased (10005725)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood pressure abnormal (10005728)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood pressure increased (10005750)	4	0.1	0.0	0.2	2	0.0	0.0	0.1	12	0.2	0.1	0.3	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood sodium decreased (10005802)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood testosterone decreased (10005814)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood thyroid stimulating hormone increased (10005833)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood triglycerides increased (10005839)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood uric acid increased (10005861)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood urine present (10018870)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Body temperature increased (10005911)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	C-reactive protein decreased (10049220)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	C-reactive protein increased (10006825)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carbohydrate antigen 125 increased (10051414)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carbohydrate antigen 15-3 increased (10051415)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carcinoembryonic antigen increased (10007266)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac murmur (10007586)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Catheterisation cardiac (10007815)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chest x-ray abnormal (10008499)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colonoscopy (10010007)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Electrocardiogram abnormal (10014363)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Electrocardiogram change (10061116)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gamma-glutamyltransferase increased (10017693)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Grip strength decreased (10062556)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemoglobin decreased (10018884)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Heart rate increased (10019303)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Heart rate irregular (10019304)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Helicobacter test positive (10070101)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hormone level abnormal (10061210)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	International normalised ratio increased (10022595)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intraocular pressure increased (10022806)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Liver function test abnormal (10024690)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Occult blood positive (10061880)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Platelet count decreased (10035528)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Precancerous cells present (10049673)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostatic specific antigen increased (10036975)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Protein urine (10037018)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Protein urine present (10053123)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Red blood cell sedimentation rate increased (10049187)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Serum ferritin decreased (10040249)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Serum ferritin increased (10040250)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Smear cervix abnormal (10041206)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Total bile acids increased (10064558)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Transaminases increased (10054889)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ultrasound scan (10045434)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urine analysis abnormal (10062226)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vitamin b12 decreased (10047608)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vitamin d decreased (10062189)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Weight decreased (10047895)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	7	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Metabolism and nutrition disorders (10027433)	At least one PT related to the corresponding SOC	76	1.3	1.0	1.6	74	1.3	1.0	1.6	147	2.4	2.0	2.8	132	2.1	1.8	2.5	49	3.1	2.3	4.1	45	3.1	2.3	4.1	1	1.7	0.0	9.1	2	2.8	0.3	9.7
	Abnormal loss of weight (10000159)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cachexia (10006895)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Decreased appetite (10061428)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	7	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dehydration (10012174)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	7	0.1	0.0	0.2	4	0.1	0.0	0.2	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetes mellitus (10012601)	13	0.2	0.1	0.4	6	0.1	0.0	0.2	24	0.4	0.3	0.6	17	0.3	0.2	0.4	3	0.2	0.0	0.6	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetes mellitus inadequate control (10012607)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Diabetic ketoacidosis (10012671)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dyslipidaemia (10058108)	15	0.3	0.1	0.4	10	0.2	0.1	0.3	17	0.3	0.2	0.4	14	0.2	0.1	0.4	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Electrolyte imbalance (10014418)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Feeding disorder (10061148)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fluid retention (10016807)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Folate deficiency (10016880)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glucose tolerance impaired (10018429)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gout (10018627)	8	0.1	0.1	0.3	10	0.2	0.1	0.3	19	0.3	0.2	0.5	14	0.2	0.1	0.4	11	0.7	0.3	1.2	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypercalcaemia (10020583)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypercholesterolaemia (10020603)	12	0.2	0.1	0.4	18	0.3	0.2	0.5	19	0.3	0.2	0.5	12	0.2	0.1	0.3	3	0.2	0.0	0.6	4	0.3	0.1	0.7	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Hyperglycaemia (10020635)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.2	0.0	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperkalaemia (10020646)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperlipidaemia (10062060)	13	0.2	0.1	0.4	7	0.1	0.0	0.3	12	0.2	0.1	0.3	15	0.2	0.1	0.4	6	0.4	0.1	0.8	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertriglyceridaemia (10020869)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperuricaemia (10020903)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	9	0.1	0.1	0.3	5	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Hypocalcaemia (10020947)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypoglycaemia (10020993)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	7	0.1	0.0	0.2	6	0.1	0.0	0.2	3	0.2	0.0	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypokalaemia (10021015)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.3	0.1	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypomagnesaemia (10021027)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyponatraemia (10021036)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypophagia (10063743)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypovitaminosis (10021135)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Iron deficiency (10022970)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lactose intolerance (10023681)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malnutrition (10061273)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Obesity (10029883)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Type 1 diabetes mellitus (10067584)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Type 2 diabetes mellitus (10067585)	6	0.1	0.0	0.2	8	0.1	0.1	0.3	22	0.4	0.2	0.5	15	0.2	0.1	0.4	5	0.3	0.1	0.7	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vitamin b12 deficiency (10047609)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vitamin d deficiency (10047626)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	6	0.1	0.0	0.2	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Musculoskeletal and connective tissue disorders (10028395)	At least one PT related to the corresponding SOC	361	6.2	5.6	6.9	354	6.2	5.6	6.8	546	9.0	8.3	9.7	565	9.1	8.4	9.8	184	11.7	10.1	13.4	181	12.4	10.7	14.2	4	6.8	1.9	16.5	4	5.6	1.5	13.6
	Acquired claw toe (10057689)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

22-OCT-2019

0835a07c1bad60fc585b66058de150c427ab0011

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Arthralgia (10003239)	40	0.7	0.5	0.9	69	1.2	0.9	1.5	90	1.5	1.2	1.8	80	1.3	1.0	1.6	28	1.8	1.2	2.6	25	1.7	1.1	2.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthritis (10003246)	8	0.1	0.1	0.3	8	0.1	0.1	0.3	18	0.3	0.2	0.5	8	0.1	0.1	0.3	3	0.2	0.0	0.6	2	0.1	0.0	0.5	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Arthropathy (10003285)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	4	0.1	0.0	0.2	8	0.1	0.1	0.3	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Back pain (10003988)	77	1.3	1.1	1.7	60	1.0	0.8	1.3	104	1.7	1.4	2.1	107	1.7	1.4	2.1	41	2.6	1.9	3.5	36	2.5	1.7	3.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Bone decalcification (10070817)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bone disorder (10005956)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bone pain (10006002)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bursitis (10006811)	8	0.1	0.1	0.3	8	0.1	0.1	0.3	16	0.3	0.2	0.4	15	0.2	0.1	0.4	4	0.3	0.1	0.6	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervical spinal stenosis (10008313)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chondrocalcinosis (10061761)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chondropathy (10061762)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coccydynia (10009829)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Costochondritis (10011219)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dupuytren's contracture (10013872)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Exostosis (10015688)	6	0.1	0.0	0.2	3	0.1	0.0	0.2	5	0.1	0.0	0.2	4	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fasciitis (10016228)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fibromyalgia (10048439)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Flank pain (10016750)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Foot deformity (10061159)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	7	0.1	0.0	0.2	6	0.1	0.0	0.2	0	0.0	0.0	0.2	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gouty arthritis (10018634)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gouty tophus (10018641)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Groin pain (10018735)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Iliolumbar syndrome (10063442)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intervertebral disc degeneration (10061246)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intervertebral disc disorder (10061521)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intervertebral disc displacement (10022636)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intervertebral disc protrusion (10050296)	5	0.1	0.0	0.2	8	0.1	0.1	0.3	6	0.1	0.0	0.2	10	0.2	0.1	0.3	3	0.2	0.0	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint contracture (10023201)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint effusion (10023215)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint stiffness (10023230)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint swelling (10023232)	2	0.0	0.0	0.1	7	0.1	0.0	0.3	8	0.1	0.1	0.3	3	0.0	0.0	0.1	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ligament disorder (10061222)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Limb deformity (10053652)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Limb discomfort (10061224)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Lumbar spinal stenosis (10025005)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meniscal degeneration (10069364)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metatarsalgia (10027487)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mobility decreased (10048334)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Monarthritis (10027811)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle contracture (10062575)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle disorder (10028300)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle rigidity (10028330)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle spasms (10028334)	9	0.2	0.1	0.3	7	0.1	0.0	0.3	12	0.2	0.1	0.3	13	0.2	0.1	0.4	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle tightness (10049816)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscular weakness (10028372)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Musculoskeletal chest pain (10050819)	3	0.1	0.0	0.2	6	0.1	0.0	0.2	9	0.1	0.1	0.3	5	0.1	0.0	0.2	1	0.1	0.0	0.4	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Musculoskeletal discomfort (10053156)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Musculoskeletal pain (10028391)	21	0.4	0.2	0.6	24	0.4	0.3	0.6	35	0.6	0.4	0.8	35	0.6	0.4	0.8	9	0.6	0.3	1.1	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Musculoskeletal stiffness (10052904)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myalgia (10028411)	11	0.2	0.1	0.3	12	0.2	0.1	0.4	22	0.4	0.2	0.5	17	0.3	0.2	0.4	9	0.6	0.3	1.1	5	0.3	0.1	0.8	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Myofascial pain syndrome (10048780)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myokymia (10028632)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myosclerosis (10064584)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myositis (10028653)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neck mass (10049146)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neck pain (10028836)	11	0.2	0.1	0.3	14	0.2	0.1	0.4	14	0.2	0.1	0.4	25	0.4	0.3	0.6	5	0.3	0.1	0.7	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteitis (10031149)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteitis deformans (10031151)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteoarthritis (10031161)	37	0.6	0.5	0.9	42	0.7	0.5	1.0	102	1.7	1.4	2.0	97	1.6	1.3	1.9	36	2.3	1.6	3.2	30	2.0	1.4	2.9	1	1.7	0.0	9.1	2	2.8	0.3	9.7
	Osteochondrosis (10031233)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteolysis (10031248)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteonecrosis (10031264)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteopenia (10049088)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	9	0.1	0.1	0.3	8	0.1	0.1	0.3	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteoporosis (10031282)	11	0.2	0.1	0.3	6	0.1	0.0	0.2	7	0.1	0.0	0.2	18	0.3	0.2	0.5	4	0.3	0.1	0.6	9	0.6	0.3	1.2	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Osteoporotic fracture (10031290)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pain in extremity (10033425)	41	0.7	0.5	1.0	24	0.4	0.3	0.6	44	0.7	0.5	1.0	48	0.8	0.6	1.0	13	0.8	0.4	1.4	14	1.0	0.5	1.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Pain in jaw (10033433)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Palmar fasciitis (10067366)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Periarthritis (10034464)	6	0.1	0.0	0.2	8	0.1	0.1	0.3	2	0.0	0.0	0.1	6	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Periostitis (10034551)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Plantar fascial fibromatosis (10035154)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Plantar fasciitis (10035155)	2	0.0	0.0	0.1	5	0.1	0.0	0.2	3	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polyarthritis (10036030)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polymyalgia rheumatica (10036099)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	7	0.1	0.0	0.2	6	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polymyositis (10036102)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pseudarthrosis (10048617)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhabdomyolysis (10039020)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rheumatic disorder (10072736)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rheumatoid arthritis (10039073)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	4	0.1	0.0	0.2	6	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rotator cuff syndrome (10039227)	8	0.1	0.1	0.3	2	0.0	0.0	0.1	7	0.1	0.0	0.2	12	0.2	0.1	0.3	3	0.2	0.0	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Scoliosis (10039722)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sjogren's syndrome (10040767)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Soft tissue disorder (10061366)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Soft tissue mass (10071051)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal column stenosis (10041540)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	8	0.1	0.1	0.3	6	0.4	0.1	0.8	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal disorder (10061368)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal osteoarthritis (10041591)	8	0.1	0.1	0.3	10	0.2	0.1	0.3	12	0.2	0.1	0.3	15	0.2	0.1	0.4	4	0.3	0.1	0.6	11	0.8	0.4	1.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Spinal pain (10072005)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spondyloarthropathy (10051265)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spondylolisthesis (10063550)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spondylolysis (10052013)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Still's disease adult onset (10064056)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Synovial cyst (10042858)	5	0.1	0.0	0.2	2	0.0	0.0	0.1	7	0.1	0.0	0.2	5	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Synovitis (10042868)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Temporomandibular joint syndrome (10043220)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tendon disorder (10043239)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tendon pain (10066371)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tendonitis (10043255)	17	0.3	0.2	0.5	16	0.3	0.2	0.5	20	0.3	0.2	0.5	18	0.3	0.2	0.5	9	0.6	0.3	1.1	4	0.3	0.1	0.7	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Tenosynovitis (10043261)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

22-OCT-2019

0835a07c1bad60fc585b66058de150c427ab0011

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Tenosynovitis stenosaurs (10056698)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Torticollis (10044074)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Trigger finger (10044654)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	4	0.1	0.0	0.2	8	0.1	0.1	0.3	4	0.3	0.1	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vertebral foraminal stenosis (10069690)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vertebral osteophyte (10055042)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	At least one PT related to the corresponding SOC	85	1.5	1.2	1.8	86	1.5	1.2	1.8	136	2.2	1.9	2.6	157	2.5	2.1	2.9	33	2.1	1.4	2.9	30	2.0	1.4	2.9	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Abdominal neoplasm (10060925)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acral lentiginous melanoma (10000583)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acrochordon (10000591)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute myeloid leukaemia (10000880)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute promyelocytic leukaemia (10001019)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adenocarcinoma (10001141)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adenocarcinoma gastric (10001150)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adenocarcinoma of colon (10001167)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adenocarcinoma pancreas (10052747)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adenoma benign (10001233)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adrenal adenoma (10001323)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adrenal gland cancer (10073152)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anogenital warts (10059313)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	B-cell lymphoma (10003899)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Basal cell carcinoma (10004146)	9	0.2	0.1	0.3	11	0.2	0.1	0.3	15	0.2	0.1	0.4	22	0.4	0.2	0.5	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Benign breast neoplasm (10004243)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Benign ear neoplasm (10069051)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Benign hepatic neoplasm (10004269)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Benign neoplasm (10060999)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Benign neoplasm of bladder (10004302)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Benign neoplasm of orbit (10004355)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Benign neoplasm of skin (10004398)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Benign neoplasm of thyroid gland (10004412)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Benign soft tissue neoplasm (10061004)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bile duct cancer (10004593)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bladder cancer (10005003)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	8	0.1	0.1	0.3	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bladder cancer recurrent (10005005)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bladder neoplasm (10005056)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bladder papilloma (10005064)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bladder transitional cell carcinoma (10005084)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bowen's disease (10006059)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Brain neoplasm benign (10006129)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast cancer (10006187)	7	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast cancer in situ (10006189)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast cancer metastatic (10055113)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast fibroma (10063088)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchial carcinoma (10006417)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchial neoplasm (10052245)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carcinoid tumour of the small bowel (10052819)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervix carcinoma (10008342)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholangiocarcinoma (10008593)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic lymphocytic leukaemia (10008958)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic myeloid leukaemia (10009013)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colon adenoma (10048832)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colon cancer (10009944)	6	0.1	0.0	0.2	5	0.1	0.0	0.2	3	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colon neoplasm (10061045)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diffuse large b-cell lymphoma (10012818)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Dysplastic naevus (10062805)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Endometrial adenocarcinoma (10014720)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Endometrial cancer (10014733)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Essential thrombocythaemia (10015493)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fibroma (10016629)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fibrous histiocytoma (10053717)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric cancer (10017758)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal neoplasm (10061174)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal tract adenoma (10051635)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glioblastoma multiforme (10018337)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glioma (10018338)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glomus tumour (10018381)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemangioma (10018814)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemangioma of spleen (10068123)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hair follicle tumour benign (10019043)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic cancer (10073069)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic cancer metastatic (10055110)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic neoplasm (10019695)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatocellular carcinoma (10073071)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypergammaglobulinaemia benign monoclonal (10020631)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intraductal proliferative breast lesion (10073094)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Invasive ductal breast carcinoma (10073095)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Invasive papillary breast carcinoma (10073098)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Keratoacanthoma (10023347)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Large cell lung cancer (10023774)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Large intestine benign neoplasm (10073394)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Laryngeal neoplasm (10023841)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Leukaemia (10024288)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip squamous cell carcinoma (10064055)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lipoma (10024612)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung adenocarcinoma (10025031)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung adenocarcinoma stage iii (10025037)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung cancer metastatic (10050017)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung neoplasm (10062042)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung neoplasm malignant (10058467)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymphoma (10025310)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malignant melanoma (10025650)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malignant melanoma in situ (10025652)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malignant neoplasm of eye (10025910)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malignant ovarian cyst (10026662)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malignant palate neoplasm (10026663)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Melanocytic naevus (10027145)	1	0.0	0.0	0.1	8	0.1	0.1	0.3	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meningioma (10027191)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meningioma benign (10027192)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mesothelioma (10027406)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastases to bone (10027452)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastases to central nervous system (10059282)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastases to liver (10027457)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastases to lung (10027458)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastases to lymph nodes (10027459)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastases to peritoneum (10051676)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Metastatic malignant melanoma (10027480)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastatic neoplasm (10061289)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastatic squamous cell carcinoma (10063569)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myelodysplastic syndrome (10028533)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasopharyngeal cancer (10061306)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasopharyngeal neoplasm benign (10028802)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neoplasm malignant (10028997)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neoplasm of orbit (10061863)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neoplasm skin (10029098)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Non-hodgkin's lymphoma (10029547)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Non-small cell lung cancer (10061873)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Non-small cell lung cancer stage iv (10029522)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal carcinoma (10030155)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal squamous cell carcinoma (10061534)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ovarian cancer (10033128)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ovarian cancer recurrent (10066697)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ovarian epithelial cancer (10061328)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ovarian germ cell teratoma benign (10033236)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ovarian neoplasm (10061535)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatic carcinoma (10033609)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatic carcinoma metastatic (10033610)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatic neoplasm (10061902)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatic neuroendocrine tumour (10067517)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Papillary thyroid cancer (10033701)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Papilloma (10033713)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Paraganglion neoplasm (10061332)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Phaeochromocytoma (10034800)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pituitary tumour benign (10061538)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Plasma cell myeloma (10035226)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pleomorphic adenoma (10073372)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostate cancer (10060862)	7	0.1	0.0	0.2	9	0.2	0.1	0.3	14	0.2	0.1	0.4	7	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostate cancer metastatic (10036909)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostate cancer recurrent (10036911)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostatic adenoma (10036940)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyogenic granuloma (10037649)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal adenocarcinoma (10038019)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal adenoma (10048829)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal cancer (10038038)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal cancer recurrent (10038046)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal cancer (10038389)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal cell carcinoma (10067946)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal neoplasm (10061482)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal oncocytoma (10050176)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Salivary gland cancer (10061934)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sarcoma (10039491)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Schwannoma (10039667)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Seborrhoeic keratosis (10039796)	6	0.1	0.0	0.2	5	0.1	0.0	0.2	6	0.1	0.0	0.2	9	0.1	0.1	0.3	3	0.2	0.0	0.6	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin cancer (10040808)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin papilloma (10040907)	7	0.1	0.0	0.2	8	0.1	0.1	0.3	12	0.2	0.1	0.3	9	0.1	0.1	0.3	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Small cell lung cancer (10041067)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Squamous cell carcinoma (10041823)	4	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Squamous cell carcinoma of lung (10041826)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Squamous cell carcinoma of skin (10041834)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Squamous cell carcinoma of the oral cavity (10041857)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Testicular neoplasm (10061379)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thyroid adenoma (10043688)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thyroid cancer (10066474)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thyroid neoplasm (10043744)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Transitional cell carcinoma (10044412)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tumour haemorrhage (10049750)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urethral neoplasm (10062223)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Uterine cancer (10046766)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Uterine leiomyoma (10046798)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	137	2.4	2.0	2.8	139	2.4	2.0	2.9	270	4.4	3.9	5.0	272	4.4	3.9	4.9	103	6.5	5.4	7.9	104	7.1	5.8	8.5	3	5.1	1.1	14.1	1	1.4	0.0	7.5
	Amnesia (10001949)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Amnesic disorder (10061423)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Amyotrophic lateral sclerosis (10002026)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Apallid syndrome (10002941)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aphasia (10002948)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aphonia (10002953)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Autonomic nervous system imbalance (10003840)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Balance disorder (10049848)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	5	0.1	0.0	0.2	5	0.1	0.0	0.2	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Basal ganglia infarction (10069020)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Basilar artery occlusion (10048963)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Brain stem infarction (10006147)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Brain stem syndrome (10063292)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Burning sensation (10006784)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carotid arteriosclerosis (10067116)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carotid artery occlusion (10048964)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Carotid artery stenosis (10007687)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carotid artery thrombosis (10007688)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carotid sinus syndrome (10050202)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carpal tunnel syndrome (10007697)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	10	0.2	0.1	0.3	11	0.2	0.1	0.3	4	0.3	0.1	0.6	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Central nervous system lesion (10051290)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebellar haemorrhage (10008030)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral arteriosclerosis (10065559)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral artery occlusion (10008089)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral artery thrombosis (10008092)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral atrophy (10008096)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral disorder (10054938)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral haemorrhage (10008111)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral infarction (10008118)	4	0.1	0.0	0.2	0	0.0	0.0	0.1	5	0.1	0.0	0.2	9	0.1	0.1	0.3	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral ischaemia (10008120)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebrospinal fluid leakage (10008164)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebrovascular accident (10008190)	5	0.1	0.0	0.2	4	0.1	0.0	0.2	11	0.2	0.1	0.3	8	0.1	0.1	0.3	7	0.4	0.2	0.9	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebrovascular disorder (10008196)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebrovascular stenosis (10061751)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervical myelopathy (10008289)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervical radiculopathy (10050217)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervicobrachial syndrome (10008334)	1	0.0	0.0	0.1	4	0.1	0.0	0.2	13	0.2	0.1	0.4	8	0.1	0.1	0.3	3	0.2	0.0	0.6	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cognitive disorder (10057668)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Complex regional pain syndrome (10064332)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
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		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Convulsions local (10010920)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cubital tunnel syndrome (10056473)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dementia (10012267)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dementia alzheimer's type (10012271)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dementia with lewy bodies (10067889)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Demyelinating polyneuropathy (10061811)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Demyelination (10012305)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic neuropathy (10012680)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	7	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Disturbance in attention (10013496)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dizziness (10013573)	22	0.4	0.2	0.6	21	0.4	0.2	0.6	51	0.8	0.6	1.1	39	0.6	0.4	0.9	19	1.2	0.7	1.9	18	1.2	0.7	1.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dizziness postural (10013578)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysaesthesia (10013886)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysgeusia (10013911)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dyskinesia (10013916)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Encephalopathy (10014625)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epilepsy (10015037)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Essential tremor (10015496)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Facial neuralgia (10061594)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Facial spasm (10063006)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Generalised tonic-clonic seizure (10018100)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glossopharyngeal neuralgia (10018391)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Guillain-barre syndrome (10018767)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhage intracranial (10018985)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhagic stroke (10019016)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Head discomfort (10019194)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Headache (10019211)	23	0.4	0.3	0.6	22	0.4	0.2	0.6	47	0.8	0.6	1.0	36	0.6	0.4	0.8	16	1.0	0.6	1.6	10	0.7	0.3	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hydrocephalus (10020508)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperaesthesia (10020568)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypersomnia (10020765)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertonia (10020852)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

22-OCT-2019

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CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

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		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hypoaesthesia (10020937)	8	0.1	0.1	0.3	6	0.1	0.0	0.2	11	0.2	0.1	0.3	7	0.1	0.0	0.2	2	0.1	0.0	0.5	6	0.4	0.2	0.9	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Hypokinesia (10021021)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypoxic-ischaemic encephalopathy (10070511)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intention tremor (10022520)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intercostal neuralgia (10049949)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intracranial aneurysm (10022758)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intraventricular haemorrhage (10022840)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ischaemic stroke (10061256)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lacunar infarction (10051078)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lethargy (10024264)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Loss of consciousness (10024855)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lumbar radiculopathy (10050219)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Memory impairment (10027175)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metabolic encephalopathy (10062190)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Migraine (10027599)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Migraine without aura (10052787)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mixed dementia (10075174)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mononeuritis (10027910)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Morton's neuralgia (10052288)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Multiple sclerosis (10028245)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle contractions involuntary (10028293)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myasthenic syndrome (10028424)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myelopathy (10028570)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nerve compression (10029174)	5	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nervous system disorder (10029202)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neuralgia (10029223)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neuritis (10029240)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neuritis cranial (10029244)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neuromuscular blockade (10029315)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

22-OCT-2019

0835a07c1bad60fc585b66058de150c427ab0011

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Neuropathy peripheral (10029331)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Olfactory nerve disorder (10056388)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Paraesthesia (10033775)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	5	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Parkinson's disease (10061536)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Parkinsonism (10034010)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polyneuropathy (10036105)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Poor quality sleep (10062519)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post polio syndrome (10036239)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post-traumatic headache (10036313)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Presyncope (10036653)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Radicular pain (10059604)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Radiculitis brachial (10037778)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Radiculopathy (10037779)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Restless legs syndrome (10058920)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ruptured cerebral aneurysm (10039330)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sciatic nerve neuropathy (10048950)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sciatica (10039674)	13	0.2	0.1	0.4	10	0.2	0.1	0.3	24	0.4	0.3	0.6	37	0.6	0.4	0.8	9	0.6	0.3	1.1	8	0.5	0.2	1.1	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Seizure (10039906)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Senile dementia (10039966)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sensory disturbance (10040026)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sensory loss (10040030)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinus headache (10040744)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Somnolence (10041349)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal claudication (10041539)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spondylitic myelopathy (10041670)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Stupor (10042264)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Subarachnoid haemorrhage (10042316)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sudden onset of sleep (10050014)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Syncope (10042772)	10	0.2	0.1	0.3	6	0.1	0.0	0.2	12	0.2	0.1	0.3	18	0.3	0.2	0.5	11	0.7	0.3	1.2	9	0.6	0.3	1.2	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tension headache (10043269)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Thalamic infarction (10064961)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombotic cerebral infarction (10067347)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Transient global amnesia (10044380)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Transient ischaemic attack (10044390)	3	0.1	0.0	0.2	6	0.1	0.0	0.2	14	0.2	0.1	0.4	5	0.1	0.0	0.2	5	0.3	0.1	0.7	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tremor (10044565)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Trigeminal nerve disorder (10060890)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Trigeminal neuralgia (10044652)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vascular dementia (10057678)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vascular encephalopathy (10063661)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vertebrobasilar insufficiency (10047334)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Viith nerve paralysis (10050040)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Visual field defect (10047555)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Psychiatric disorders (10037175)	At least one PT related to the corresponding SOC	45	0.8	0.6	1.0	52	0.9	0.7	1.2	98	1.6	1.3	2.0	93	1.5	1.2	1.8	45	2.9	2.1	3.8	41	2.8	2.0	3.8	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Acute psychosis (10001022)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute stress disorder (10001084)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adjustment disorder (10061621)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adjustment disorder with anxiety (10001296)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Affective disorder (10001443)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Agoraphobia (10001502)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Alcohol withdrawal syndrome (10053164)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Alcoholism (10001639)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anxiety (10002855)	9	0.2	0.1	0.3	10	0.2	0.1	0.3	17	0.3	0.2	0.4	24	0.4	0.2	0.6	9	0.6	0.3	1.1	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anxiety disorder (10057666)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bipolar disorder (10057667)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breathing-related sleep disorder (10006344)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Completed suicide (10010144)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Confusional state (10010305)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Conversion disorder (10010893)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Delirium (10012218)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Depressed mood (10012374)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

22-OCT-2019

0835a07c1bad60fc585b66058de150c427ab0011

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Depression (10012378)	12	0.2	0.1	0.4	20	0.3	0.2	0.5	33	0.5	0.4	0.8	26	0.4	0.3	0.6	10	0.6	0.3	1.2	12	0.8	0.4	1.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Depressive symptom (10054089)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Disorientation (10013395)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysthymic disorder (10013982)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Emotional disorder (10014551)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Emotional distress (10049119)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Generalised anxiety disorder (10018075)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Grief reaction (10018724)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hallucination (10019063)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hallucination, visual (10019075)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypomania (10021030)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hysterical psychosis (10062645)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Insomnia (10022437)	14	0.2	0.1	0.4	11	0.2	0.1	0.3	24	0.4	0.3	0.6	21	0.3	0.2	0.5	15	1.0	0.5	1.6	13	0.9	0.5	1.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Irritability (10022998)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Korsakoff's syndrome (10070997)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Libido decreased (10024419)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Major depression (10057840)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mental disorder (10061284)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mental status changes (10048294)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mood altered (10027940)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nervousness (10029216)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Obsessive thoughts (10029897)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Panic attack (10033664)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Panic disorder (10033666)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Psychosomatic disease (10049587)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Psychotic disorder (10061920)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Restlessness (10038743)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Schizoaffective disorder bipolar type (10068889)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Schizophrenia (10039626)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Schizophrenia, paranoid type (10039639)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sleep disorder (10040984)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	5	0.1	0.0	0.2	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Somatiform disorder (10054153)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Somatoform disorder gastrointestinal (10041322)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Stress (10042209)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Suicide attempt (10042464)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tearfulness (10043169)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tic (10043833)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Renal and urinary disorders (10038359)	At least one PT related to the corresponding SOC	46	0.8	0.6	1.1	27	0.5	0.3	0.7	74	1.2	1.0	1.5	74	1.2	0.9	1.5	41	2.6	1.9	3.5	35	2.4	1.7	3.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute kidney injury (10069339)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	4	0.1	0.0	0.2	5	0.3	0.1	0.7	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute prerenal failure (10001017)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anuria (10002847)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bladder dysfunction (10069632)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bladder irritation (10005052)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bladder perforation (10063575)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bladder prolapse (10048475)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bladder spasm (10048994)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Calculus bladder (10006987)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Calculus ureteric (10007025)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Calculus urinary (10007027)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic kidney disease (10064848)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	5	0.1	0.0	0.2	2	0.1	0.0	0.5	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cystitis interstitial (10011796)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic nephropathy (10061835)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysuria (10013990)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	5	0.3	0.1	0.7	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haematuria (10018867)	10	0.2	0.1	0.3	1	0.0	0.0	0.1	12	0.2	0.1	0.3	13	0.2	0.1	0.4	2	0.1	0.0	0.5	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemoglobinuria (10018906)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hydronephrosis (10020524)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertonic bladder (10020853)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Incontinence (10021639)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lower urinary tract symptoms (10071289)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Microalbuminuria (10027525)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Micturition disorder (10027561)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Micturition urgency (10027566)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nephritis (10029117)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nephrolithiasis (10029148)	4	0.1	0.0	0.2	5	0.1	0.0	0.2	5	0.1	0.0	0.2	12	0.2	0.1	0.3	3	0.2	0.0	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nephropathy (10029151)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nephropathy toxic (10029155)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Neurogenic bladder (10029279)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nocturia (10029446)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pollakiuria (10036018)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	6	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polyuria (10036142)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Proteinuria (10037032)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal artery arteriosclerosis (10065561)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal artery occlusion (10048988)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal artery stenosis (10038378)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal colic (10038419)	7	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal cyst (10038423)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	7	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal failure (10038435)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.2	0.0	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal hypertension (10038464)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal impairment (10062237)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal pain (10038490)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal vessel disorder (10038553)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Stress urinary incontinence (10066218)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tubulointerstitial nephritis (10048302)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urethral obstruction (10046459)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urethral polyp (10051507)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urethral stenosis (10065584)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urge incontinence (10046494)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urinary hesitation (10046542)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urinary incontinence (10046543)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	7	0.1	0.0	0.2	3	0.0	0.0	0.1	5	0.3	0.1	0.7	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urinary retention (10046555)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	6	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urinary tract disorder (10046566)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urine flow decreased (10046640)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Reproductive system and breast disorders (10038604)	At least one PT related to the corresponding SOC	45	0.8	0.6	1.0	54	0.9	0.7	1.2	84	1.4	1.1	1.7	79	1.3	1.0	1.6	14	0.9	0.5	1.5	22	1.5	0.9	2.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Adnexa uteri pain (10058841)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrophic vulvovaginitis (10003693)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Balanoposthitis (10004078)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Benign prostatic hyperplasia (10004446)	11	0.2	0.1	0.3	21	0.4	0.2	0.6	29	0.5	0.3	0.7	26	0.4	0.3	0.6	7	0.4	0.2	0.9	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast calcifications (10048782)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast cyst (10006220)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast discharge (10006223)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast disorder (10061021)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast dysplasia (10006237)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast enlargement (10006242)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast inflammation (10006262)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast mass (10006272)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast pain (10006298)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast tenderness (10006313)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast ulceration (10073419)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervical cyst (10008254)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervical dysplasia (10008263)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervical polyp (10008297)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cystocele (10011803)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysfunctional uterine bleeding (10013908)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysmenorrhoea (10013935)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Endometrial hyperplasia (10014755)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Endometrial hypertrophy (10014756)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Endometriosis (10014778)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epididymal cyst (10014994)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erectile dysfunction (10061461)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fibrocystic breast disease (10016621)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Genital discomfort (10066887)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Genital disorder male (10061177)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Genital rash (10018175)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haematospermia (10018866)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Male sexual dysfunction (10057672)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Menopausal disorder (10058825)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Menopausal symptoms (10027304)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	5	0.1	0.0	0.2	6	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Menorrhagia (10027313)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nipple disorder (10029417)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Organic erectile dysfunction (10052004)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ovarian cyst (10033132)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pelvic pain (10034263)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Penile pain (10034310)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Postmenopausal haemorrhage (10055870)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostate induration (10057263)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostatic disorder (10036956)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostatic obstruction (10055026)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostatism (10036976)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostatitis (10036978)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	8	0.1	0.1	0.3	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostatomegaly (10051482)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pruritus genital (10037093)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectocele (10038084)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Scrotal oedema (10039755)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sexual dysfunction (10040477)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spermatocele (10041490)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Testicular mass (10058901)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Testicular pain (10043345)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Uterine enlargement (10046782)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Uterine haemorrhage (10046788)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Uterine polyp (10046811)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Uterine prolapse (10046814)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Uterovaginal prolapse (10046830)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaginal cyst (10046900)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaginal discharge (10046901)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaginal dysplasia (10046905)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaginal erosion (10062558)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaginal haemorrhage (10046910)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vaginal inflammation (10046916)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vulva cyst (10050475)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vulval haematoma (10047756)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vulvovaginal burning sensation (10067641)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Respiratory, thoracic and mediastinal disorders (10038738)	Vulvovaginal dryness (10047791)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vulvovaginal pruritus (10056530)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	At least one PT related to the corresponding SOC	146	2.5	2.1	3.0	146	2.5	2.2	3.0	238	3.9	3.4	4.4	267	4.3	3.8	4.8	106	6.7	5.5	8.1	100	6.8	5.6	8.2	2	3.4	0.4	11.7	4	5.6	1.5	13.6
	Acute pulmonary oedema (10001029)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute respiratory failure (10001053)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Allergic bronchitis (10052613)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Allergic cough (10053779)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Allergic respiratory disease (10063532)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aspiration (10003504)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Asthma (10003553)	10	0.2	0.1	0.3	4	0.1	0.0	0.2	16	0.3	0.2	0.4	23	0.4	0.2	0.6	9	0.6	0.3	1.1	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atelectasis (10003598)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchial hyperreactivity (10066091)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchial obstruction (10006440)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchiectasis (10006445)	0	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchitis chronic (10006458)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	7	0.1	0.0	0.2	5	0.1	0.0	0.2	5	0.3	0.1	0.7	2	0.1	0.0	0.5	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Bronchospasm (10006482)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Catarrh (10007774)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Choking (10008589)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic obstructive pulmonary disease (10009033)	6	0.1	0.0	0.2	2	0.0	0.0	0.1	19	0.3	0.2	0.5	18	0.3	0.2	0.5	15	1.0	0.5	1.6	17	1.2	0.7	1.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cough (10011224)	62	1.1	0.8	1.4	63	1.1	0.8	1.4	98	1.6	1.3	2.0	99	1.6	1.3	1.9	36	2.3	1.6	3.2	32	2.2	1.5	3.1	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Diaphragmatic disorder (10061106)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dry throat (10013789)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dysphonia (10013952)	1	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dyspnoea (10013968)	5	0.1	0.0	0.2	1	0.0	0.0	0.1	17	0.3	0.2	0.4	17	0.3	0.2	0.4	12	0.8	0.4	1.3	14	1.0	0.5	1.6	0	0.0	0.0	6.1	2	2.8	0.3	9.7
	Dyspnoea exertional (10013971)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Emphysema (10014561)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epiglottic cyst (10057437)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epistaxis (10015090)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	9	0.1	0.1	0.3	8	0.1	0.1	0.3	2	0.1	0.0	0.5	6	0.4	0.2	0.9	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Haemoptysis (10018964)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemothorax (10019027)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hiccups (10020039)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hyperventilation (10020910)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypoxia (10021143)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Idiopathic pulmonary fibrosis (10021240)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Increased upper airway secretion (10062717)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Laryngeal oedema (10023845)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lower respiratory tract congestion (10075565)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung disorder (10025082)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung infiltration (10025102)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal congestion (10028735)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	6	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal disorder (10062209)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal dryness (10028740)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal odour (10051181)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal polyps (10028756)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal septum deviation (10028762)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nasal turbinate hypertrophy (10028779)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Obstructive airways disorder (10061877)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oropharyngeal discomfort (10068318)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oropharyngeal pain (10068319)	18	0.3	0.2	0.5	21	0.4	0.2	0.6	19	0.3	0.2	0.5	23	0.4	0.2	0.6	4	0.3	0.1	0.6	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Paranasal cyst (10062321)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Paranasal sinus discomfort (10052438)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pharyngeal inflammation (10065716)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pickwickian syndrome (10035004)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pleural adhesion (10035588)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pleural calcification (10035592)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pleural effusion (10035598)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pleurisy (10035618)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pleuritic pain (10035623)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumonia aspiration (10035669)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Pneumothorax (10035759)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Productive cough (10036790)	1	0.0	0.0	0.1	5	0.1	0.0	0.2	3	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary arterial hypertension (10064911)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary bulla (10051688)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary cavitation (10051738)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary congestion (10037368)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary embolism (10037377)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	7	0.1	0.0	0.2	10	0.2	0.1	0.3	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary fibrosis (10037383)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary granuloma (10037391)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary hypertension (10037400)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary mass (10056342)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary oedema (10037423)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rales (10037833)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Respiratory disorder (10038683)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Respiratory distress (10038687)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Respiratory failure (10038695)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.0	0.0	0.1	5	0.3	0.1	0.7	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Respiratory tract congestion (10052251)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinalgia (10051496)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinitis allergic (10039085)	5	0.1	0.0	0.2	8	0.1	0.1	0.3	12	0.2	0.1	0.3	17	0.3	0.2	0.4	4	0.3	0.1	0.6	10	0.7	0.3	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinitis hypertrophic (10059235)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinitis perennial (10039094)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhinorrhoea (10039101)	7	0.1	0.0	0.2	4	0.1	0.0	0.2	6	0.1	0.0	0.2	7	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinus congestion (10040742)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinus disorder (10062244)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinus polyp (10040749)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sleep apnoea syndrome (10040979)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	9	0.1	0.1	0.3	5	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sneezing (10041232)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sputum discoloured (10041807)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sputum increased (10041812)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Throat irritation (10043521)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Throat tightness (10043528)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Upper respiratory tract congestion (10052252)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Upper respiratory tract inflammation (10049590)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Upper-airway cough syndrome (10070488)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vocal cord polyp (10047675)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vocal cord thickening (10047676)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wheezing (10047924)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	3	0.2	0.0	0.6	1	1.7	0.0	9.1	0	0.0	0.0	5.0
Skin and subcutaneous tissue disorders (10040785)	At least one PT related to the corresponding SOC	169	2.9	2.5	3.4	187	3.3	2.8	3.8	249	4.1	3.6	4.6	271	4.4	3.9	4.9	95	6.0	4.9	7.3	95	6.5	5.3	7.9	1	1.7	0.0	9.1	5	6.9	2.3	15.5
	Acne (10000496)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Actinic keratosis (10000614)	4	0.1	0.0	0.2	6	0.1	0.0	0.2	6	0.1	0.0	0.2	9	0.1	0.1	0.3	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Alopecia (10001760)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Alopecia areata (10001761)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Angioedema (10002424)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blister (10005191)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bromhidrosis (10055000)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chloasma (10008570)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cutis laxa (10011692)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Decubitus ulcer (10011985)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermal cyst (10012426)	0	0.0	0.0	0.1	9	0.2	0.1	0.3	5	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Dermatitis (10012431)	12	0.2	0.1	0.4	17	0.3	0.2	0.5	20	0.3	0.2	0.5	24	0.4	0.2	0.6	11	0.7	0.3	1.2	5	0.3	0.1	0.8	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Dermatitis allergic (10012434)	13	0.2	0.1	0.4	10	0.2	0.1	0.3	10	0.2	0.1	0.3	7	0.1	0.0	0.2	5	0.3	0.1	0.7	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatitis atopic (10012438)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Dermatitis contact (10012442)	10	0.2	0.1	0.3	11	0.2	0.1	0.3	17	0.3	0.2	0.4	16	0.3	0.1	0.4	4	0.3	0.1	0.6	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatitis diaper (10012444)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatitis exfoliative (10012455)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatomyositis (10012503)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatosis (10048768)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic dermopathy (10053695)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic foot (10060734)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Drug eruption (10013687)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dry skin (10013786)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dyshidrotic eczema (10013913)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ecchymosis (10014080)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eczema (10014184)	30	0.5	0.4	0.7	35	0.6	0.4	0.8	49	0.8	0.6	1.1	52	0.8	0.6	1.1	19	1.2	0.7	1.9	18	1.2	0.7	1.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Eczema asteatotic (10014190)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erythema (10015150)	5	0.1	0.0	0.2	5	0.1	0.0	0.2	4	0.1	0.0	0.2	8	0.1	0.1	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erythema nodosum (10015226)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hair disorder (10019037)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hand dermatitis (10058898)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hangnail (10058109)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperhidrosis (10020642)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperkeratosis (10020649)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	8	0.1	0.1	0.3	7	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypersensitivity vasculitis (10020764)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ingrowing nail (10022013)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	8	0.1	0.1	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ingrown hair (10052899)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intertrigo (10022622)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Keloid scar (10023330)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lentigo (10024217)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Leukoplakia (10062037)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lichen planus (10024429)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lichen sclerosus (10024434)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lichenoid keratosis (10064000)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Miliaria (10027627)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nail bed inflammation (10064088)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nail disorder (10028694)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nail growth abnormal (10064764)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neurodermatitis (10029263)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Night sweats (10029410)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Onycholysis (10030337)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Onychomadesis (10049274)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Papule (10033733)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Parapsoriasis (10033898)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pemphigus (10034280)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Petechiae (10034754)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Photosensitivity reaction (10034972)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pigmentation disorder (10062080)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pityriasis alba (10035111)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pityriasis rosea (10035114)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Precancerous skin lesion (10049422)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prurigo (10037083)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pruritus (10037087)	13	0.2	0.1	0.4	13	0.2	0.1	0.4	22	0.4	0.2	0.5	21	0.3	0.2	0.5	15	1.0	0.5	1.6	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pruritus allergic (10063438)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pruritus generalised (10052576)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Psoriasis (10037153)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Purpura senile (10037560)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pustular psoriasis (10037575)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash (10037844)	26	0.4	0.3	0.7	17	0.3	0.2	0.5	19	0.3	0.2	0.5	31	0.5	0.3	0.7	12	0.8	0.4	1.3	9	0.6	0.3	1.2	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Rash erythematous (10037855)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash generalised (10037858)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash macular (10037867)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash maculo-papular (10037868)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash papular (10037876)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rash pruritic (10037884)	3	0.1	0.0	0.2	4	0.1	0.0	0.2	6	0.1	0.0	0.2	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rosacea (10039218)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sebaceous gland disorder (10061511)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Seborrhoea (10039792)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Seborrhoeic dermatitis (10039793)	1	0.0	0.0	0.1	5	0.1	0.0	0.2	8	0.1	0.1	0.3	5	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Senile pruritus (10039986)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin discolouration (10040829)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin disorder (10040831)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin exfoliation (10040844)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin fissures (10040849)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Skin irritation (10040880)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin lesion (10040882)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	10	0.2	0.1	0.3	10	0.2	0.1	0.3	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin maceration (10048625)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin mass (10067868)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin necrosis (10040893)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin reaction (10040914)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin ulcer (10040943)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	6	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.2	0.0	0.6	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin warm (10040952)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Solar dermatitis (10041303)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Solar lentigo (10064127)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Stasis dermatitis (10041955)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	8	0.1	0.1	0.3	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Subacute cutaneous lupus erythematosus (10057903)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urticaria (10046735)	10	0.2	0.1	0.3	12	0.2	0.1	0.4	15	0.2	0.1	0.4	19	0.3	0.2	0.5	4	0.3	0.1	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urticaria chronic (10052568)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Xeroderma (10048218)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Social circumstances (10041244)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Immobile (10021417)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Menopause (10027308)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tobacco user (10057581)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Surgical and medical procedures (10042613)	At least one PT related to the corresponding SOC	11	0.2	0.1	0.3	18	0.3	0.2	0.5	11	0.2	0.1	0.3	19	0.3	0.2	0.5	6	0.4	0.1	0.8	5	0.3	0.1	0.8	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Abdominal operation (10061609)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthroscopic surgery (10058471)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac pacemaker replacement (10049434)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardioversion (10007661)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carpal tunnel decompression (10007695)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cataract operation (10063797)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coronary arterial stent insertion (10052086)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coronary artery bypass (10011077)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Dental implantation (10064143)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dental operation (10061812)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ear operation (10061831)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Endodontic procedure (10051085)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye laser surgery (10057105)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hip arthroplasty (10020096)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hospitalisation (10054112)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Implantable defibrillator replacement (10057459)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Inguinal hernia repair (10022020)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intraocular lens implant (10067434)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Knee arthroplasty (10023469)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Knee operation (10049548)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Meniscus operation (10054948)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mole excision (10027805)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mouth cyst excision (10052179)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oophorectomy (10061889)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Papilloma excision (10033714)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal polypectomy (10038075)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sebaceous cyst excision (10039779)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Shoulder operation (10062242)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin lesion excision (10062250)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin neoplasm excision (10059443)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Suture insertion (10052665)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tendon sheath incision (10043250)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tooth extraction (10062132)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Transurethral prostatectomy (10044445)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Umbilical hernia repair (10045462)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vasectomy (10047133)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	101	1.7	1.4	2.1	110	1.9	1.6	2.3	163	2.7	2.3	3.1	187	3.0	2.6	3.5	66	4.2	3.3	5.3	82	5.6	4.5	6.9	1	1.7	0.0	9.1	4	5.6	1.5	13.6
	Aneurysm (10002329)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aneurysm ruptured (10048380)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Angiodysplasia (10061636)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Angiopathy (10059245)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic aneurysm (10002882)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	6	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic arteriosclerosis (10065558)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic calcification (10054208)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic dissection (10002895)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic stenosis (10002906)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arterial disorder (10060963)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arteriosclerosis (10003210)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arteriovenous fistula (10003226)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Behcet's syndrome (10004213)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bleeding varicose vein (10005144)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Blood pressure fluctuation (10005746)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood pressure inadequately controlled (10051128)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Circulatory collapse (10009192)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Deep vein thrombosis (10051055)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	6	0.1	0.0	0.2	5	0.1	0.0	0.2	5	0.3	0.1	0.7	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic vascular disorder (10061815)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Essential hypertension (10015488)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Femoral artery occlusion (10052019)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Flushing (10016825)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haematoma (10018852)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	3	0.0	0.0	0.1	6	0.1	0.0	0.2	3	0.2	0.0	0.6	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhage (10055798)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hot flush (10060800)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperaemia (10020565)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertension (10020772)	69	1.2	0.9	1.5	75	1.3	1.0	1.6	83	1.4	1.1	1.7	100	1.6	1.3	2.0	19	1.2	0.7	1.9	39	2.7	1.9	3.6	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Hypertensive crisis (10020802)	4	0.1	0.0	0.2	6	0.1	0.0	0.2	10	0.2	0.1	0.3	14	0.2	0.1	0.4	5	0.3	0.1	0.7	1	0.1	0.0	0.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Hypotension (10021097)	1	0.0	0.0	0.1	4	0.1	0.0	0.2	8	0.1	0.1	0.3	12	0.2	0.1	0.3	4	0.3	0.1	0.6	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Infarction (10061216)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intermittent claudication (10022562)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Internal haemorrhage (10075192)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ischaemia (10061255)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymphoedema (10025282)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Orthostatic hypertension (10065508)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Orthostatic hypotension (10031127)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peripheral arterial occlusive disease (10062585)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.1	0.0	0.5	4	0.3	0.1	0.7	0	0.0	0.0	6.1	2	2.8	0.3	9.7
	Peripheral artery aneurysm (10057521)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peripheral artery stenosis (10072563)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peripheral artery thrombosis (10072564)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Peripheral coldness (10034568)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peripheral embolism (10061340)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peripheral ischaemia (10034576)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peripheral vascular disorder (10034636)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peripheral venous disease (10075049)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	3	0.0	0.0	0.1	6	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Phlebitis (10034879)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	6	0.1	0.0	0.2	6	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Phlebitis deep (10034897)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post thrombotic syndrome (10048591)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Raynaud's phenomenon (10037912)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Shock haemorrhagic (10049771)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spider vein (10062696)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Subgaleal haematoma (10069510)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Temporal arteritis (10043207)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombophlebitis (10043570)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombophlebitis superficial (10043595)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombosis (10043607)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.1	0.0	0.2	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Varicose ulceration (10046995)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Varicose vein (10046996)	4	0.1	0.0	0.2	2	0.0	0.0	0.1	5	0.1	0.0	0.2	5	0.1	0.0	0.2	2	0.1	0.0	0.5	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vascular pain (10047095)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vascular rupture (10053649)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vasospasm (10047163)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Venous occlusion (10058990)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Venous thrombosis (10047249)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Venous thrombosis limb (10061408)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

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N = number of subjects with at least one administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

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Table 14.3.1.34 Percentage of doses with unsolicited symptoms classified by MedDRA Primary System Organ Class and Preferred Term with medically attended visit, from first vaccination up to month 8 post first vaccination by frailty status (Total Vaccinated Cohort)

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	At least one symptom	2196	19.4	18.6	20.1	2270	20.1	19.3	20.8	3166	26.8	26.0	27.6	3268	26.8	26.0	27.6	1035	34.2	32.5	35.9	979	34.8	33.0	36.6	24	21.2	14.1	29.9	35	25.9	18.8	34.2
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	17	0.1	0.1	0.2	11	0.1	0.0	0.2	33	0.3	0.2	0.4	37	0.3	0.2	0.4	17	0.6	0.3	0.9	23	0.8	0.5	1.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anaemia (10002034)	11	0.1	0.0	0.2	3	0.0	0.0	0.1	14	0.1	0.1	0.2	14	0.1	0.1	0.2	9	0.3	0.1	0.6	15	0.5	0.3	0.9	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anaemia megaloblastic (10002065)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anaemia vitamin b12 deficiency (10002080)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Coagulopathy (10009802)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Disseminated intravascular coagulation (10013442)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eosinophilia (10014950)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemorrhagic anaemia (10052293)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Heparin-induced thrombocytopenia (10062506)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hilar lymphadenopathy (10020094)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypersplenism (10020769)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypochromic anaemia (10020969)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Immune thrombocytopenic purpura (10074667)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Increased tendency to bruise (10021688)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Iron deficiency anaemia (10022972)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.1	8	0.1	0.0	0.1	5	0.2	0.1	0.4	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Leukopenia (10024384)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymphadenitis (10025188)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymphadenopathy (10025197)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	4	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Macrocytosis (10025382)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Microcytic anaemia (10027538)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

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		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Nephrogenic anaemia (10058116)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Normochromic normocytic anaemia (10029783)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Splenic cyst (10051169)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Splenic infarction (10041648)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thrombocytopenia (10043554)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thrombocytosis (10043563)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Cardiac disorders (10007541)	At least one PT related to the corresponding SOC	71	0.6	0.5	0.8	57	0.5	0.4	0.7	158	1.3	1.1	1.6	161	1.3	1.1	1.5	76	2.5	2.0	3.1	99	3.5	2.9	4.3	2	1.8	0.2	6.2	2	1.5	0.2	5.2
	Acute coronary syndrome (10051592)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute myocardial infarction (10000891)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	6	0.1	0.0	0.1	10	0.1	0.0	0.2	4	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Angina pectoris (10002383)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.0	0.0	0.1	10	0.1	0.0	0.2	9	0.3	0.1	0.6	10	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Angina unstable (10002388)	4	0.0	0.0	0.1	0	0.0	0.0	0.0	5	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aortic valve disease (10061589)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aortic valve incompetence (10002915)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aortic valve sclerosis (10002917)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aortic valve stenosis (10002918)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arrhythmia (10003119)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	22	0.2	0.1	0.3	14	0.1	0.1	0.2	4	0.1	0.0	0.3	7	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arrhythmia supraventricular (10003130)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arteriosclerosis coronary artery (10003211)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atrial fibrillation (10003658)	10	0.1	0.0	0.2	9	0.1	0.0	0.2	33	0.3	0.2	0.4	28	0.2	0.2	0.3	12	0.4	0.2	0.7	18	0.6	0.4	1.0	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atrial flutter (10003662)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	5	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.2	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atrioventricular block (10003671)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Atrioventricular block complete (10003673)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atrioventricular block first degree (10003674)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atrioventricular block second degree (10003677)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bradycardia (10006093)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	6	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Bundle branch block right (1006582)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac aneurysm (10007513)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac arrest (10007515)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac discomfort (10054211)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac disorder (10061024)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Cardiac failure (10007554)	5	0.0	0.0	0.1	0	0.0	0.0	0.0	13	0.1	0.1	0.2	16	0.1	0.1	0.2	10	0.3	0.2	0.6	14	0.5	0.3	0.8	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac failure acute (10007556)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac failure chronic (10007558)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac failure congestive (10007559)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	11	0.1	0.0	0.2	11	0.4	0.2	0.6	12	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac flutter (10052840)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac valve disease (10061406)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardio-respiratory arrest (10007617)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiogenic shock (10007625)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiomegaly (10007632)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiomyopathy (10007636)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiovascular disorder (10007649)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Chronotropic incompetence (10068627)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Congestive cardiomyopathy (10056370)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cor pulmonale (10010968)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Coronary artery disease (10011078)	3	0.0	0.0	0.1	6	0.1	0.0	0.1	13	0.1	0.1	0.2	10	0.1	0.0	0.2	13	0.4	0.2	0.7	12	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Coronary artery occlusion (10011086)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Coronary artery stenosis (10011089)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diastolic dysfunction (10052337)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Extrasystoles (10015856)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Heart valve incompetence (10067660)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertensive heart disease (10020823)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Intracardiac thrombus (10048620)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ischaemic cardiomyopathy (10048858)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Left ventricular dysfunction (10049694)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Left ventricular failure (10024119)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Left ventricular hypertrophy (10049773)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mitral valve disease (10061532)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mitral valve incompetence (10027727)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mitral valve prolapse (10027730)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myocardial infarction (10028596)	2	0.0	0.0	0.1	6	0.1	0.0	0.1	9	0.1	0.0	0.1	9	0.1	0.0	0.1	8	0.3	0.1	0.5	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myocardial ischaemia (10028600)	7	0.1	0.0	0.1	3	0.0	0.0	0.1	11	0.1	0.0	0.2	14	0.1	0.1	0.2	4	0.1	0.0	0.3	6	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myocarditis (10028606)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Palpitations (10033557)	10	0.1	0.0	0.2	3	0.0	0.0	0.1	5	0.0	0.0	0.1	8	0.1	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Pericardial haemorrhage (10034476)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pericarditis (10034484)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Right ventricular failure (10039163)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinus bradycardia (10040741)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinus node dysfunction (10075889)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Supraventricular extrasystoles (10042602)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Supraventricular tachycardia (10042604)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tachyarrhythmia (10049447)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tachycardia (10043071)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tachycardia paroxysmal (10043079)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tricuspid valve incompetence (10044640)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ventricular arrhythmia (10047281)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
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		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Ventricular extrasystoles (10047289)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ventricular fibrillation (10047290)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ventricular tachycardia (10047302)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Congenital, familial and genetic disorders (10010331)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Birth mark (10004950)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Congenital cystic kidney disease (10010428)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Corneal dystrophy (10011005)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertrophic cardiomyopathy (10020871)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lipidosis (10024585)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Malformation venous (10025532)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Phimosis (10034878)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spina bifida occulta (10041525)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thyroglossal cyst (10051320)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Ear and labyrinth disorders (10013993)	At least one PT related to the corresponding SOC	45	0.4	0.3	0.5	55	0.5	0.4	0.6	101	0.9	0.7	1.0	103	0.8	0.7	1.0	24	0.8	0.5	1.2	31	1.1	0.7	1.6	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Cerumen impaction (10050337)	4	0.0	0.0	0.1	7	0.1	0.0	0.1	20	0.2	0.1	0.3	8	0.1	0.0	0.1	4	0.1	0.0	0.3	5	0.2	0.1	0.4	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Cupulolithiasis (10056454)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Deafness (10011878)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.0	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Deafness bilateral (10052556)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Deafness neurosensory (10011891)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Deafness unilateral (10048812)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear discomfort (10052137)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear disorder (10014004)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear haemorrhage (10014009)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear pain (10014020)	1	0.0	0.0	0.0	4	0.0	0.0	0.1	8	0.1	0.0	0.1	8	0.1	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear pruritus (10052138)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear swelling (10014025)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eustachian tube disorder (10061462)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eustachian tube dysfunction (10015543)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Eustachian tube obstruction (10015544)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eustachian tube stenosis (10067764)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hearing impaired (10019245)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypoacusis (10048865)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	8	0.1	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Inner ear disorder (10061524)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Meniere's disease (10027183)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Middle ear effusion (10062545)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Middle ear inflammation (10065838)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mixed deafness (10027757)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Motion sickness (10027990)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neurosensory hypoacusis (10067587)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Presbycusis (10036626)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sudden hearing loss (10061373)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinnitus (10043882)	5	0.0	0.0	0.1	10	0.1	0.0	0.2	10	0.1	0.0	0.2	14	0.1	0.1	0.2	6	0.2	0.1	0.4	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tympanic membrane perforation (10045210)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vertigo (10047340)	17	0.1	0.1	0.2	18	0.2	0.1	0.3	43	0.4	0.3	0.5	42	0.3	0.2	0.5	8	0.3	0.1	0.5	12	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vertigo positional (10047348)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vestibular disorder (10047386)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Endocrine disorders (10014698)	At least one PT related to the corresponding SOC	16	0.1	0.1	0.2	15	0.1	0.1	0.2	20	0.2	0.1	0.3	21	0.2	0.1	0.3	7	0.2	0.1	0.5	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Androgen deficiency (10002261)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Autoimmune thyroiditis (10049046)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Basedow's disease (10004161)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetes insipidus (10012599)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Goitre (10018498)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperparathyroidism (10020705)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperthyroidism (10020850)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypogonadism (10058359)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypopituitarism (10021067)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypothyroidism (10021114)	11	0.1	0.0	0.2	9	0.1	0.0	0.2	12	0.1	0.1	0.2	12	0.1	0.1	0.2	5	0.2	0.1	0.4	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Primary hyperaldosteronism (10036692)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thyroid cyst (10043706)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Eye disorders (10015919)	Thyroiditis (10043778)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thyroiditis subacute (10043784)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	At least one PT related to the corresponding SOC	86	0.8	0.6	0.9	85	0.8	0.6	0.9	123	1.0	0.9	1.2	139	1.1	1.0	1.3	47	1.6	1.1	2.1	33	1.2	0.8	1.6	1	0.9	0.0	4.8	1	0.7	0.0	4.1
	Acquired corneal dystrophy (10065058)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Age-related macular degeneration (10064930)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Amaurosis (10001902)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Asthenopia (10003552)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	6	0.1	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blepharitis (10005148)	1	0.0	0.0	0.0	5	0.0	0.0	0.1	1	0.0	0.0	0.0	8	0.1	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blepharitis allergic (10005149)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cataract (10007739)	18	0.2	0.1	0.3	23	0.2	0.1	0.3	28	0.2	0.2	0.3	40	0.3	0.2	0.4	14	0.5	0.3	0.8	14	0.5	0.3	0.8	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cataract nuclear (10007759)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chalazion (10008388)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chorioretinal atrophy (10008762)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chorioretinopathy (10063118)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Choroidal effusion (10063970)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctival degeneration (10010705)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctival haemorrhage (10010719)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	7	0.1	0.0	0.1	10	0.1	0.0	0.2	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctival hyperaemia (10051625)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctivitis allergic (10010744)	3	0.0	0.0	0.1	4	0.0	0.0	0.1	8	0.1	0.0	0.1	6	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Corneal erosion (10011013)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Corneal irritation (10056476)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dacryostenosis acquired (10053990)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetic retinopathy (10012689)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diplopia (10013036)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dry age-related macular degeneration (10075567)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dry eye (10013774)	11	0.1	0.0	0.2	3	0.0	0.0	0.1	6	0.1	0.0	0.1	15	0.1	0.1	0.2	4	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eczema eyelids (10014194)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Enophthalmos (10014853)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Entropion (10061842)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Episcleritis (10015084)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erythema of eyelid (10015237)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye allergy (10015907)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye discharge (10015915)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye disorder (10015916)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye haemorrhage (10015926)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye inflammation (10015943)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye irritation (10015946)	1	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye pain (10015958)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye pruritus (10052140)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye swelling (10015967)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eyelid cyst (10063692)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eyelid dermatochalasis (10075309)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eyelid disorder (10061130)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eyelid oedema (10015993)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Eyelid ptosis (10015995)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Foreign body sensation in eyes (10051116)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glaucoma (10018304)	4	0.0	0.0	0.1	4	0.0	0.0	0.1	7	0.1	0.0	0.1	10	0.1	0.0	0.2	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Iridocyclitis (10022941)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Keratitis (10023332)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lacrimal disorder (10061525)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lacrimation decreased (10023642)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lacrimation increased (10023644)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lens dislocation (10024203)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Macular cyst (10025407)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Macular degeneration (10025409)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	7	0.1	0.0	0.1	3	0.0	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Macular fibrosis (10071392)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Macular hole (10051058)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Macular oedema (10025415)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Macular scar (10063185)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Maculopathy (10025425)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myopia (10028651)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Narrow anterior chamber angle (10068960)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Neovascular age-related macular degeneration (10071129)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ocular discomfort (10052143)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ocular hyperaemia (10030041)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ocular hypertension (10030043)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ocular myasthenia (10049168)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ocular vascular disorder (10052896)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Open angle glaucoma (10030348)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ophthalmic vein thrombosis (10074349)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Optic ischaemic neuropathy (10030924)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Panophthalmitis (10033683)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Parophthalmia (10059407)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Photopsia (10034962)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Posterior capsule opacification (10036346)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Presbyopia (10036628)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinal artery thrombosis (10038831)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinal degeneration (10038845)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinal detachment (10038848)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinal disorder (10038853)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinal haemorrhage (10038867)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinal tear (10038897)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinal vein occlusion (10038907)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinopathy (10038923)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinopathy hypertensive (10038926)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Trichiasis (10044604)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ulcerative keratitis (10064996)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Uveitis (10046851)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vision blurred (10047513)	4	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Visual acuity reduced (10047531)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Visual impairment (10047571)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vitreous degeneration (10047649)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vitreous detachment (10047650)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vitreous floaters (10047654)	0	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vitreous haemorrhage (10047655)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vitreous opacities (10047658)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Xerophthalmia (10048221)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Gastrointestinal disorders (10017947)	At least one PT related to the corresponding SOC	231	2.0	1.8	2.3	272	2.4	2.1	2.7	394	3.3	3.0	3.7	412	3.4	3.1	3.7	124	4.1	3.4	4.9	138	4.9	4.1	5.8	4	3.5	1.0	8.8	3	2.2	0.5	6.4
	Abdominal discomfort (10000059)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.0	0.0	0.1	4	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal distension (10000060)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal hernia (10060954)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal mass (10000077)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal pain (10000081)	10	0.1	0.0	0.2	12	0.1	0.1	0.2	23	0.2	0.1	0.3	18	0.1	0.1	0.2	9	0.3	0.1	0.6	11	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal pain lower (10000084)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	4	0.1	0.0	0.4	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Abdominal pain upper (10000087)	12	0.1	0.1	0.2	23	0.2	0.1	0.3	25	0.2	0.1	0.3	27	0.2	0.1	0.3	9	0.3	0.1	0.6	6	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal strangulated hernia (10053203)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acid peptic disease (10075494)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aerophagia (10052813)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anal fissure (10002153)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anal fistula (10002156)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anal haemorrhage (10049555)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anal inflammation (10050247)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anal polyp (10002168)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anal prolapse (10065360)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anal pruritus (10068172)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aphthous stomatitis (10002958)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ascites (10003445)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Barrett's oesophagus (10004137)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Change of bowel habit (10008399)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cheilitis (10008417)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Chronic gastritis (10008882)	5	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	5	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Coeliac disease (10009839)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Colitis (10009887)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Colitis ischaemic (10009895)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Colitis microscopic (10056979)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Colitis ulcerative (10009900)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Constipation (10010774)	8	0.1	0.0	0.1	14	0.1	0.1	0.2	34	0.3	0.2	0.4	28	0.2	0.2	0.3	13	0.4	0.2	0.7	15	0.5	0.3	0.9	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Crohn's disease (10011401)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dental alveolar anomaly (10012316)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dental caries (10012318)	5	0.0	0.0	0.1	8	0.1	0.0	0.1	5	0.0	0.0	0.1	8	0.1	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Dental necrosis (10012327)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diaphragmatic hernia (10012713)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diarrhoea (10012735)	18	0.2	0.1	0.3	29	0.3	0.2	0.4	36	0.3	0.2	0.4	45	0.4	0.3	0.5	12	0.4	0.2	0.7	17	0.6	0.4	1.0	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diverticular perforation (10061820)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diverticulum (10013554)	7	0.1	0.0	0.1	2	0.0	0.0	0.1	5	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diverticulum intestinal (10013559)	0	0.0	0.0	0.0	4	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dry mouth (10013781)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	5	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Duodenal ulcer (10013836)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dyspepsia (10013946)	15	0.1	0.1	0.2	8	0.1	0.0	0.1	20	0.2	0.1	0.3	30	0.2	0.2	0.4	5	0.2	0.1	0.4	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysphagia (10013950)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	5	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Enteritis (10014866)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Enterovesical fistula (10062570)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epigastric discomfort (10053155)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erosive oesophagitis (10063655)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Faecal incontinence (10016092)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Faecaloma (10056325)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Faeces discoloured (10016100)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Faeces pale (10016102)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Flatulence (10016766)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	5	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Food poisoning (10016952)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Functional gastrointestinal disorder (10071275)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastric dilatation (10017779)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastric disorder (10056819)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Gastric polyps (10017817)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastric ulcer (10017822)	3	0.0	0.0	0.1	4	0.0	0.0	0.1	7	0.1	0.0	0.1	5	0.0	0.0	0.1	6	0.2	0.1	0.4	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastric ulcer haemorrhage (10017826)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastritis (10017853)	9	0.1	0.0	0.2	18	0.2	0.1	0.3	39	0.3	0.2	0.5	31	0.3	0.2	0.4	4	0.1	0.0	0.3	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastritis alcoholic (10017856)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastritis erosive (10017865)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastritis haemorrhagic (10017866)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastroduodenitis (10048714)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal angiodysplasia (10017928)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal disorder (10017944)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Gastrointestinal haemorrhage (10017955)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal motility disorder (10061173)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal sounds abnormal (10067715)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrooesophageal heterotopia (10051335)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrooesophageal reflux disease (10017885)	17	0.1	0.1	0.2	22	0.2	0.1	0.3	23	0.2	0.1	0.3	29	0.2	0.2	0.3	9	0.3	0.1	0.6	7	0.2	0.1	0.5	1	0.9	0.0	4.8	1	0.7	0.0	4.1
	Gastrooesophageal sphincter insufficiency (10062879)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gingival bleeding (10018276)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gingival blister (10049304)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gingival disorder (10018280)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gingival pain (10018286)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gingival swelling (10018291)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glossitis (10018386)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glossodynia (10018388)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haematemesis (10018830)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haematochezia (10018836)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemorrhoidal haemorrhage (10054787)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemorrhoids (10019022)	13	0.1	0.1	0.2	23	0.2	0.1	0.3	26	0.2	0.1	0.3	22	0.2	0.1	0.3	9	0.3	0.1	0.6	7	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemorrhoids thrombosed (10019023)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Hiatus hernia (10020028)	6	0.1	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	8	0.1	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypoaesthesia oral (10057371)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ileus (10021328)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Impaired gastric emptying (10021518)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Incarcerated umbilical hernia (10064492)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Inguinal hernia (10022016)	7	0.1	0.0	0.1	6	0.1	0.0	0.1	8	0.1	0.0	0.1	11	0.1	0.0	0.2	4	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intestinal cyst (10062023)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intestinal haemorrhage (10059175)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intestinal mass (10059017)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intestinal obstruction (10022687)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intestinal perforation (10022694)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intestinal polyp (10048616)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intestinal prolapse (10056990)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Irritable bowel syndrome (10023003)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	5	0.0	0.0	0.1	5	0.0	0.0	0.1	4	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Large intestine perforation (10023804)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Large intestine polyp (10051589)	8	0.1	0.0	0.1	8	0.1	0.0	0.1	6	0.1	0.0	0.1	13	0.1	0.1	0.2	2	0.1	0.0	0.2	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip blister (10049307)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip oedema (10024558)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip pain (10024561)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip swelling (10024570)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip ulceration (10024572)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Loose tooth (10065612)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lumbar hernia (10024995)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mallory-weiss syndrome (10026712)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Melanosis coli (10027158)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mesenteritis (10069665)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mouth cyst (10028020)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mouth haemorrhage (10028024)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mouth ulceration (10028034)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	6	0.1	0.0	0.1	11	0.1	0.0	0.2	3	0.1	0.0	0.3	4	0.1	0.0	0.4	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Nausea (10028813)	12	0.1	0.1	0.2	9	0.1	0.0	0.2	7	0.1	0.0	0.1	18	0.1	0.1	0.2	5	0.2	0.1	0.4	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Noninfective gingivitis (10074863)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Noninfective sialoadenitis (10075243)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Odynophagia (10030094)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophageal discomfort (10053634)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophageal disorder (10061318)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophageal haemorrhage (10030172)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophageal spasm (10030184)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophageal ulcer (10030201)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophageal ulcer haemorrhage (10030202)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophagitis (10030216)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	6	0.1	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral disorder (10067621)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral lichen planus (10030983)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral mucosal blistering (10030995)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral mucosal erythema (10067418)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral pain (10031009)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Palatal oedema (10056998)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pancreatic cyst (10033615)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pancreatic disorder (10033616)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pancreatic steatosis (10072787)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pancreatitis (10033645)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pancreatitis acute (10033647)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	4	0.0	0.0	0.1	4	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Parotid duct obstruction (10034021)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peptic ulcer (10034341)	1	0.0	0.0	0.0	4	0.0	0.0	0.1	3	0.0	0.0	0.1	7	0.1	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peptic ulcer haemorrhage (10034344)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Periodontal disease (10034536)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peritoneal cyst (10051942)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Portal hypertensive gastropathy (10050897)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Proctalgia (10036772)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Proctitis (10036774)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Proctitis ulcerative (10036783)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rectal haemorrhage (10038063)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	7	0.1	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

22-OCT-2019

0835a07c1bad60fc585b66058de150c427ab0011

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Rectal polyp (10038074)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rectal prolapse (10038077)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Reflux gastritis (10057969)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retching (10038776)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retropertitoneal haemorrhage (10038980)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Salivary gland calculus (10039394)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Salivary gland cyst (10052248)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Salivary gland mucocoele (10060870)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Salivary hypersecretion (10039424)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Small intestinal obstruction (10041101)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Stomatitis (10042128)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Subileus (10050396)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Swollen tongue (10042727)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thrombosis mesenteric vessel (10043626)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue blistering (10043942)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue disorder (10043951)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue eruption (10052002)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue geographic (10043957)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue oedema (10043967)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue pruritus (10070072)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tongue ulceration (10043991)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth deposit (10044029)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth disorder (10044034)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth erosion (10044038)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth impacted (10044042)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Toothache (10044055)	24	0.2	0.1	0.3	27	0.2	0.2	0.3	23	0.2	0.1	0.3	21	0.2	0.1	0.3	2	0.1	0.0	0.2	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Umbilical hernia (10045458)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Upper gastrointestinal haemorrhage (10046274)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vomiting (10047700)	7	0.1	0.0	0.1	7	0.1	0.0	0.1	5	0.0	0.0	0.1	11	0.1	0.0	0.2	7	0.2	0.1	0.5	6	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
General disorders and administration site conditions (10018065)	At least one PT related to the corresponding SOC	134	1.2	1.0	1.4	78	0.7	0.5	0.9	197	1.7	1.4	1.9	155	1.3	1.1	1.5	73	2.4	1.9	3.0	60	2.1	1.6	2.7	0	0.0	0.0	3.2	3	2.2	0.5	6.4
	Abasia (10049460)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Administration site erythema (10074796)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Administration site pain (10058049)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adverse drug reaction (10061623)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Asthenia (10003549)	5	0.0	0.0	0.1	4	0.0	0.0	0.1	10	0.1	0.0	0.2	10	0.1	0.0	0.2	6	0.2	0.1	0.4	5	0.2	0.1	0.4	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Axillary pain (10048750)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Calcinosis (10006938)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chest discomfort (10008469)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chest pain (10008479)	22	0.2	0.1	0.3	13	0.1	0.1	0.2	34	0.3	0.2	0.4	40	0.3	0.2	0.4	9	0.3	0.1	0.6	11	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chills (10008531)	4	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chronic fatigue syndrome (10008874)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cyst (10011732)	4	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	7	0.1	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Death (10011906)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Device battery issue (10071172)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Device breakage (10012575)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Device malfunction (10063829)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Device occlusion (10064685)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Discomfort (10013082)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Drug intolerance (10061822)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Drug withdrawal syndrome (10013754)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Face oedema (10016029)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Facial pain (10016059)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fatigue (10016256)	12	0.1	0.1	0.2	2	0.0	0.0	0.1	14	0.1	0.1	0.2	18	0.1	0.1	0.2	3	0.1	0.0	0.3	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling abnormal (10016322)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling cold (10016326)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeling hot (10016334)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gait disturbance (10017577)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	General physical health deterioration (10049438)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Generalised oedema (10018092)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Hernia (10019909)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ill-defined disorder (10061520)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Incarcerated hernia (10021610)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Inflammation (10061218)	4	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Inflammatory pain (10065390)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Influenza like illness (10022004)	11	0.1	0.0	0.2	8	0.1	0.0	0.1	7	0.1	0.0	0.1	8	0.1	0.0	0.1	2	0.1	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site erythema (10022061)	10	0.1	0.0	0.2	0	0.0	0.0	0.0	15	0.1	0.1	0.2	0	0.0	0.0	0.0	5	0.2	0.1	0.4	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site haematoma (10022066)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site haemorrhage (10022067)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site hypersensitivity (10022071)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site induration (10022075)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site inflammation (10022078)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site joint pain (10049261)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site mass (10022081)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site nodule (10057880)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site oedema (10022085)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site pain (10022086)	20	0.2	0.1	0.3	1	0.0	0.0	0.0	27	0.2	0.2	0.3	0	0.0	0.0	0.0	7	0.2	0.1	0.5	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site pruritus (10022093)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site rash (10022094)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site swelling (10053425)	9	0.1	0.0	0.2	0	0.0	0.0	0.0	8	0.1	0.0	0.1	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site urticaria (10022107)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site warmth (10022112)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injury associated with device (10069803)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Local swelling (10024770)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Malaise (10025482)	2	0.0	0.0	0.1	5	0.0	0.0	0.1	6	0.1	0.0	0.1	4	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Medical device complication (10057281)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metaplasia (10054949)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Mucous membrane disorder (10028133)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Multi-organ failure (10028154)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nodule (10054107)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Non-cardiac chest pain (10062501)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oedema (10030095)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	5	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oedema peripheral (10030124)	7	0.1	0.0	0.1	2	0.0	0.0	0.1	20	0.2	0.1	0.3	20	0.2	0.1	0.3	10	0.3	0.2	0.6	9	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Organ failure (10053159)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pain (10033371)	6	0.1	0.0	0.1	4	0.0	0.0	0.1	10	0.1	0.0	0.2	4	0.0	0.0	0.1	5	0.2	0.1	0.4	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pelvic mass (10034260)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral swelling (10048959)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	4	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.1	0.0	0.2	6	0.2	0.1	0.5	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Polyp (10061529)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyrexia (10037660)	27	0.2	0.2	0.3	12	0.1	0.1	0.2	23	0.2	0.1	0.3	16	0.1	0.1	0.2	12	0.4	0.2	0.7	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Strangulated hernia (10042166)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sudden death (10042434)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Swelling (10042674)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Systemic inflammatory response syndrome (10051379)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thirst (10043458)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thrombosis in device (10062546)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ulcer haemorrhage (10061577)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site erythema (10059079)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site pain (10068879)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site reaction (10059080)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination site swelling (10069620)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Xerosis (10048222)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Hepatobiliary disorders (10019805)	At least one PT related to the corresponding SOC	15	0.1	0.1	0.2	20	0.2	0.1	0.3	28	0.2	0.2	0.3	47	0.4	0.3	0.5	9	0.3	0.1	0.6	16	0.6	0.3	0.9	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Bile duct obstruction (10056375)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bile duct stenosis (10051341)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bile duct stone (10004637)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Biliary colic (10004663)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Biliary dilatation (10057202)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Biliary tract disorder (10061008)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Cholangitis (10008604)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholangitis acute (10008605)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholecystitis (10008612)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	6	0.1	0.0	0.1	6	0.0	0.0	0.1	1	0.0	0.0	0.2	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholecystitis acute (10008614)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholecystitis chronic (10008617)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholelithiasis (10008629)	3	0.0	0.0	0.1	9	0.1	0.0	0.2	5	0.0	0.0	0.1	20	0.2	0.1	0.3	7	0.2	0.1	0.5	6	0.2	0.1	0.5	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Chronic hepatitis (10008909)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cirrhosis alcoholic (10009208)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gallbladder disorder (10017626)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gallbladder polyp (10049704)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatic cirrhosis (10019641)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatic cyst (10019646)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Hepatic function abnormal (10019670)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatic lesion (10061998)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatic steatosis (10019708)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatitis (10019717)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatotoxicity (10019851)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperbilirubinaemia (10020578)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertransaminasaemia (10068237)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Jaundice cholestatic (10023129)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Liver disorder (10024670)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Immune system disorders (10021428)	At least one PT related to the corresponding SOC	10	0.1	0.0	0.2	21	0.2	0.1	0.3	20	0.2	0.1	0.3	19	0.2	0.1	0.2	7	0.2	0.1	0.5	6	0.2	0.1	0.5	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Allergy to arthropod bite (10058285)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Allergy to arthropod sting (10058284)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Allergy to plants (10054928)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Amyloidosis (10002022)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anaphylactic reaction (10002198)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Atopy (10003645)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Contrast media allergy (10066973)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Drug hypersensitivity (10013700)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	5	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Food allergy (10016946)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hypersensitivity (10020751)	2	0.0	0.0	0.1	11	0.1	0.0	0.2	10	0.1	0.0	0.2	8	0.1	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Milk allergy (10027633)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Multiple allergies (10028164)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mycotic allergy (10052758)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sarcoidosis (10039486)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Seasonal allergy (10048908)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	7	0.1	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	905	8.0	7.5	8.5	897	7.9	7.4	8.4	1187	10.0	9.5	10.6	1228	10.1	9.5	10.6	384	12.7	11.5	13.9	386	13.7	12.5	15.0	7	6.2	2.5	12.3	10	7.4	3.6	13.2
	Abdominal abscess (10060921)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal infection (10056519)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abdominal wall abscess (10000099)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abscess (10000269)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abscess jaw (10053573)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abscess limb (10050473)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Abscess oral (10000311)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acarodermatitis (10063409)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute sinusitis (10001076)	1	0.0	0.0	0.0	4	0.0	0.0	0.1	5	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute tonsillitis (10001093)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Alcaligenes infection (10068911)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Alveolar osteitis (10066995)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	American trypanosomiasis (10001935)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anal abscess (10048946)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anorectal cellulitis (10002643)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Appendiceal abscess (10049764)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Appendicitis (10003011)	0	0.0	0.0	0.0	4	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Appendicitis perforated (10003012)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arteriosclerotic gangrene (10003222)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arthritis bacterial (10053555)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arthritis infective (10060968)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bacteraemia (10003997)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bacterial infection (10060945)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bacteriuria (10004056)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Balanitis candida (10004074)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Biliary tract infection (10061695)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Blastocystis infection (10005092)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Body tinea (10005913)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Borrelia infection (10061591)	7	0.1	0.0	0.1	10	0.1	0.0	0.2	1	0.0	0.0	0.0	6	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast abscess (10006171)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchiolitis (10006448)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchitis (10006451)	56	0.5	0.4	0.6	68	0.6	0.5	0.8	146	1.2	1.0	1.5	128	1.0	0.9	1.2	49	1.6	1.2	2.1	49	1.7	1.3	2.3	0	0.0	0.0	3.2	2	1.5	0.2	5.2
	Bronchitis bacterial (10061736)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchitis viral (10053160)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchopneumonia (10006469)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Candida infection (10074170)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	7	0.1	0.0	0.1	5	0.2	0.1	0.4	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Candida sepsis (10053166)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Carbuncle (10007247)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Catheter site infection (10056520)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cellulitis (10007882)	9	0.1	0.0	0.2	10	0.1	0.0	0.2	18	0.2	0.1	0.2	25	0.2	0.1	0.3	5	0.2	0.1	0.4	18	0.6	0.4	1.0	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Cellulitis orbital (10007918)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervicitis (10008323)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholecystitis infective (10062631)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chorioretinitis (10008769)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chronic hepatitis b (10008910)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chronic sinusitis (10009137)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Clostridium difficile colitis (10009657)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Clostridium difficile infection (10054236)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctivitis (10010741)	16	0.1	0.1	0.2	16	0.1	0.1	0.2	25	0.2	0.1	0.3	48	0.4	0.3	0.5	19	0.6	0.4	1.0	18	0.6	0.4	1.0	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Conjunctivitis bacterial (10061784)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cutaneous tuberculosis (10011684)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cystitis (10011781)	30	0.3	0.2	0.4	29	0.3	0.2	0.4	46	0.4	0.3	0.5	45	0.4	0.3	0.5	11	0.4	0.2	0.6	11	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cystitis klebsiella (10011797)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dacryocanalculitis (10011843)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dacryocystitis (10011844)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dengue fever (10012310)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dental fistula (10065268)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatophytosis (10012504)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Device related infection (10064687)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetic foot infection (10060803)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetic gangrene (10012665)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diarrhoea infectious (10012742)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diverticulitis (10013538)	6	0.1	0.0	0.1	8	0.1	0.0	0.1	8	0.1	0.0	0.1	10	0.1	0.0	0.2	7	0.2	0.1	0.5	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear infection (10014011)	10	0.1	0.0	0.2	17	0.2	0.1	0.2	20	0.2	0.1	0.3	13	0.1	0.1	0.2	7	0.2	0.1	0.5	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eczema impetiginous (10051890)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eczema infected (10014199)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Empyema (10014568)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Encephalitis viral (10014612)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Encephalomyelitis (10014619)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Endocarditis (10014665)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Endometritis (10014791)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Endophthalmitis (10014801)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Enteritis infectious (10058839)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Enterobiasis (10014881)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epididymitis (10015000)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erysipelas (10015145)	0	0.0	0.0	0.0	4	0.0	0.0	0.1	4	0.0	0.0	0.1	5	0.0	0.0	0.1	6	0.2	0.1	0.4	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erythema infectiosum (10015214)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erythema migrans (10062488)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Escherichia infection (10061126)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Escherichia sepsis (10015296)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Escherichia urinary tract infection (10052238)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	External ear cellulitis (10015729)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Extrapulmonary tuberculosis (10064445)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye infection (10015929)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye infection bacterial (10015930)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eyelid infection (10015988)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Folliculitis (10016936)	10	0.1	0.0	0.2	5	0.0	0.0	0.1	8	0.1	0.0	0.1	9	0.1	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fungal infection (10017533)	5	0.0	0.0	0.1	5	0.0	0.0	0.1	7	0.1	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fungal skin infection (10017543)	3	0.0	0.0	0.1	6	0.1	0.0	0.1	7	0.1	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Furuncle (10017553)	1	0.0	0.0	0.0	4	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Gangrene (10017711)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastric infection (10056663)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastritis viral (10051791)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastroenteritis (10017888)	28	0.2	0.2	0.4	28	0.2	0.2	0.4	39	0.3	0.2	0.5	38	0.3	0.2	0.4	10	0.3	0.2	0.6	12	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastroenteritis clostridial (10017898)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastroenteritis salmonella (10017914)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastroenteritis viral (10017918)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal fungal infection (10049479)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Genital abscess (10062316)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Genital candidiasis (10018143)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Genital herpes (10018150)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Genital infection (10048461)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Genital infection fungal (10061180)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gingival abscess (10052359)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gingivitis (10018292)	9	0.1	0.0	0.2	14	0.1	0.1	0.2	3	0.0	0.0	0.1	8	0.1	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gonorrhoea (10018612)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Graft infection (10056559)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Groin abscess (10050269)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Groin infection (10050821)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	H1n1 influenza (10069767)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haematoma infection (10051564)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemorrhoid infection (10051541)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Helicobacter gastritis (10054272)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Helicobacter infection (10054263)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatic infection (10056522)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatitis a (10019719)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatitis b (10019731)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Herpangina (10019936)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Herpes simplex (10019948)	6	0.1	0.0	0.1	8	0.1	0.0	0.1	7	0.1	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Herpes zoster (10019974)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Herpes zoster disseminated (10065038)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Herpes zoster oticus (10063491)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hordeolum (10020377)	2	0.0	0.0	0.1	6	0.1	0.0	0.1	4	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Impetigo (10021531)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infected bites (10021769)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infected cyst (10058015)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infected dermal cyst (10071367)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infected skin ulcer (10021784)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infected varicose vein (10057258)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infection (10021789)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	4	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infection parasitic (10021857)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infectious colitis (10021905)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infective exacerbation of chronic obstructive airways disease (10056971)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Infective glossitis (10070963)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Influenza (10022000)	24	0.2	0.1	0.3	21	0.2	0.1	0.3	14	0.1	0.1	0.2	29	0.2	0.2	0.3	6	0.2	0.1	0.4	10	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site cellulitis (10050057)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	5	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injection site infection (10022076)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intestinal gangrene (10022651)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Kidney infection (10023424)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Klebsiella bacteraemia (10058856)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Klebsiella sepsis (10054160)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Labyrinthitis (10023567)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	8	0.1	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Laryngitis (10023874)	6	0.1	0.0	0.1	9	0.1	0.0	0.2	9	0.1	0.0	0.1	7	0.1	0.0	0.1	4	0.1	0.0	0.3	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Liver abscess (10024652)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lobar pneumonia (10024738)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Localised infection (10024774)	5	0.0	0.0	0.1	6	0.1	0.0	0.1	9	0.1	0.0	0.1	8	0.1	0.0	0.1	4	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Lower respiratory tract infection (10024968)	13	0.1	0.1	0.2	15	0.1	0.1	0.2	35	0.3	0.2	0.4	38	0.3	0.2	0.4	23	0.8	0.5	1.1	17	0.6	0.4	1.0	1	0.9	0.0	4.8	1	0.7	0.0	4.1
	Lung abscess (10025028)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Lung infection (10061229)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lyme disease (10025169)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	5	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymph node tuberculosis (10025183)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymphangitis (10025226)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mastitis (10026883)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mastoiditis (10026900)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Meningitis (10027199)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Meningitis pneumococcal (10027253)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nail infection (10061304)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal abscess (10028720)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal herpes (10074936)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasopharyngitis (10028810)	180	1.6	1.4	1.8	213	1.9	1.6	2.2	218	1.8	1.6	2.1	233	1.9	1.7	2.2	51	1.7	1.3	2.2	41	1.5	1.0	2.0	1	0.9	0.0	4.8	1	0.7	0.0	4.1
	Neuroborreliosis (10052057)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neutropenic sepsis (10049151)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophageal candidiasis (10030154)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Omphalitis (10030306)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Onychomycosis (10030338)	14	0.1	0.1	0.2	13	0.1	0.1	0.2	17	0.1	0.1	0.2	23	0.2	0.1	0.3	4	0.1	0.0	0.3	7	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ophthalmic herpes simplex (10073938)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ophthalmic herpes zoster (10030865)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral candidiasis (10030963)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral fungal infection (10061324)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral herpes (10067152)	10	0.1	0.0	0.2	9	0.1	0.0	0.2	10	0.1	0.0	0.2	9	0.1	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oral infection (10048685)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Orchitis (10031064)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oropharyngeal candidiasis (10050346)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteomyelitis (10031252)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Otitis externa (10033072)	6	0.1	0.0	0.1	8	0.1	0.0	0.1	15	0.1	0.1	0.2	17	0.1	0.1	0.2	1	0.0	0.0	0.2	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Otitis externa fungal (10052557)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Otitis media (10033078)	8	0.1	0.0	0.1	7	0.1	0.0	0.1	8	0.1	0.0	0.1	11	0.1	0.0	0.2	1	0.0	0.0	0.2	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Otitis media acute (10033079)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	6	0.1	0.0	0.1	5	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Otitis media chronic (10033081)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Otosalpingitis (10033102)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Overgrowth bacterial (10033302)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Parasitic gastroenteritis (10067720)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Paronychia (10034016)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Parotitis (10034038)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pasteurella infection (10034106)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pelvic abscess (10034236)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Perichondritis (10062067)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Periodontitis (10034539)	5	0.0	0.0	0.1	4	0.0	0.0	0.1	9	0.1	0.0	0.1	6	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Periorbital cellulitis (10057182)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peritonitis (10034674)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peritonsillar abscess (10034686)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pertussis (10034738)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pharyngitis (10034835)	47	0.4	0.3	0.6	33	0.3	0.2	0.4	55	0.5	0.4	0.6	69	0.6	0.4	0.7	12	0.4	0.2	0.7	10	0.4	0.2	0.7	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Pharyngitis bacterial (10057869)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pharyngitis streptococcal (10034839)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pharyngotonsillitis (10049140)	7	0.1	0.0	0.1	6	0.1	0.0	0.1	2	0.0	0.0	0.1	6	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pilonidal cyst (10035043)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pneumonia (10035664)	30	0.3	0.2	0.4	18	0.2	0.1	0.3	45	0.4	0.3	0.5	40	0.3	0.2	0.4	18	0.6	0.4	0.9	25	0.9	0.6	1.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pneumonia bacterial (10060946)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pneumonia chlamydial (10035673)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pneumonia klebsiella (10035717)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pneumonia pneumococcal (10035728)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pneumonia viral (10035737)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post procedural infection (10067268)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	6	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Postoperative wound infection (10036410)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostate infection (10050662)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pseudomembranous colitis (10037128)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Psittacosis (10037151)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Psoas abscess (10056517)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary tuberculosis (10037440)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulpitis dental (10037464)	4	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.1	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Purulence (10061926)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Purulent discharge (10037569)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyelonephritis (10037596)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	6	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyelonephritis acute (10037597)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyelonephritis chronic (10037601)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyoderma (10037632)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyuria (10037686)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash pustular (10037888)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal abscess (10038351)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory tract infection (10062352)	17	0.1	0.1	0.2	8	0.1	0.0	0.1	24	0.2	0.1	0.3	21	0.2	0.1	0.3	10	0.3	0.2	0.6	5	0.2	0.1	0.4	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Respiratory tract infection viral (10062106)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Retinitis (10038910)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinitis (10039083)	12	0.1	0.1	0.2	16	0.1	0.1	0.2	10	0.1	0.0	0.2	12	0.1	0.1	0.2	4	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinolaryngitis (10057442)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinotracheitis (10051497)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinovirus infection (10061494)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Root canal infection (10075136)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rotavirus infection (10067470)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Salmonellosis (10039447)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Salpingitis (10039453)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Scrotal abscess (10049571)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sepsis (10040047)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Septic shock (10040070)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Shigella infection (10054178)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sialoadenitis (10040628)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinobronchitis (10048979)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinusitis (10040753)	52	0.5	0.3	0.6	58	0.5	0.4	0.7	59	0.5	0.4	0.6	47	0.4	0.3	0.5	16	0.5	0.3	0.9	20	0.7	0.4	1.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinusitis bacterial (10060841)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin bacterial infection (10052891)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin candida (10054152)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin infection (10040872)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	6	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Soft tissue infection (10062255)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Staphylococcal infection (10058080)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Streptococcal infection (10061372)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Streptococcal sepsis (10048960)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Subcutaneous abscess (10042343)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Syphilis (10062120)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Testicular abscess (10064724)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinea capitis (10043866)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinea cruris (10043868)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinea infection (10060889)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	6	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinea manuum (10067197)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinea pedis (10043873)	9	0.1	0.0	0.2	9	0.1	0.0	0.2	8	0.1	0.0	0.1	8	0.1	0.0	0.1	4	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tinea versicolour (10056131)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tonsillitis (10044008)	13	0.1	0.1	0.2	6	0.1	0.0	0.1	4	0.0	0.0	0.1	9	0.1	0.0	0.1	1	0.0	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tonsillitis bacterial (10065235)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tonsillitis streptococcal (10044013)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth abscess (10044016)	14	0.1	0.1	0.2	15	0.1	0.1	0.2	11	0.1	0.0	0.2	11	0.1	0.0	0.2	4	0.1	0.0	0.3	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth infection (10048762)	18	0.2	0.1	0.3	6	0.1	0.0	0.1	5	0.0	0.0	0.1	6	0.0	0.0	0.1	2	0.1	0.0	0.2	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Toxoplasmosis (10044272)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tracheitis (10044302)	6	0.1	0.0	0.1	4	0.0	0.0	0.1	5	0.0	0.0	0.1	6	0.0	0.0	0.1	5	0.2	0.1	0.4	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tracheobronchitis (10044314)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tuberculosis (10044755)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Upper respiratory tract infection (10046306)	111	1.0	0.8	1.2	90	0.8	0.6	1.0	141	1.2	1.0	1.4	126	1.0	0.9	1.2	42	1.4	1.0	1.9	34	1.2	0.8	1.7	0	0.0	0.0	3.2	2	1.5	0.2	5.2
	Upper respiratory tract infection bacterial (10057868)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urethritis (10046480)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Urinary tract infection (10046571)	74	0.7	0.5	0.8	80	0.7	0.6	0.9	127	1.1	0.9	1.3	104	0.9	0.7	1.0	50	1.7	1.2	2.2	42	1.5	1.1	2.0	2	1.8	0.2	6.2	2	1.5	0.2	5.2
	Urinary tract infection bacterial (10054088)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urinary tract infection staphylococcal (10062280)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urosepsis (10048709)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaginal infection (10046914)	3	0.0	0.0	0.1	5	0.0	0.0	0.1	7	0.1	0.0	0.1	12	0.1	0.1	0.2	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vestibular neuritis (10047393)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Viral infection (10047461)	5	0.0	0.0	0.1	5	0.0	0.0	0.1	9	0.1	0.0	0.1	7	0.1	0.0	0.1	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Viral sinusitis (10051513)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	6	0.1	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Visceral leishmaniasis (10047505)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vulvitis (10047780)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vulvovaginal candidiasis (10047784)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vulvovaginal mycotic infection (10064899)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vulvovaginitis (10047794)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Wound infection (10048038)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	10	0.1	0.0	0.2	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Wound infection pseudomonas (10059444)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Wound infection staphylococcal (10059442)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Injury, poisoning and procedural complications (10022117)	At least one PT related to the corresponding SOC	192	1.7	1.5	1.9	213	1.9	1.6	2.2	319	2.7	2.4	3.0	299	2.5	2.2	2.7	111	3.7	3.0	4.4	107	3.8	3.1	4.6	5	4.4	1.5	10.0	3	2.2	0.5	6.4
	Abdominal injury (10060924)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Accident (10000369)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acetabulum fracture (10000397)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anaesthetic complication neurological (10002105)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aneurysm perforation (10075395)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Animal bite (10002515)	3	0.0	0.0	0.1	7	0.1	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ankle fracture (10002544)	9	0.1	0.0	0.2	6	0.1	0.0	0.1	5	0.0	0.0	0.1	6	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arthropod bite (10003399)	11	0.1	0.0	0.2	11	0.1	0.0	0.2	18	0.2	0.1	0.2	10	0.1	0.0	0.2	3	0.1	0.0	0.3	1	0.0	0.0	0.2	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Arthropod sting (10003402)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Back injury (10003986)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bite (10004966)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bone contusion (10066251)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bone fissure (10064210)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast injury (10059391)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Burns first degree (10006797)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Burns second degree (10006802)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Burns third degree (10006803)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Cartilage injury (10007710)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cataract operation complication (10057419)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervical vertebral fracture (10049946)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chemical poisoning (10008428)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chest injury (10061386)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chillblains (10008528)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Clavicle fracture (10009245)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Comminuted fracture (10052614)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Compression fracture (10010214)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Concussion (10010254)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	4	0.0	0.0	0.1	5	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Contrast media reaction (10010836)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Contusion (10050584)	13	0.1	0.1	0.2	22	0.2	0.1	0.3	44	0.4	0.3	0.5	38	0.3	0.2	0.4	18	0.6	0.4	0.9	13	0.5	0.2	0.8	1	0.9	0.0	4.8	1	0.7	0.0	4.1
	Corneal abrasion (10010984)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Coronary artery reocclusion (10053261)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cranioerebral injury (10070976)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Crush injury (10061097)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Deafness traumatic (10011903)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Deep vein thrombosis postoperative (10066881)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epicondylitis (10014971)	4	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epiphyseal fracture (10053962)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Excoriation (10049796)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye contusion (10073354)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye injury (10061128)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye penetration (10015960)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eyelid injury (10069200)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Face injury (10050392)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Facial bones fracture (10016042)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fall (10016173)	7	0.1	0.0	0.1	11	0.1	0.0	0.2	19	0.2	0.1	0.3	16	0.1	0.1	0.2	12	0.4	0.2	0.7	13	0.5	0.2	0.8	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Femoral neck fracture (10016450)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Femur fracture (10016454)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	10	0.1	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Fibula fracture (10016667)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Foot fracture (10016970)	7	0.1	0.0	0.1	3	0.0	0.0	0.1	7	0.1	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Forearm fracture (10016997)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Foreign body (10070245)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	5	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Foreign body in eye (10017012)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fracture (10017076)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fractured coccyx (10049164)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fractured sacrum (10017308)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hair injury (10074924)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hand fracture (10019114)	5	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Head injury (10019196)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	7	0.1	0.0	0.1	6	0.0	0.0	0.1	4	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Heat stroke (10019345)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hip fracture (10020100)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Humerus fracture (10020462)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.1	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Incarcerated incisional hernia (10076387)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Incisional hernia (10021619)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Inflammation of wound (10054923)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injury (10022116)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Injury corneal (10022120)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Jaw fracture (10023149)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint dislocation (10023204)	3	0.0	0.0	0.1	4	0.0	0.0	0.1	7	0.1	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint injury (10060820)	4	0.0	0.0	0.1	4	0.0	0.0	0.1	7	0.1	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Kidney contusion (10023413)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Laceration (10023572)	11	0.1	0.0	0.2	11	0.1	0.0	0.2	12	0.1	0.1	0.2	16	0.1	0.1	0.2	3	0.1	0.0	0.3	8	0.3	0.1	0.6	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Laryngeal injury (10057441)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ligament injury (10061223)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ligament rupture (10065433)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ligament sprain (10024453)	20	0.2	0.1	0.3	25	0.2	0.1	0.3	22	0.2	0.1	0.3	22	0.2	0.1	0.3	4	0.1	0.0	0.3	5	0.2	0.1	0.4	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Limb crushing injury (10064031)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Limb injury (10061225)	10	0.1	0.0	0.2	12	0.1	0.1	0.2	17	0.1	0.1	0.2	11	0.1	0.0	0.2	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lip injury (10055082)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lower limb fracture (10061599)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lumbar vertebral fracture (10049947)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Meniscus injury (10072970)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	7	0.1	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Mouth injury (10049294)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Multiple fractures (10028200)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Multiple injuries (10028224)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle contusion (10070757)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle injury (10028314)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle rupture (10028331)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle strain (10050031)	7	0.1	0.0	0.1	5	0.0	0.0	0.1	12	0.1	0.1	0.2	7	0.1	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nerve root injury cervical (10029183)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Open fracture (10030527)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Optic nerve injury (10030938)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Overdose (10033295)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Patella fracture (10034122)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pelvic fracture (10061161)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Periorbital contusion (10062515)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Poisoning (10061355)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post procedural complication (10058046)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post procedural haematuria (10066225)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post procedural haemorrhage (10051077)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post procedural inflammation (10063101)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post procedural pulmonary embolism (10063909)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post-traumatic neck syndrome (10071366)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post-traumatic pain (10065016)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Postoperative wound complication (10061468)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Procedural complication (10057765)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Procedural pain (10064882)	4	0.0	0.0	0.1	6	0.1	0.0	0.1	8	0.1	0.0	0.1	9	0.1	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pubis fracture (10070286)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Radius fracture (10037802)	4	0.0	0.0	0.1	10	0.1	0.0	0.2	8	0.1	0.0	0.1	11	0.1	0.0	0.2	5	0.2	0.1	0.4	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rib fracture (10039117)	4	0.0	0.0	0.1	10	0.1	0.0	0.2	10	0.1	0.0	0.2	6	0.0	0.0	0.1	3	0.1	0.0	0.3	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Road traffic accident (10039203)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Scapula fracture (10039579)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Seroma (10040102)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skeletal injury (10061363)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Skin abrasion (10064990)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin injury (10061364)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin wound (10072170)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skull fracture (10061365)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skull fractured base (10040960)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Snake bite (10041230)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Soft tissue injury (10041291)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	2	0.1	0.0	0.3	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Spinal column injury (10069689)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal compression fracture (10041541)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	6	0.1	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Spinal cord injury (10041552)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal cord injury cervical (10041554)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal cord injury lumbar (10041555)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal fracture (10041569)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sternal fracture (10042015)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Subcutaneous haematoma (10042345)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Subdural haematoma (10042361)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sunburn (10042496)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Synovial rupture (10042862)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tendon injury (10043242)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tendon rupture (10043248)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thermal burn (10053615)	5	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thoracic vertebral fracture (10049948)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tibia fracture (10043827)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth fracture (10062544)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Toxicity to various agents (10070863)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Traumatic arthropathy (10044502)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Traumatic haematoma (10044522)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Traumatic intracranial haemorrhage (10061387)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ulna fracture (10045375)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Upper limb fracture (10061394)	5	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.0	0.0	0.1	7	0.1	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaccination complication (10046861)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vascular graft occlusion (10049060)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vascular injury (10047080)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vascular pseudoaneurysm (10048975)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vascular pseudoaneurysm ruptured (10053949)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Wound (10052428)	7	0.1	0.0	0.1	3	0.0	0.0	0.1	14	0.1	0.1	0.2	12	0.1	0.1	0.2	6	0.2	0.1	0.4	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Wound complication (10053692)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Wound dehiscence (10048031)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Wrist fracture (10048049)	6	0.1	0.0	0.1	8	0.1	0.0	0.1	5	0.0	0.0	0.1	8	0.1	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Investigations (10022891)	At least one PT related to the corresponding SOC	17	0.1	0.1	0.2	19	0.2	0.1	0.3	49	0.4	0.3	0.5	39	0.3	0.2	0.4	10	0.3	0.2	0.6	17	0.6	0.4	1.0	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Alanine aminotransferase increased (10001551)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Amylase increased (10002016)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anticoagulation drug level above therapeutic (10060320)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood alkaline phosphatase increased (10059570)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood cholesterol increased (10005425)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood creatine phosphokinase increased (10005470)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood creatinine increased (10005483)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood folate decreased (10005527)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood glucose abnormal (10005554)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood glucose fluctuation (10049803)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood glucose increased (10005557)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	6	0.0	0.0	0.1	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood heavy metal increased (10061718)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Blood iron decreased (10005619)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood oestrogen decreased (10005687)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood potassium decreased (10005724)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood potassium increased (10005725)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood pressure abnormal (10005728)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood pressure increased (10005750)	4	0.0	0.0	0.1	2	0.0	0.0	0.1	12	0.1	0.1	0.2	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood sodium decreased (10005802)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood testosterone decreased (10005814)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood thyroid stimulating hormone increased (10005833)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood triglycerides increased (10005839)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood uric acid increased (10005861)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood urine present (10018870)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Body temperature increased (10005911)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	C-reactive protein decreased (10049220)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	C-reactive protein increased (10006825)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Carbohydrate antigen 125 increased (10051414)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Carbohydrate antigen 15-3 increased (10051415)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Carcinoembryonic antigen increased (10007266)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac murmur (10007586)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Catheterisation cardiac (10007815)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chest x-ray abnormal (10008499)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
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		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Colonoscopy (10010007)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Electrocardiogram abnormal (10014363)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Electrocardiogram change (10061116)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gamma-glutamyltransferase increased (10017693)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Grip strength decreased (10062556)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemoglobin decreased (10018884)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Heart rate increased (10019303)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Heart rate irregular (10019304)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Helicobacter test positive (10070101)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hormone level abnormal (10061210)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	International normalised ratio increased (10022595)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intraocular pressure increased (10022806)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Liver function test abnormal (10024690)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Occult blood positive (10061880)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Platelet count decreased (10035528)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Precancerous cells present (10049673)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostatic specific antigen increased (10036975)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Protein urine (10037018)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Protein urine present (10053123)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Red blood cell sedimentation rate increased (10049187)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Serum ferritin decreased (10040249)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Serum ferritin increased (10040250)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

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Report Final

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		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Smear cervix abnormal (10041206)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Total bile acids increased (10064558)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Transaminases increased (10054889)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ultrasound scan (10045434)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urine analysis abnormal (10062226)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vitamin b12 decreased (10047608)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vitamin d decreased (10062189)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Weight decreased (10047895)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	7	0.1	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Metabolism and nutrition disorders (10027433)	At least one PT related to the corresponding SOC	77	0.7	0.5	0.8	74	0.7	0.5	0.8	150	1.3	1.1	1.5	134	1.1	0.9	1.3	49	1.6	1.2	2.1	47	1.7		2.2	1	0.9	0.0	4.8	2	1.5	0.2	5.2
	Abnormal loss of weight (10000159)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cachexia (10006895)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Decreased appetite (10061428)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	7	0.1	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dehydration (10012174)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	7	0.1	0.0	0.1	4	0.0	0.0	0.1	4	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetes mellitus (10012601)	14	0.1	0.1	0.2	6	0.1	0.0	0.1	24	0.2	0.1	0.3	17	0.1	0.1	0.2	3	0.1	0.0	0.3	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetes mellitus inadequate control (10012607)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Diabetic ketoacidosis (10012671)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dyslipidaemia (10058108)	15	0.1	0.1	0.2	10	0.1	0.0	0.2	17	0.1	0.1	0.2	14	0.1	0.1	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Electrolyte imbalance (10014418)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Feeding disorder (10061148)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fluid retention (10016807)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Folate deficiency (10016880)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glucose tolerance impaired (10018429)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gout (10018627)	8	0.1	0.0	0.1	10	0.1	0.0	0.2	20	0.2	0.1	0.3	15	0.1	0.1	0.2	11	0.4	0.2	0.6	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypercalcaemia (10020583)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypercholesterolaemia (10020603)	12	0.1	0.1	0.2	18	0.2	0.1	0.3	19	0.2	0.1	0.3	12	0.1	0.1	0.2	3	0.1	0.0	0.3	4	0.1	0.0	0.4	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Hyperglycaemia (10020635)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperkalaemia (10020646)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hyperlipidaemia (10062060)	13	0.1	0.1	0.2	7	0.1	0.0	0.1	12	0.1	0.1	0.2	15	0.1	0.1	0.2	6	0.2	0.1	0.4	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertriglyceridaemia (10020869)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperuricaemia (10020903)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	9	0.1	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Hypocalcaemia (10020947)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypoglycaemia (10020993)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	7	0.1	0.0	0.1	6	0.0	0.0	0.1	3	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypokalaemia (10021015)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	5	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypomagnesaemia (10021027)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyponatraemia (10021036)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypophagia (10063743)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypovitaminosis (10021135)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Iron deficiency (10022970)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lactose intolerance (10023681)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Malnutrition (10061273)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Obesity (10029883)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Type 1 diabetes mellitus (10067584)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Type 2 diabetes mellitus (10067585)	6	0.1	0.0	0.1	8	0.1	0.0	0.1	22	0.2	0.1	0.3	15	0.1	0.1	0.2	5	0.2	0.1	0.4	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vitamin b12 deficiency (10047609)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vitamin d deficiency (10047626)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	6	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Musculoskeletal and connective tissue disorders (10028395)	At least one PT related to the corresponding SOC	368	3.2	2.9	3.6	366	3.2	2.9	3.6	577	4.9	4.5	5.3	585	4.8	4.4	5.2	196	6.5	5.6	7.4	189	6.7	5.8	7.7	4	3.5	1.0	8.8	4	3.0	0.8	7.4
	Acquired claw toe (10057689)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arthralgia (10003239)	41	0.4	0.3	0.5	70	0.6	0.5	0.8	90	0.8	0.6	0.9	80	0.7	0.5	0.8	28	0.9	0.6	1.3	25	0.9	0.6	1.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arthritis (10003246)	8	0.1	0.0	0.1	8	0.1	0.0	0.1	18	0.2	0.1	0.2	8	0.1	0.0	0.1	3	0.1	0.0	0.3	2	0.1	0.0	0.3	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Arthropathy (10003285)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	10	0.1	0.0	0.2	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Back pain (10003988)	77	0.7	0.5	0.8	60	0.5	0.4	0.7	105	0.9	0.7	1.1	109	0.9	0.7	1.1	43	1.4	1.0	1.9	36	1.3	0.9	1.8	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Bone decalcification (10070817)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bone disorder (10005956)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bone pain (10006002)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bursitis (10006811)	8	0.1	0.0	0.1	8	0.1	0.0	0.1	16	0.1	0.1	0.2	15	0.1	0.1	0.2	4	0.1	0.0	0.3	6	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervical spinal stenosis (10008313)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chondrocalcinosis (10061761)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chondropathy (10061762)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Coccydynia (10009829)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Costochondritis (10011219)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dupuytren's contracture (10013872)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Exostosis (10015688)	6	0.1	0.0	0.1	3	0.0	0.0	0.1	5	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fasciitis (10016228)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fibromyalgia (10048439)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Flank pain (10016750)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Foot deformity (10061159)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	7	0.1	0.0	0.1	6	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gouty arthritis (10018634)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gouty tophus (10018641)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Groin pain (10018735)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	5	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Iliolumbar syndrome (10063442)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intervertebral disc degeneration (10061246)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intervertebral disc disorder (10061521)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intervertebral disc displacement (10022636)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intervertebral disc protrusion (10050296)	5	0.0	0.0	0.1	8	0.1	0.0	0.1	6	0.1	0.0	0.1	10	0.1	0.0	0.2	3	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint contracture (10023201)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint effusion (10023215)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint stiffness (10023230)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Joint swelling (10023232)	2	0.0	0.0	0.1	7	0.1	0.0	0.1	8	0.1	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ligament disorder (10061222)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Limb deformity (10053652)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Limb discomfort (10061224)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Lumbar spinal stenosis (10025005)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Meniscal degeneration (10069364)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metatarsalgia (10027487)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mobility decreased (10048334)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Monarthritis (10027811)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle contracture (10062575)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle disorder (10028300)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle rigidity (10028330)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle spasms (10028334)	9	0.1	0.0	0.2	7	0.1	0.0	0.1	12	0.1	0.1	0.2	14	0.1	0.1	0.2	2	0.1	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle tightness (10049816)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Muscular weakness (10028372)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Musculoskeletal chest pain (10050819)	3	0.0	0.0	0.1	6	0.1	0.0	0.1	9	0.1	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	6	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Musculoskeletal discomfort (10053156)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Musculoskeletal pain (10028391)	21	0.2	0.1	0.3	25	0.2	0.1	0.3	35	0.3	0.2	0.4	35	0.3	0.2	0.4	9	0.3	0.1	0.6	6	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Musculoskeletal stiffness (10052904)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myalgia (10028411)	11	0.1	0.0	0.2	12	0.1	0.1	0.2	22	0.2	0.1	0.3	17	0.1	0.1	0.2	9	0.3	0.1	0.6	5	0.2	0.1	0.4	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Myofascial pain syndrome (10048780)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myokymia (10028632)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myosclerosis (10064584)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myositis (10028653)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neck mass (10049146)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neck pain (10028836)	11	0.1	0.0	0.2	14	0.1	0.1	0.2	15	0.1	0.1	0.2	25	0.2	0.1	0.3	5	0.2	0.1	0.4	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteitis (10031149)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteitis deformans (10031151)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteoarthritis (10031161)	37	0.3	0.2	0.4	42	0.4	0.3	0.5	105	0.9	0.7	1.1	99	0.8	0.7	1.0	37	1.2	0.9	1.7	30	1.1	0.7	1.5	1	0.9	0.0	4.8	2	1.5	0.2	5.2
	Osteochondrosis (10031233)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteolysis (10031248)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteonecrosis (10031264)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteopenia (10049088)	5	0.0	0.0	0.1	0	0.0	0.0	0.0	9	0.1	0.0	0.1	8	0.1	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Osteoporosis (10031282)	11	0.1	0.0	0.2	6	0.1	0.0	0.1	7	0.1	0.0	0.1	18	0.1	0.1	0.2	4	0.1	0.0	0.3	9	0.3	0.1	0.6	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Osteoporotic fracture (10031290)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pain in extremity (10033425)	42	0.4	0.3	0.5	24	0.2	0.1	0.3	44	0.4	0.3	0.5	48	0.4	0.3	0.5	13	0.4	0.2	0.7	14	0.5	0.3	0.8	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pain in jaw (10033433)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Palmar fasciitis (10067366)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Periarthritis (10034464)	6	0.1	0.0	0.1	8	0.1	0.0	0.1	2	0.0	0.0	0.1	6	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Periostitis (10034551)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Plantar fascial fibromatosis (10035154)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Plantar fasciitis (10035155)	2	0.0	0.0	0.1	5	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Polyarthritis (10036030)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Polymyalgia rheumatica (10036099)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	7	0.1	0.0	0.1	6	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Polymyositis (10036102)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Pseudarthrosis (10048617)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhabdomyolysis (10039020)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rheumatic disorder (10072736)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rheumatoid arthritis (10039073)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	4	0.0	0.0	0.1	6	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rotator cuff syndrome (10039227)	8	0.1	0.0	0.1	2	0.0	0.0	0.1	7	0.1	0.0	0.1	12	0.1	0.1	0.2	3	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Scoliosis (10039722)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sjogren's syndrome (10040767)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Soft tissue disorder (10061366)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Soft tissue mass (10071051)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal column stenosis (10041540)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	8	0.1	0.0	0.1	6	0.2	0.1	0.4	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal disorder (10061368)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal osteoarthritis (10041591)	8	0.1	0.0	0.1	11	0.1	0.0	0.2	12	0.1	0.1	0.2	16	0.1	0.1	0.2	4	0.1	0.0	0.3	11	0.4	0.2	0.7	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Spinal pain (10072005)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spondyloarthropathy (10051265)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spondylolisthesis (10063550)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spondylolysis (10052013)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Still's disease adult onset (10064056)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Synovial cyst (10042858)	5	0.0	0.0	0.1	2	0.0	0.0	0.1	7	0.1	0.0	0.1	5	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Synovitis (10042868)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Temporomandibular joint syndrome (10043220)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tendon disorder (10043239)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tendon pain (10066371)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tendonitis (10043255)	17	0.1	0.1	0.2	16	0.1	0.1	0.2	20	0.2	0.1	0.3	18	0.1	0.1	0.2	9	0.3	0.1	0.6	4	0.1	0.0	0.4	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Tenosynovitis (10043261)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tenosynovitis stenosans (10056698)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Torticollis (10044074)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Trigger finger (10044654)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	8	0.1	0.0	0.1	5	0.2	0.1	0.4	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vertebral foraminal stenosis (10069690)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vertebral osteophyte (10055042)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	At least one PT related to the corresponding SOC	85	0.7	0.6	0.9	87	0.8	0.6	0.9	142	1.2	1.0	1.4	160	1.3	1.1	1.5	33	1.1	0.8	1.5	32	1.1	0.8	1.6	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Abdominal neoplasm (10060925)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acral lentiginous melanoma (10000583)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acrochordon (10000591)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute myeloid leukaemia (10000880)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute promyelocytic leukaemia (10001019)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adenocarcinoma (10001141)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adenocarcinoma gastric (10001150)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adenocarcinoma of colon (10001167)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adenocarcinoma pancreas (10052747)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adenoma benign (10001233)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adrenal adenoma (10001323)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adrenal gland cancer (10073152)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anogenital warts (10059313)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	B-cell lymphoma (10003899)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Basal cell carcinoma (10004146)	9	0.1	0.0	0.2	11	0.1	0.0	0.2	15	0.1	0.1	0.2	23	0.2	0.1	0.3	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Benign breast neoplasm (10004243)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Benign ear neoplasm (10069051)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Benign hepatic neoplasm (10004269)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Benign neoplasm (10060999)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Benign neoplasm of bladder (10004302)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Benign neoplasm of orbit (10004355)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Benign neoplasm of skin (10004398)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	4	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Benign neoplasm of thyroid gland (10004412)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Benign soft tissue neoplasm (10061004)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bile duct cancer (10004593)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bladder cancer (10005003)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	8	0.1	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bladder cancer recurrent (10005005)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bladder neoplasm (10005056)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bladder papilloma (10005064)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bladder transitional cell carcinoma (10005084)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bowen's disease (10006059)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Brain neoplasm benign (10006129)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast cancer (10006187)	7	0.1	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast cancer in situ (10006189)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast cancer metastatic (10055113)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast fibroma (10063088)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchial carcinoma (10006417)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchial neoplasm (10052245)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Carcinoid tumour of the small bowel (10052819)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervix carcinoma (10008342)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cholangiocarcinoma (10008593)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chronic lymphocytic leukaemia (10008958)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chronic myeloid leukaemia (10009013)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Colon adenoma (10048832)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Colon cancer (10009944)	6	0.1	0.0	0.1	5	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Colon neoplasm (10061045)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diffuse large b-cell lymphoma (10012818)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysplastic naevus (10062805)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Endometrial adenocarcinoma (10014720)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Endometrial cancer (10014733)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Essential thrombocythaemia (10015493)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fibroma (10016629)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fibrous histiocytoma (10053717)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastric cancer (10017758)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal neoplasm (10061174)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Gastrointestinal tract adenoma (10051635)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glioblastoma multiforme (10018337)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glioma (10018338)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glomus tumour (10018381)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemangioma (10018814)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemangioma of spleen (10068123)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hair follicle tumour benign (10019043)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatic cancer (10073069)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatic cancer metastatic (10055110)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatic neoplasm (10019695)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hepatocellular carcinoma (10073071)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypergammaglobulinaemia benign monoclonal (10020631)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intraductal proliferative breast lesion (10073094)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Invasive ductal breast carcinoma (10073095)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Invasive papillary breast carcinoma (10073098)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Keratoacanthoma (10023347)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Large cell lung cancer (10023774)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Large intestine benign neoplasm (10073394)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Laryngeal neoplasm (10023841)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Leukaemia (10024288)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Lip squamous cell carcinoma (10064055)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lipoma (10024612)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	5	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lung adenocarcinoma (10025031)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lung adenocarcinoma stage iii (10025037)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lung cancer metastatic (10050017)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lung neoplasm (10062042)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lung neoplasm malignant (10058467)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymphoma (10025310)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Malignant melanoma (10025650)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	5	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Malignant melanoma in situ (10025652)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Malignant neoplasm of eye (10025910)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Malignant ovarian cyst (10026662)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Malignant palate neoplasm (10026663)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Melanocytic naevus (10027145)	1	0.0	0.0	0.0	8	0.1	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Meningioma (10027191)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Meningioma benign (10027192)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mesothelioma (10027406)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metastases to bone (10027452)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metastases to central nervous system (10059282)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metastases to liver (10027457)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metastases to lung (10027458)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metastases to lymph nodes (10027459)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metastases to peritoneum (10051676)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metastatic malignant melanoma (10027480)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metastatic neoplasm (10061289)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Metastatic squamous cell carcinoma (10063569)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myelodysplastic syndrome (10028533)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasopharyngeal cancer (10061306)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasopharyngeal neoplasm benign (10028802)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neoplasm malignant (10028997)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neoplasm of orbit (10061863)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neoplasm skin (10029098)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Non-hodgkin's lymphoma (10029547)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Non-small cell lung cancer (10061873)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Non-small cell lung cancer stage iv (10029522)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophageal carcinoma (10030155)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oesophageal squamous cell carcinoma (10061534)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ovarian cancer (10033128)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ovarian cancer recurrent (10066697)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ovarian epithelial cancer (10061328)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ovarian germ cell teratoma benign (10033236)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ovarian neoplasm (10061535)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pancreatic carcinoma (10033609)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pancreatic carcinoma metastatic (10033610)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pancreatic neoplasm (10061902)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pancreatic neuroendocrine tumour (10067517)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Papillary thyroid cancer (10033701)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Papilloma (10033713)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Paraganglion neoplasm (10061332)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Phaeochromocytoma (10034800)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pituitary tumour benign (10061538)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Plasma cell myeloma (10035226)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pleomorphic adenoma (10073372)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostate cancer (10060862)	7	0.1	0.0	0.1	9	0.1	0.0	0.2	14	0.1	0.1	0.2	7	0.1	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostate cancer metastatic (10036909)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostate cancer recurrent (10036911)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostatic adenoma (10036940)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pyogenic granuloma (10037649)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rectal adenocarcinoma (10038019)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rectal adenoma (10048829)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rectal cancer (10038038)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rectal cancer recurrent (10038046)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal cancer (10038389)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal cell carcinoma (10067946)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal neoplasm (10061482)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal oncocytoma (10050176)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Salivary gland cancer (10061934)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sarcoma (10039491)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Schwannoma (10039667)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Seborrhoeic keratosis (10039796)	6	0.1	0.0	0.1	5	0.0	0.0	0.1	6	0.1	0.0	0.1	9	0.1	0.0	0.1	3	0.1	0.0	0.3	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin cancer (10040808)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin papilloma (10040907)	7	0.1	0.0	0.1	9	0.1	0.0	0.2	12	0.1	0.1	0.2	9	0.1	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Small cell lung cancer (10041067)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Squamous cell carcinoma (10041823)	4	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Squamous cell carcinoma of lung (10041826)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Squamous cell carcinoma of skin (10041834)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Squamous cell carcinoma of the oral cavity (10041857)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Testicular neoplasm (10061379)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thyroid adenoma (10043688)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thyroid cancer (10066474)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thyroid neoplasm (10043744)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Transitional cell carcinoma (10044412)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tumour haemorrhage (10049750)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urethral neoplasm (10062223)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Uterine cancer (10046766)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Uterine leiomyoma (10046798)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	138	1.2	1.0	1.4	140	1.2	1.0	1.5	274	2.3	2.1	2.6	274	2.2	2.0	2.5	107	3.5	2.9	4.3	105	3.7	3.1	4.5	4	3.5	1.0	8.8	1	0.7	0.0	4.1
	Amnesia (10001949)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Amnesic disorder (10061423)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Amyotrophic lateral sclerosis (10002026)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Apallic syndrome (10002941)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aphasia (10002948)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aphonia (10002953)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Autonomic nervous system imbalance (10003840)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Balance disorder (10049848)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	5	0.0	0.0	0.1	5	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Basal ganglia infarction (10069020)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Basilar artery occlusion (10048963)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Brain stem infarction (10006147)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Brain stem syndrome (10063292)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Burning sensation (10006784)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Carotid arteriosclerosis (10067116)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Carotid artery occlusion (10048964)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Carotid artery stenosis (10007687)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Carotid artery thrombosis (10007688)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Carotid sinus syndrome (10050202)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Carpal tunnel syndrome (10007697)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	10	0.1	0.0	0.2	11	0.1	0.0	0.2	4	0.1	0.0	0.3	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Central nervous system lesion (10051290)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebellar haemorrhage (10008030)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebral arteriosclerosis (10065559)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebral artery occlusion (10008089)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebral artery thrombosis (10008092)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebral atrophy (10008096)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebral disorder (10054938)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebral haemorrhage (10008111)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebral infarction (10008118)	4	0.0	0.0	0.1	0	0.0	0.0	0.0	5	0.0	0.0	0.1	9	0.1	0.0	0.1	1	0.0	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebral ischaemia (10008120)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebrospinal fluid leakage (10008164)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebrovascular accident (10008190)	5	0.0	0.0	0.1	4	0.0	0.0	0.1	11	0.1	0.0	0.2	8	0.1	0.0	0.1	7	0.2	0.1	0.5	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebrovascular disorder (10008196)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cerebrovascular stenosis (10061751)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervical myelopathy (10008289)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervical radiculopathy (10050217)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervicobrachial syndrome (10008334)	1	0.0	0.0	0.0	4	0.0	0.0	0.1	13	0.1	0.1	0.2	8	0.1	0.0	0.1	3	0.1	0.0	0.3	7	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cognitive disorder (10057668)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	1	0.9	0.0	4.8	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Complex regional pain syndrome (10064332)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Convulsions local (10010920)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cubital tunnel syndrome (10056473)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dementia (10012267)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dementia alzheimer's type (10012271)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dementia with lewy bodies (10067889)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Demyelinating polyneuropathy (10061811)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Demyelination (10012305)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetic neuropathy (10012680)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	7	0.1	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Disturbance in attention (10013496)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dizziness (10013573)	22	0.2	0.1	0.3	21	0.2	0.1	0.3	53	0.4	0.3	0.6	39	0.3	0.2	0.4	20	0.7	0.4	1.0	18	0.6	0.4	1.0	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dizziness postural (10013578)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysaesthesia (10013886)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysgeusia (10013911)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dyskinesia (10013916)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Encephalopathy (10014625)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epilepsy (10015037)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Essential tremor (10015496)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Facial neuralgia (10061594)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Facial spasm (10063006)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Generalised tonic-clonic seizure (10018100)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Glossopharyngeal neuralgia (10018391)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Guillain-barre syndrome (10018767)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemorrhage intracranial (10018985)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemorrhagic stroke (10019016)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Head discomfort (10019194)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Headache (10019211)	24	0.2	0.1	0.3	22	0.2	0.1	0.3	47	0.4	0.3	0.5	36	0.3	0.2	0.4	16	0.5	0.3	0.9	10	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hydrocephalus (10020508)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperaesthesia (10020568)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Hypersomnia (10020765)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertonia (10020852)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypoaesthesia (10020937)	8	0.1	0.0	0.1	6	0.1	0.0	0.1	11	0.1	0.0	0.2	7	0.1	0.0	0.1	2	0.1	0.0	0.2	6	0.2	0.1	0.5	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Hypokinesia (10021021)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypoxic-ischaemic encephalopathy (10070511)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intention tremor (10022520)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intercostal neuralgia (10049949)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intracranial aneurysm (10022758)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intraventricular haemorrhage (10022840)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ischaemic stroke (10061256)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lacunar infarction (10051078)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lethargy (10024264)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Loss of consciousness (10024855)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lumbar radiculopathy (10050219)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Memory impairment (10027175)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Metabolic encephalopathy (10062190)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Migraine (10027599)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	6	0.1	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Migraine without aura (10052787)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mixed dementia (10075174)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mononeuritis (10027910)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Morton's neuralgia (10052288)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Multiple sclerosis (10028245)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Muscle contractions involuntary (10028293)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myasthenic syndrome (10028424)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Myelopathy (10028570)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nerve compression (10029174)	5	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nervous system disorder (10029202)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neuralgia (10029223)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neuritis (10029240)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Neuritis cranial (10029244)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neuromuscular blockade (10029315)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neuropathy peripheral (10029331)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Olfactory nerve disorder (10056388)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Paraesthesia (10033775)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Parkinson's disease (10061536)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Parkinsonism (10034010)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Polyneuropathy (10036105)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Poor quality sleep (10062519)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post polio syndrome (10036239)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post-traumatic headache (10036313)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Presyncope (10036653)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Radicular pain (10059604)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Radiculitis brachial (10037778)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Radiculopathy (10037779)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Restless legs syndrome (10058920)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ruptured cerebral aneurysm (10039330)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sciatic nerve neuropathy (10048950)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sciatica (10039674)	13	0.1	0.1	0.2	11	0.1	0.0	0.2	24	0.2	0.1	0.3	37	0.3	0.2	0.4	9	0.3	0.1	0.6	8	0.3	0.1	0.6	2	1.8	0.2	6.2	0	0.0	0.0	2.7
	Seizure (10039906)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Senile dementia (10039966)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sensory disturbance (10040026)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sensory loss (10040030)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinus headache (10040744)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Somnolence (10041349)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spinal claudication (10041539)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spondylitic myelopathy (10041670)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Stupor (10042264)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Subarachnoid haemorrhage (10042316)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sudden onset of sleep (10050014)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Syncope (10042772)	10	0.1	0.0	0.2	6	0.1	0.0	0.1	12	0.1	0.1	0.2	18	0.1	0.1	0.2	11	0.4	0.2	0.6	9	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tension headache (10043269)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thalamic infarction (10064961)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thrombotic cerebral infarction (10067347)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Transient global amnesia (10044380)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Transient ischaemic attack (10044390)	3	0.0	0.0	0.1	6	0.1	0.0	0.1	14	0.1	0.1	0.2	5	0.0	0.0	0.1	5	0.2	0.1	0.4	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tremor (10044565)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Trigeminal nerve disorder (10060890)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Trigeminal neuralgia (10044652)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vascular dementia (10057678)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vascular encephalopathy (10063661)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vertebrobasilar insufficiency (10047334)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Viith nerve paralysis (10050040)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Visual field defect (10047555)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Psychiatric disorders (10037175)	At least one PT related to the corresponding SOC	46	0.4	0.3	0.5	52	0.5	0.3	0.6	99	0.8	0.7	1.0	94	0.8	0.6	0.9	47	1.6	1.1	2.1	41	1.5	1.0	2.0	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Acute psychosis (10001022)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute stress disorder (10001084)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adjustment disorder (10061621)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Adjustment disorder with anxiety (10001296)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Affective disorder (10001443)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Agoraphobia (10001502)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Alcohol withdrawal syndrome (10053164)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Alcoholism (10001639)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anxiety (10002855)	9	0.1	0.0	0.2	10	0.1	0.0	0.2	17	0.1	0.1	0.2	24	0.2	0.1	0.3	9	0.3	0.1	0.6	7	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anxiety disorder (10057666)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bipolar disorder (10057667)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breathing-related sleep disorder (10006344)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Completed suicide (10010144)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Confusional state (10010305)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Conversion disorder (10010893)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Delirium (10012218)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Depressed mood (10012374)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Depression (10012378)	12	0.1	0.1	0.2	20	0.2	0.1	0.3	33	0.3	0.2	0.4	26	0.2	0.1	0.3	10	0.3	0.2	0.6	12	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Depressive symptom (10054089)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Disorientation (10013395)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysthymic disorder (10013982)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Emotional disorder (10014551)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Emotional distress (10049119)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Generalised anxiety disorder (10018075)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Grief reaction (10018724)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hallucination (10019063)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hallucination, visual (10019075)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypomania (10021030)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hysterical psychosis (10062645)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Insomnia (10022437)	14	0.1	0.1	0.2	11	0.1	0.0	0.2	24	0.2	0.1	0.3	21	0.2	0.1	0.3	15	0.5	0.3	0.8	13	0.5	0.2	0.8	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Irritability (10022998)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Korsakoff's syndrome (10070997)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Libido decreased (10024419)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Major depression (10057840)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mental disorder (10061284)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mental status changes (10048294)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mood altered (10027940)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nervousness (10029216)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Obsessive thoughts (10029897)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Panic attack (10033664)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Panic disorder (10033666)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Psychosomatic disease (10049587)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Psychotic disorder (10061920)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Restlessness (10038743)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Schizoaffective disorder bipolar type (10068889)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Schizophrenia (10039626)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Schizophrenia, paranoid type (10039639)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sleep disorder (10040984)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	4	0.0	0.0	0.1	5	0.0	0.0	0.1	1	0.0	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Somatoform disorder (10054153)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Somatoform disorder gastrointestinal (10041322)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Stress (10042209)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Suicide attempt (10042464)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tearfulness (10043169)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tic (10043833)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Renal and urinary disorders (10038359)	At least one PT related to the corresponding SOC	48	0.4	0.3	0.6	27	0.2	0.2	0.3	75	0.6	0.5	0.8	75	0.6	0.5	0.8	43	1.4	1.0	1.9	35	1.2	0.9	1.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute kidney injury (10069339)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	5	0.0	0.0	0.1	4	0.0	0.0	0.1	5	0.2	0.1	0.4	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute prerenal failure (10001017)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Anuria (10002847)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bladder dysfunction (10069632)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bladder irritation (10005052)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bladder perforation (10063575)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bladder prolapse (10048475)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bladder spasm (10048994)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Calculus bladder (10006987)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Calculus ureteric (10007025)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Calculus urinary (10007027)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chronic kidney disease (10064848)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	4	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	6	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cystitis interstitial (10011796)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetic nephropathy (10061835)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysuria (10013990)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	5	0.2	0.1	0.4	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haematuria (10018867)	10	0.1	0.0	0.2	1	0.0	0.0	0.0	12	0.1	0.1	0.2	13	0.1	0.1	0.2	2	0.1	0.0	0.2	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemoglobinuria (10018906)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hydronephrosis (10020524)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertonic bladder (10020853)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Incontinence (10021639)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lower urinary tract symptoms (10071289)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Microalbuminuria (10027525)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Micturition disorder (10027561)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Micturition urgency (10027566)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nephritis (10029117)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nephrolithiasis (10029148)	4	0.0	0.0	0.1	5	0.0	0.0	0.1	5	0.0	0.0	0.1	12	0.1	0.1	0.2	3	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nephropathy (10029151)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nephropathy toxic (10029155)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neurogenic bladder (10029279)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nocturia (10029446)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pollakiuria (10036018)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Polyuria (10036142)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Proteinuria (10037032)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal artery arteriosclerosis (10065561)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal artery occlusion (10048988)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal artery stenosis (10038378)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal colic (10038419)	7	0.1	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal cyst (10038423)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	7	0.1	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal failure (10038435)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.1	0.0	0.3	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal hypertension (10038464)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal impairment (10062237)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal pain (10038490)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Renal vessel disorder (10038553)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Stress urinary incontinence (10066218)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tubulointerstitial nephritis (10048302)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urethral obstruction (10046459)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urethral polyp (10051507)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urethral stenosis (10065584)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urge incontinence (10046494)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urinary hesitation (10046542)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urinary incontinence (10046543)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	7	0.1	0.0	0.1	3	0.0	0.0	0.1	5	0.2	0.1	0.4	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urinary retention (10046555)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	6	0.1	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urinary tract disorder (10046566)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Urine flow decreased (10046640)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Reproductive system and breast disorders (10038604)	At least one PT related to the corresponding SOC	45	0.4	0.3	0.5	54	0.5	0.4	0.6	85	0.7	0.6	0.9	80	0.7	0.5	0.8	14	0.5	0.3	0.8	23	0.8	0.5	1.2	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Adnexa uteri pain (10058841)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atrophic vulvovaginitis (10003693)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Balanoposthitis (10004078)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Benign prostatic hyperplasia (10004446)	11	0.1	0.0	0.2	21	0.2	0.1	0.3	29	0.2	0.2	0.4	26	0.2	0.1	0.3	7	0.2	0.1	0.5	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast calcifications (10048782)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast cyst (10006220)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast discharge (10006223)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast disorder (10061021)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast dysplasia (10006237)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast enlargement (10006242)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast inflammation (10006262)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast mass (10006272)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast pain (10006298)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast tenderness (10006313)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Breast ulceration (10073419)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervical cyst (10008254)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervical dysplasia (10008263)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cervical polyp (10008297)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cystocele (10011803)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysfunctional uterine bleeding (10013908)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysmenorrhoea (10013935)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Endometrial hyperplasia (10014755)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Endometrial hypertrophy (10014756)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Endometriosis (10014778)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epididymal cyst (10014994)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erectile dysfunction (10061461)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Fibrocystic breast disease (10016621)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Genital discomfort (10066887)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Genital disorder male (10061177)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Genital rash (10018175)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haematospermia (10018866)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Male sexual dysfunction (10057672)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Menopausal disorder (10058825)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Menopausal symptoms (10027304)	2	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.0	0.0	0.1	6	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Menorrhagia (10027313)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nipple disorder (10029417)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Organic erectile dysfunction (10052004)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ovarian cyst (10033132)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pelvic pain (10034263)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Penile pain (10034310)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Postmenopausal haemorrhage (10055870)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostate induration (10057263)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostatic disorder (10036956)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostatic obstruction (10055026)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostatism (10036976)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostatitis (10036978)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	8	0.1	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prostatomegaly (10051482)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pruritus genital (10037093)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rectocele (10038084)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Scrotal oedema (10039755)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sexual dysfunction (10040477)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spermatocele (10041490)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Testicular mass (10058901)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Testicular pain (10043345)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Uterine enlargement (10046782)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Uterine haemorrhage (10046788)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Uterine polyp (10046811)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Uterine prolapse (10046814)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Uterovaginal prolapse (10046830)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Vaginal cyst (10046900)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaginal discharge (10046901)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaginal dysplasia (10046905)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaginal erosion (10062558)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaginal haemorrhage (10046910)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vaginal inflammation (10046916)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vulva cyst (10050475)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vulval haematoma (10047756)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vulvovaginal burning sensation (10067641)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vulvovaginal dryness (10047791)	4	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vulvovaginal pruritus (10056530)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Respiratory, thoracic and mediastinal disorders (10038738)	At least one PT related to the corresponding SOC	149	1.3	1.1	1.5	150	1.3	1.1	1.6	245	2.1	1.8	2.3	277	2.3	2.0	2.5	110	3.6	3.0	4.4	108	3.8	3.2	4.6	2	1.8	0.2	6.2	4	3.0	0.8	7.4
	Acute pulmonary oedema (10001029)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Acute respiratory failure (10001053)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Allergic bronchitis (10052613)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Allergic cough (10053779)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Allergic respiratory disease (10063532)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aspiration (10003504)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Asthma (10003553)	10	0.1	0.0	0.2	4	0.0	0.0	0.1	17	0.1	0.1	0.2	23	0.2	0.1	0.3	9	0.3	0.1	0.6	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Atelectasis (10003598)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchial hyperreactivity (10066091)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchial obstruction (10006440)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchiectasis (10006445)	0	0.0	0.0	0.0	4	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bronchitis chronic (10006458)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	7	0.1	0.0	0.1	7	0.1	0.0	0.1	5	0.2	0.1	0.4	2	0.1	0.0	0.3	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Bronchospasm (10006482)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Catarrh (10007774)	4	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Choking (10008589)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Chronic obstructive pulmonary disease (10009033)	6	0.1	0.0	0.1	2	0.0	0.0	0.1	19	0.2	0.1	0.3	18	0.1	0.1	0.2	15	0.5	0.3	0.8	18	0.6	0.4	1.0	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cough (10011224)	63	0.6	0.4	0.7	65	0.6	0.4	0.7	98	0.8	0.7	1.0	101	0.8	0.7	1.0	37	1.2	0.9	1.7	34	1.2	0.8	1.7	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Diaphragmatic disorder (10061106)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dry throat (10013789)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dysphonia (10013952)	1	0.0	0.0	0.0	4	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dyspnoea (10013968)	5	0.0	0.0	0.1	1	0.0	0.0	0.0	17	0.1	0.1	0.2	17	0.1	0.1	0.2	12	0.4	0.2	0.7	14	0.5	0.3	0.8	0	0.0	0.0	3.2	2	1.5	0.2	5.2
	Dyspnoea exertional (10013971)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Emphysema (10014561)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epiglottic cyst (10057437)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Epistaxis (10015090)	5	0.0	0.0	0.1	3	0.0	0.0	0.1	9	0.1	0.0	0.1	8	0.1	0.0	0.1	2	0.1	0.0	0.2	7	0.2	0.1	0.5	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Haemoptysis (10018964)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemothorax (10019027)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hiccups (10020039)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperventilation (10020910)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypoxia (10021143)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Idiopathic pulmonary fibrosis (10021240)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Increased upper airway secretion (10062717)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Laryngeal oedema (10023845)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lower respiratory tract congestion (10075565)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lung disorder (10025082)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lung infiltration (10025102)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal congestion (10028735)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	4	0.0	0.0	0.1	6	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal disorder (10062209)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal dryness (10028740)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal odour (10051181)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal polyps (10028756)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal septum deviation (10028762)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nasal turbinate hypertrophy (10028779)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Obstructive airways disorder (10061877)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oropharyngeal discomfort (10068318)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Oropharyngeal pain (10068319)	18	0.2	0.1	0.3	21	0.2	0.1	0.3	19	0.2	0.1	0.3	24	0.2	0.1	0.3	4	0.1	0.0	0.3	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Paranasal cyst (10062321)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Paranasal sinus discomfort (10052438)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pharyngeal inflammation (10065716)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pickwickian syndrome (10035004)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pleural adhesion (10035588)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pleural calcification (10035592)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pleural effusion (10035598)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pleurisy (10035618)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pleuritic pain (10035623)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pneumonia aspiration (10035669)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pneumothorax (10035759)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Productive cough (10036790)	1	0.0	0.0	0.0	5	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary arterial hypertension (10064911)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary bulla (10051688)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary cavitation (10051738)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary congestion (10037368)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary embolism (10037377)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	7	0.1	0.0	0.1	10	0.1	0.0	0.2	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary fibrosis (10037383)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary granuloma (10037391)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary hypertension (10037400)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary mass (10056342)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pulmonary oedema (10037423)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rales (10037833)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory disorder (10038683)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory distress (10038687)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory failure (10038695)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	5	0.2	0.1	0.4	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Respiratory tract congestion (10052251)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinalgia (10051496)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Rhinitis allergic (10039085)	5	0.0	0.0	0.1	8	0.1	0.0	0.1	12	0.1	0.1	0.2	17	0.1	0.1	0.2	4	0.1	0.0	0.3	10	0.4	0.2	0.7	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinitis hypertrophic (10059235)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinitis perennial (10039094)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rhinorrhoea (10039101)	7	0.1	0.0	0.1	4	0.0	0.0	0.1	6	0.1	0.0	0.1	7	0.1	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinus congestion (10040742)	3	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinus disorder (10062244)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sinus polyp (10040749)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sleep apnoea syndrome (10040979)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	9	0.1	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sneezing (10041232)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sputum discoloured (10041807)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sputum increased (10041812)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Throat irritation (10043521)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Throat tightness (10043528)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tonsillar hypertrophy (10044003)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Upper respiratory tract congestion (10052252)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Upper respiratory tract inflammation (10049590)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Upper-airway cough syndrome (10070488)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vocal cord polyp (10047675)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vocal cord thickening (10047676)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Wheezing (10047924)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.1	0.0	0.3	1	0.9	0.0	4.8	0	0.0	0.0	2.7
Skin and subcutaneous tissue disorders (10040785)	At least one PT related to the corresponding SOC	175	1.5	1.3	1.8	191	1.7	1.5	1.9	253	2.1	1.9	2.4	278	2.3	2.0	2.6	99	3.3	2.7	4.0	98	3.5	2.8	4.2	1	0.9	0.0	4.8	5	3.7	1.2	8.4
	Acne (10000496)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Actinic keratosis (10000614)	4	0.0	0.0	0.1	6	0.1	0.0	0.1	6	0.1	0.0	0.1	9	0.1	0.0	0.1	3	0.1	0.0	0.3	2	0.1	0.0	0.3	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Alopecia (10001760)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Alopecia areata (10001761)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Angioedema (10002424)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blister (10005191)	3	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bromhidrosis (10055000)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Chloasma (10008570)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cutis laxa (10011692)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Decubitus ulcer (10011985)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Dermal cyst (10012426)	0	0.0	0.0	0.0	9	0.1	0.0	0.2	5	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Dermatitis (10012431)	12	0.1	0.1	0.2	17	0.2	0.1	0.2	20	0.2	0.1	0.3	24	0.2	0.1	0.3	11	0.4	0.2	0.6	5	0.2	0.1	0.4	1	0.9	0.0	4.8	0	0.0	0.0	2.7
	Dermatitis allergic (10012434)	13	0.1	0.1	0.2	10	0.1	0.0	0.2	10	0.1	0.0	0.2	7	0.1	0.0	0.1	5	0.2	0.1	0.4	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatitis atopic (10012438)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Dermatitis contact (10012442)	10	0.1	0.0	0.2	11	0.1	0.0	0.2	17	0.1	0.1	0.2	16	0.1	0.1	0.2	4	0.1	0.0	0.3	7	0.2	0.1	0.5	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatitis diaper (10012444)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatitis exfoliative (10012455)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatomyositis (10012503)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dermatosis (10048768)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetic dermopathy (10053695)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetic foot (10060734)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Drug eruption (10013687)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dry skin (10013786)	4	0.0	0.0	0.1	0	0.0	0.0	0.0	4	0.0	0.0	0.1	4	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dyshidrotic eczema (10013913)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ecchymosis (10014080)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eczema (10014184)	32	0.3	0.2	0.4	36	0.3	0.2	0.4	49	0.4	0.3	0.5	52	0.4	0.3	0.6	19	0.6	0.4	1.0	18	0.6	0.4	1.0	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eczema asteatotic (10014190)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erythema (10015150)	5	0.0	0.0	0.1	5	0.0	0.0	0.1	4	0.0	0.0	0.1	9	0.1	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Erythema nodosum (10015226)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hair disorder (10019037)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hand dermatitis (10058898)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hangnail (10058109)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperhidrosis (10020642)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperkeratosis (10020649)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	9	0.1	0.0	0.1	7	0.1	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypersensitivity vasculitis (10020764)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ingrowing nail (10022013)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	4	0.0	0.0	0.1	8	0.1	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ingrown hair (10052899)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intertrigo (10022622)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Keloid scar (10023330)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lentigo (10024217)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Leukoplakia (10062037)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lichen planus (10024429)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lichen sclerosus (10024434)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lichenoid keratosis (10064000)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Miliaria (10027627)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nail bed inflammation (10064088)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Nail disorder (10028694)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Nail growth abnormal (10064764)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Neurodermatitis (10029263)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Night sweats (10029410)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Onycholysis (10030337)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Onychomadesis (10049274)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Papule (10033733)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Parapsoriasis (10033898)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pemphigus (10034280)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Petechiae (10034754)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Photosensitivity reaction (10034972)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pigmentation disorder (10062080)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pityriasis alba (10035111)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pityriasis rosea (10035114)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Precancerous skin lesion (10049422)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Prurigo (10037083)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pruritus (10037087)	13	0.1	0.1	0.2	14	0.1	0.1	0.2	22	0.2	0.1	0.3	21	0.2	0.1	0.3	15	0.5	0.3	0.8	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pruritus allergic (10063438)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pruritus generalised (10052576)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Psoriasis (10037153)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Purpura senile (10037560)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Pustular psoriasis (10037575)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash (10037844)	26	0.2	0.1	0.3	17	0.2	0.1	0.2	19	0.2	0.1	0.3	32	0.3	0.2	0.4	13	0.4	0.2	0.7	10	0.4	0.2	0.7	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Rash erythematous (10037855)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash generalised (10037858)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash macular (10037867)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash maculo-papular (10037868)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash papular (10037876)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rash pruritic (10037884)	3	0.0	0.0	0.1	4	0.0	0.0	0.1	6	0.1	0.0	0.1	4	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rosacea (10039218)	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sebaceous gland disorder (10061511)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Seborrhoea (10039792)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Seborrhoeic dermatitis (10039793)	1	0.0	0.0	0.0	5	0.0	0.0	0.1	8	0.1	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Senile pruritus (10039986)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin discolouration (10040829)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin disorder (10040831)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin exfoliation (10040844)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin fissures (10040849)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Skin irritation (10040880)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin lesion (10040882)	4	0.0	0.0	0.1	3	0.0	0.0	0.1	10	0.1	0.0	0.2	10	0.1	0.0	0.2	2	0.1	0.0	0.2	3	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin maceration (10048625)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin mass (10067868)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin necrosis (10040893)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin reaction (10040914)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin ulcer (10040943)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	6	0.1	0.0	0.1	4	0.0	0.0	0.1	3	0.1	0.0	0.3	5	0.2	0.1	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin warm (10040952)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Solar dermatitis (10041303)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Solar lentigo (10064127)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Stasis dermatitis (10041955)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.0	0.0	0.1	8	0.1	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Subacute cutaneous lupus erythematosus (10057903)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urticaria (10046735)	10	0.1	0.0	0.2	12	0.1	0.1	0.2	15	0.1	0.1	0.2	19	0.2	0.1	0.2	4	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Urticaria chronic (10052568)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Xeroderma (10048218)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Social circumstances (10041244)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Immobile (10021417)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Menopause (10027308)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tobacco user (10057581)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
Surgical and medical procedures (10042613)	At least one PT related to the corresponding SOC	11	0.1	0.0	0.2	19	0.2	0.1	0.3	11	0.1	0.0	0.2	20	0.2	0.1	0.3	6	0.2	0.1	0.4	5	0.2	0.1	0.4	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Abdominal operation (10061609)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arthroscopic surgery (10058471)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardiac pacemaker replacement (10049434)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cardioversion (10007661)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Carpal tunnel decompression (10007695)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Cataract operation (10063797)	2	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Coronary arterial stent insertion (10052086)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Organ Class (CODE)	Coronary artery bypass (10011077)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Dental implantation (10064143)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Dental operation (10061812)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ear operation (10061831)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Endodontic procedure (10051085)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Eye laser surgery (10057105)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hip arthroplasty (10020096)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hospitalisation (10054112)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Implantable defibrillator replacement (10057459)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Inguinal hernia repair (10022020)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intraocular lens implant (10067434)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Knee arthroplasty (10023469)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Knee operation (10049548)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Meniscus operation (10054948)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mole excision (10027805)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Mouth cyst excision (10052179)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Oophorectomy (10061889)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Papilloma excision (10033714)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Rectal polypectomy (10038075)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Sebaceous cyst excision (10039779)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Shoulder operation (10062242)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin lesion excision (10062250)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Skin neoplasm excision (10059443)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Suture insertion (10052665)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tendon sheath incision (10043250)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Tooth extraction (10062132)	2	0.0	0.0	0.1	4	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Transurethral prostatectomy (10044445)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Umbilical hernia repair (10045462)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vasectomy (10047133)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	101	0.9	0.7	1.1	112	1.0	0.8	1.2	165	1.4	1.2	1.6	189	1.5	1.3	1.8	70	2.3	1.8	2.9	85	3.0	2.4	3.7	1	0.9	0.0	4.8	4	3.0	0.8	7.4
	Aneurysm (10002329)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aneurysm ruptured (10048380)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Angiodysplasia (10061636)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Angiopathy (10059245)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aortic aneurysm (10002882)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	6	0.1	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aortic arteriosclerosis (10065558)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aortic calcification (10054208)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aortic dissection (10002895)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Aortic stenosis (10002906)	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arterial disorder (10060963)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arteriosclerosis (10003210)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Arteriovenous fistula (10003226)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Behcet's syndrome (10004213)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Bleeding varicose vein (10005144)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood pressure fluctuation (10005746)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Blood pressure inadequately controlled (10051128)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Circulatory collapse (10009192)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Deep vein thrombosis (10051055)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	6	0.1	0.0	0.1	5	0.0	0.0	0.1	5	0.2	0.1	0.4	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Diabetic vascular disorder (10061815)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Essential hypertension (10015488)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Femoral artery occlusion (10052019)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Flushing (10016825)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haematoma (10018852)	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.0	0.0	0.1	3	0.1	0.0	0.3	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Haemorrhage (10055798)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hot flush (10060800)	1	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hyperaemia (10020565)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Hypertension (10020772)	69	0.6	0.5	0.8	75	0.7	0.5	0.8	83	0.7	0.6	0.9	102	0.8	0.7	1.0	21	0.7	0.4	1.1	41	1.5	1.0	2.0	1	0.9	0.0	4.8	1	0.7	0.0	4.1
	Hypertensive crisis (10020802)	4	0.0	0.0	0.1	6	0.1	0.0	0.1	11	0.1	0.0	0.2	14	0.1	0.1	0.2	6	0.2	0.1	0.4	1	0.0	0.0	0.2	0	0.0	0.0	3.2	1	0.7	0.0	4.1
	Hypotension (10021097)	1	0.0	0.0	0.0	4	0.0	0.0	0.1	8	0.1	0.0	0.1	12	0.1	0.1	0.2	4	0.1	0.0	0.3	8	0.3	0.1	0.6	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Infarction (10061216)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Intermittent claudication (10022562)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.2	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Internal haemorrhage (10075192)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Ischaemia (10061255)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Lymphoedema (10025282)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Orthostatic hypertension (10065508)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Orthostatic hypotension (10031127)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	5	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral arterial occlusive disease (10062585)	2	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	4	0.1	0.0	0.4	0	0.0	0.0	3.2	2	1.5	0.2	5.2
	Peripheral artery aneurysm (10057521)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral artery stenosis (10072563)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral artery thrombosis (10072564)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral coldness (10034568)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral embolism (10061340)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral ischaemia (10034576)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral vascular disorder (10034636)	1	0.0	0.0	0.0	1	0.0	0.0	0.0	3	0.0	0.0	0.1	1	0.0	0.0	0.0	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Peripheral venous disease (10075049)	1	0.0	0.0	0.0	3	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Phlebitis (10034879)	3	0.0	0.0	0.1	1	0.0	0.0	0.0	6	0.1	0.0	0.1	6	0.0	0.0	0.1	2	0.1	0.0	0.2	2	0.1	0.0	0.3	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Phlebitis deep (10034897)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Post thrombotic syndrome (10048591)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Raynaud's phenomenon (10037912)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Shock haemorrhagic (10049771)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Spider vein (10062696)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Subgaleal haematoma (10069510)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Temporal arteritis (10043207)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thrombophlebitis (10043570)	0	0.0	0.0	0.0	4	0.0	0.0	0.1	0	0.0	0.0	0.0	3	0.0	0.0	0.1	2	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 11347				Placebo N = 11303				HZ/su N = 11821				Placebo N = 12204				HZ/su N = 3024				Placebo N = 2816				HZ/su N = 113				Placebo N = 135			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Thrombophlebitis superficial (10043595)	0	0.0	0.0	0.0	1	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Thrombosis (10043607)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	3	0.0	0.0	0.1	5	0.0	0.0	0.1	3	0.1	0.0	0.3	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Varicose ulceration (10046995)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	2	0.0	0.0	0.1	1	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Varicose vein (10046996)	4	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.0	0.0	0.1	5	0.0	0.0	0.1	2	0.1	0.0	0.2	4	0.1	0.0	0.4	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vascular pain (10047095)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vascular rupture (10053649)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Vasospasm (10047163)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Venous occlusion (10058990)	0	0.0	0.0	0.0	0	0.0	0.0	0.0	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Venous thrombosis (10047249)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7
	Venous thrombosis limb (10061408)	1	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.0	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	3.2	0	0.0	0.0	2.7

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of administered doses

n/% = number/percentage of doses with the symptom

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 14.3.1.35 Global Summary of unsolicited signs and symptoms reported with medically attended visit from first vaccination up to month 8 post-first vaccination by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	1872	1957	2590	2680	817	782	20	26	5299	5445
Number of doses followed by at least one unsolicited symptom	2196	2270	3166	3268	1035	979	24	35	6421	6552
Number of unsolicited symptoms classified by MedDRA Preferred Term*	3292	3298	5282	5459	1904	1944	35	54	10513	10755
Number of unsolicited symptoms reported**	3365	3369	5422	5611	1956	2005	35	55	10778	11040

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

Table 14.3.1.36 Percentage of subjects reporting the occurrence of serious adverse events classified by MedDRA Primary System Organ Class and Preferred Term from first vaccination up to month 14 post first vaccination by frailty status (Total Vaccinated Cohort)

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		357	6.2	5.6	6.8	328	5.7	5.1	6.4	697	11.5	10.7	12.3	751	12.1	11.3	12.9	293	18.6	16.7	20.6	332	22.7	20.6	24.9	8	13.6	6.0	25.0	10	13.9	6.9	24.1
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	7	0.1	0.0	0.2	2	0.0	0.0	0.1	14	0.2	0.1	0.4	21	0.3	0.2	0.5	7	0.4	0.2	0.9	10	0.7	0.3	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anaemia (10002034)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	6	0.1	0.0	0.2	9	0.1	0.1	0.3	3	0.2	0.0	0.6	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anaemia vitamin b12 deficiency (10002080)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coagulopathy (10009802)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Disseminated intravascular coagulation (10013442)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhagic anaemia (10052293)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Heparin-induced thrombocytopenia (10062506)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypersplenism (10020769)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Immune thrombocytopenic purpura (10074667)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Iron deficiency anaemia (10022972)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymphadenitis (10025188)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymphadenopathy (10025197)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymphadenopathy mediastinal (10025205)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Microcytic anaemia (10027538)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nephrogenic anaemia (10058116)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Normochromic normocytic anaemia (10029783)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancytopenia (10033661)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Splenic infarction (10041648)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombocytopenia (10043554)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Cardiac disorders (10007541)	At least one PT related to the corresponding SOC	54	0.9	0.7	1.2	46	0.8	0.6	1.1	138	2.3	1.9	2.7	157	2.5	2.1	2.9	75	4.8	3.8	5.9	98	6.7	5.5	8.1	1	1.7	0.0	9.1	2	2.8	0.3	9.7
	Acute coronary syndrome (10051592)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute myocardial infarction (10000891)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	12	0.2	0.1	0.3	19	0.3	0.2	0.5	6	0.4	0.1	0.8	8	0.5	0.2	1.1	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Angina pectoris (10002383)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.0	0.0	0.1	7	0.4	0.2	0.9	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Angina unstable (10002388)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	6	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Aortic valve disease (10061589)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Aortic valve incompetence (10002915)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Aortic valve stenosis (10002918)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Arrhythmia (10003119)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	6	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Arrhythmia supraventricular (10003130)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Arteriosclerosis coronary artery (10003211)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Atrial fibrillation (10003658)	12	0.2	0.1	0.4	12	0.2	0.1	0.4	26	0.4	0.3	0.6	33	0.5	0.4	0.7	13	0.8	0.4	1.4	10	0.7	0.3	1.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Atrial flutter (10003662)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.1	0.0	0.5	4	0.3	0.1	0.7	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Atrial tachycardia (10003668)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Atrioventricular block (10003671)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.1	1	1.4	0.0	7.5
	Atrioventricular block complete (10003673)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Atrioventricular block first degree (10003674)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Atrioventricular block second degree (10003677)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bradyarrhythmia (10049765)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bradycardia (10006093)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	4	0.3	0.1	0.7	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cardiac arrest (10007515)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cardiac failure (10007554)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	17	0.3	0.2	0.4	24	0.4	0.2	0.6	13	0.8	0.4	1.4	15	1.0	0.6	1.7	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cardiac failure acute (10007556)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cardiac failure chronic (10007558)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cardiac failure congestive (10007559)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	8	0.1	0.1	0.3	11	0.2	0.1	0.3	13	0.8	0.4	1.4	14	1.0	0.5	1.6	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cardiac valve disease (10061406)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cardio-respiratory arrest (10007617)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	4	0.3	0.1	0.7	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cardiogenic shock (10007625)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cardiomegaly (10007632)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cardiovascular deconditioning (10050257)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Chronotropic incompetence (10068627)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Congestive cardiomyopathy (10056370)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cor pulmonale (10010968)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Coronary artery disease (10011078)	5	0.1	0.0	0.2	8	0.1	0.1	0.3	16	0.3	0.2	0.4	19	0.3	0.2	0.5	14	0.9	0.5	1.5	11	0.8	0.4	1.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Coronary artery insufficiency (10052895)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Coronary artery occlusion (10011086)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Coronary artery stenosis (10011089)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	0.5

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Diastolic dysfunction (10052337)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Extrasystoles (10015856)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Heart valve incompetence (10067660)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertensive heart disease (10020823)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intracardiac thrombus (10048620)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ischaemic cardiomyopathy (10048858)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Left ventricular failure (10024119)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mitral valve incompetence (10027727)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mitral valve prolapse (10027730)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mitral valve stenosis (10027733)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myocardial infarction (10028596)	4	0.1	0.0	0.2	11	0.2	0.1	0.3	20	0.3	0.2	0.5	17	0.3	0.2	0.4	12	0.8	0.4	1.3	13	0.9	0.5	1.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myocardial ischaemia (10028600)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	7	0.1	0.0	0.2	16	0.3	0.1	0.4	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Palpitations (10033557)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pericarditis (10034484)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Right ventricular failure (10039163)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinus arrest (10040738)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinus node dysfunction (10075889)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sinus tachycardia (10040752)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Stress cardiomyopathy (10066286)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Supraventricular tachycardia (10042604)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tachycardia (10043071)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tricuspid valve incompetence (10044640)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ventricular arrhythmia (10047281)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ventricular extrasystoles (10047289)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ventricular fibrillation (10047290)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ventricular tachycardia (10047302)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	1	1.7	0.0	9.1	0	0.0	0.0	5.0
Congenital, familial and genetic disorders (10010331)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Congenital cystic kidney disease (10010428)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hydrocele (10020488)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertrophic cardiomyopathy (10020871)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Odontogenic cyst (10063413)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyloric stenosis (10037621)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Ear and labyrinth disorders (10013993)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	7	0.1	0.0	0.3	4	0.1	0.0	0.2	6	0.1	0.0	0.2	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Deafness neurosensory (10011891)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Motion sickness (10027990)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sudden hearing loss (10061373)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vertigo (10047340)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vertigo positional (10047348)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vestibular disorder (10047386)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Endocrine disorders (10014698)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	3	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Autoimmune thyroiditis (10049046)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Basedow's disease (10004161)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cushingoid (10011655)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Goitre (10018498)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperparathyroidism primary (10020707)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperthyroidism (10020850)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypopituitarism (10021067)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypothyroidism (10021114)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thyroiditis subacute (10043784)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Eye disorders (10015919)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	10	0.2	0.1	0.3	12	0.2	0.1	0.3	12	0.2	0.1	0.3	2	0.1	0.0	0.5	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Age-related macular degeneration (10064930)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Amaurosis fugax (10001903)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cataract (10007739)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	7	0.1	0.0	0.2	7	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Choroidal effusion (10063970)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diplopia (10013036)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eyelid ptosis (10015995)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glaucoma (10018304)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Iridocele (10051450)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Iritis (10022955)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lens dislocation (10024203)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Macular cyst (10025407)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Macular hole (10051058)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neovascular age-related macular degeneration (10071129)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ocular hypertension (10030043)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Ocular vascular disorder (10052896)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Optic ischaemic neuropathy (10030924)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinal artery occlusion (10038827)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinal degeneration (10038845)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinal detachment (10038848)	1	0.0	0.0	0.1	6	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinal haemorrhage (10038867)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retinal tear (10038897)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vitreous haemorrhage (10047655)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Gastrointestinal disorders (10017947)	At least one PT related to the corresponding SOC	27	0.5	0.3	0.7	42	0.7	0.5	1.0	81	1.3	1.1	1.7	89	1.4	1.2	1.8	26	1.7	1.1	2.4	39	2.7	1.9	3.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal discomfort (10000059)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal hernia (10060954)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal pain (10000081)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal pain upper (10000087)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal strangulated hernia (10053203)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal prolapse (10065360)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ascites (10003445)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Barrett's oesophagus (10004137)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic gastritis (10008882)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colitis (10009887)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colitis ischaemic (10009895)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Constipation (10010774)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Crohn's disease (10011401)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diaphragmatic hernia (10012713)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diaphragmatic hernia, obstructive (10012723)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diarrhoea (10012735)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diverticulum (10013554)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diverticulum intestinal (10013559)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diverticulum intestinal haemorrhagic (10013560)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Duodenal ulcer (10013836)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Duodenal ulcer haemorrhage (10013839)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Duodenal ulcer perforation (10013849)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Duodenitis (10013864)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Enteritis (10014866)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Enterovesical fistula (10062570)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Faecal incontinence (10016092)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Functional gastrointestinal disorder (10071275)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric haemorrhage (10017788)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric perforation (10017815)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric polyps (10017817)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric ulcer (10017822)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric ulcer haemorrhage (10017826)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastritis (10017853)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	6	0.1	0.0	0.2	8	0.1	0.1	0.3	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastritis alcoholic (10017856)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastritis haemorrhagic (10017866)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal angiodysplasia (10017928)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal haemorrhage (10017955)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	6	0.1	0.0	0.2	4	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal polyp haemorrhage (10074437)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrooesophageal reflux disease (10017885)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gingival disorder (10018280)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haematochezia (10018836)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhoidal haemorrhage (10054787)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhoids (10019022)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hiatus hernia (10020028)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ileus (10021328)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Incarcerated inguinal hernia (10021613)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Incarcerated umbilical hernia (10064492)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Inguinal hernia (10022016)	3	0.1	0.0	0.2	7	0.1	0.0	0.3	4	0.1	0.0	0.2	7	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal congestion (10065611)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal obstruction (10022687)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	6	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal perforation (10022694)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal polyp (10048616)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Irritable bowel syndrome (10023003)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Large intestinal obstruction (10062062)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Large intestine perforation (10023804)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Large intestine polyp (10051589)	1	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Mallory-weiss syndrome (10026712)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Melaena (10027141)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Mesenteric artery thrombosis (10027397)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Mesenteritis (10069665)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Mouth ulceration (10028034)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Nausea (10028813)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Oesophageal haemorrhage (10030172)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Oesophageal spasm (10030184)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Oesophageal ulcer (10030201)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Oesophageal ulcer haemorrhage (10030202)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Oesophagitis (10030216)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pancreatic cyst (10033615)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pancreatic disorder (10033616)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pancreatic fistula (10049192)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pancreatitis (10033645)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	5	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pancreatitis acute (10033647)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	7	0.1	0.0	0.2	4	0.3	0.1	0.6	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pancreatitis necrotising (10033654)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Peptic ulcer (10034341)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Peptic ulcer haemorrhage (10034344)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Peptic ulcer perforation (10034354)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Periodontal disease (10034536)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Peritoneal cyst (10051942)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Portal hypertensive gastropathy (10050897)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Proctitis (10036774)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Rectal haemorrhage (10038063)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Rectal perforation (10038073)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Rectal polyp (10038074)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Retropertitoneal haemorrhage (10038980)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Salivary gland calculus (10039394)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Small intestinal obstruction (10041101)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Splenic artery aneurysm (10041645)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Subileus (10050396)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Thrombosis mesenteric vessel (10043626)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Umbilical hernia (10045458)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Upper gastrointestinal haemorrhage (10046274)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vomiting (10047700)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
General disorders and administration site conditions (10018065)	At least one PT related to the corresponding SOC	14	0.2	0.1	0.4	12	0.2	0.1	0.4	31	0.5	0.3	0.7	34	0.5	0.4	0.8	15	1.0	0.5	1.6	19	1.3	0.8	2.0	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Accidental death (10063746)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Administration site erythema (10074796)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Administration site pain (10058049)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Adverse drug reaction (10061623)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Asthenia (10003549)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chest discomfort (10008469)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chest pain (10008479)	6	0.1	0.0	0.2	2	0.0	0.0	0.1	15	0.2	0.1	0.4	20	0.3	0.2	0.5	5	0.3	0.1	0.7	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chills (10008531)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cyst (10011732)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Death (10011906)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Device battery issue (10071172)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Device deposit issue (10070692)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Device dislocation (10064684)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Device failure (10056871)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Device leakage (10012587)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Device occlusion (10064685)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Drug withdrawal syndrome (10013754)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fatigue (10016256)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	General physical health deterioration (10049438)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Generalised oedema (10018092)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gravitational oedema (10018713)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hernia (10019909)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Impaired healing (10021519)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Incarcerated hernia (10021610)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Inflammation (10061218)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Influenza like illness (10022004)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malaise (10025482)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Multi-organ failure (10028154)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Non-cardiac chest pain (10062501)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oedema peripheral (10030124)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Organ failure (10053159)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pain (10033371)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peripheral swelling (10048959)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polyp (10061529)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyrexia (10037660)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Strangulated hernia (10042166)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sudden death (10042434)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Systemic inflammatory response syndrome (10051379)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombosis in device (10062546)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Hepatobiliary disorders (10019805)	At least one PT related to the corresponding SOC	18	0.3	0.2	0.5	11	0.2	0.1	0.3	21	0.3	0.2	0.5	36	0.6	0.4	0.8	5	0.3	0.1	0.7	15	1.0	0.6	1.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bile duct obstruction (10056375)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bile duct stenosis (10051341)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bile duct stone (10004637)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Biliary colic (10004663)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Biliary dilatation (10057202)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholangitis (10008604)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholangitis acute (10008605)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholecystitis (10008612)	3	0.1	0.0	0.2	4	0.1	0.0	0.2	7	0.1	0.0	0.2	12	0.2	0.1	0.3	0	0.0	0.0	0.2	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholecystitis acute (10008614)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	5	0.1	0.0	0.2	5	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholecystitis chronic (10008617)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholelithiasis (10008629)	8	0.1	0.1	0.3	6	0.1	0.0	0.2	7	0.1	0.0	0.2	13	0.2	0.1	0.4	2	0.1	0.0	0.5	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cirrhosis alcoholic (10009208)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fatty liver alcoholic (10016262)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gallbladder polyp (10049704)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic cirrhosis (10019641)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic failure (10019663)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic function abnormal (10019670)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatitis acute (10019727)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatitis alcoholic (10019728)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatotoxicity (10019851)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Jaundice cholestatic (10023129)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Immune system disorders (10021428)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	3	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Allergic granulomatous angiitis (10048594)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Amyloidosis (10002022)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anaphylactic reaction (10002198)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Drug hypersensitivity (10013700)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypersensitivity (10020751)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sarcoidosis (10039486)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	69	1.2	0.9	1.5	54	0.9	0.7	1.2	132	2.2	1.8	2.6	137	2.2	1.9	2.6	68	4.3	3.4	5.4	91	6.2	5.0	7.6	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Abdominal abscess (10060921)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal infection (10056519)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abscess (10000269)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abscess neck (10053576)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acarodermatitis (10063409)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Alcaligenes infection (10068911)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal abscess (10048946)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anal fistula infection (10051540)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anorectal cellulitis (10002643)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Appendiceal abscess (10049764)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Appendicitis (10003011)	3	0.1	0.0	0.2	4	0.1	0.0	0.2	5	0.1	0.0	0.2	4	0.1	0.0	0.2	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Appendicitis perforated (10003012)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arteriosclerotic gangrene (10003222)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthritis bacterial (10053555)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthritis infective (10060968)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atypical pneumonia (10003757)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bacteraemia (10003997)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bacterial infection (10060945)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bacterial sepsis (10053840)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bacteriuria (10004056)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Biliary sepsis (10057847)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Biliary tract infection (10061695)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Breast abscess (10006171)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchitis (10006451)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.2	0.0	0.6	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchitis bacterial (10061736)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bronchopneumonia (10006469)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Candida infection (10074170)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Candida sepsis (10053166)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Catheter site infection (10056520)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cavernous sinus thrombosis (10007830)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cellulitis (10007882)	5	0.1	0.0	0.2	3	0.1	0.0	0.2	7	0.1	0.0	0.2	8	0.1	0.1	0.3	3	0.2	0.0	0.6	6	0.4	0.2	0.9	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cellulitis orbital (10007918)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cellulitis streptococcal (10007922)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cholecystitis infective (10062631)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Clostridium bacteraemia (10058852)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Clostridium difficile colitis (10009657)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Clostridium difficile infection (10054236)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Colonic abscess (10073573)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cystitis (10011781)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cystitis klebsiella (10011797)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Dengue fever (10012310)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Device related infection (10064687)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Diabetic foot infection (10060803)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Diabetic gangrene (10012665)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Diverticulitis (10013538)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	3	0.0	0.0	0.1	8	0.1	0.1	0.3	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Empyema (10014568)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Encephalitis (10014581)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Encephalitis viral (10014612)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Encephalomyelitis (10014619)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Endocarditis (10014665)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Endometritis (10014791)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Erysipelas (10015145)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.1	0.0	0.2	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Escherichia infection (10061126)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Escherichia sepsis (10015296)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Escherichia urinary tract infection (10052238)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Fungaemia (10017523)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Gangrene (10017711)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Gastroenteritis (10017888)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.2	7	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Gastroenteritis caliciviral (10064852)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Gastroenteritis clostridial (10017898)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Gastroenteritis salmonella (10017914)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Gastroenteritis viral (10017918)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	0.5

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Graft infection (10056559)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Haematoma infection (10051564)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Helicobacter gastritis (10054272)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Helicobacter infection (10054263)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Hepatitis a (10019719)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Herpes simplex (10019948)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Herpes zoster (10019974)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Herpes zoster disseminated (10065038)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Herpes zoster oticus (10063491)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Incision site infection (10065616)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Infected dermal cyst (10071367)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Infection (10021789)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Infectious colitis (10021905)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Infective exacerbation of chronic obstructive airways disease (10056971)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Influenza (10022000)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Intestinal gangrene (10022651)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Kidney infection (10023424)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Klebsiella bacteraemia (10058856)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Klebsiella sepsis (10054160)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Labyrinthitis (10023567)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Liver abscess (10024652)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Lobar pneumonia (10024738)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Localised infection (10024774)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Lower respiratory tract infection (10024968)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Lung abscess (10025028)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Lung infection (10061229)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Lymph node tuberculosis (10025183)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Medical device site infection (10075580)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Meningitis (10027199)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Meningitis pneumococcal (10027253)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Nasal abscess (10028720)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Nasopharyngitis (10028810)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Neuroborreliosis (10052057)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Neutropenic sepsis (10049151)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Oesophageal candidiasis (10030154)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Orchitis (10031064)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oropharyngeal candidiasis (10050346)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteomyelitis (10031252)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteomyelitis chronic (10031256)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Otitis media chronic (10033081)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Periodontitis (10034539)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peritonitis (10034674)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Peritonsillar abscess (10034686)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pertussis (10034738)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pharyngitis (10034835)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pharyngotonsillitis (10049140)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumonia (10035664)	16	0.3	0.2	0.4	10	0.2	0.1	0.3	39	0.6	0.5	0.9	29	0.5	0.3	0.7	22	1.4	0.9	2.1	23	1.6	1.0	2.3	1	1.7	0.0	9.1	1	1.4	0.0	7.5
	Pneumonia bacterial (10060946)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumonia klebsiella (10035717)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumonia mycoplasmal (10035724)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumonia pneumococcal (10035728)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumonia streptococcal (10035735)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumonia viral (10035737)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post procedural infection (10067268)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Postoperative abscess (10051182)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Postoperative wound infection (10036410)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pseudomembranous colitis (10037128)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pseudomonas infection (10061471)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Psittacosis (10037151)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Psoas abscess (10056517)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pulmonary tuberculosis (10037440)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Purulence (10061926)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyelonephritis (10037596)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	5	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pyelonephritis acute (10037597)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal abscess (10048947)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal abscess (10038351)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Respiratory tract infection (10062352)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sepsis (10040047)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	1	0.0	0.0	0.1	7	0.1	0.0	0.2	7	0.4	0.2	0.9	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Septic shock (10040070)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Serratia infection (10061512)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Shigella infection (10054178)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Sinusitis (10040753)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Sinusitis fungal (10058678)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Soft tissue infection (10062255)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Staphylococcal infection (10058080)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Staphylococcal osteomyelitis (10064250)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Staphylococcal sepsis (10056430)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Streptococcal sepsis (10048960)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Subcutaneous abscess (10042343)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Subdiaphragmatic abscess (10056349)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Superinfection (10042566)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Testicular abscess (10064724)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Tonsillitis (10044008)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Toxic shock syndrome (10044248)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Tracheobronchitis (10044314)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Tuberculosis (10044755)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Upper respiratory tract infection (10046306)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Upper respiratory tract infection bacterial (10057868)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Urethritis (10046480)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Urinary tract infection (10046571)	7	0.1	0.0	0.2	3	0.1	0.0	0.2	17	0.3	0.2	0.4	16	0.3	0.1	0.4	10	0.6	0.3	1.2	8	0.5	0.2	1.1	0	0.0	0.0	0.1	1	1.4	0.0	7.5
	Urinary tract infection bacterial (10054088)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Urosepsis (10048709)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.2	0.0	0.6	5	0.3	0.1	0.8	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Vestibular neuronitis (10047393)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Viral infection (10047461)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Viral upper respiratory tract infection (10047482)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Visceral leishmaniasis (10047505)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Vulvitis (10047780)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Wound infection (10048038)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Wound infection pseudomonas (10059444)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Wound infection staphylococcal (10059442)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Injury, poisoning and procedural complications (10022117)	At least one PT related to the corresponding SOC	54	0.9	0.7	1.2	49	0.9	0.6	1.1	101	1.7	1.4	2.0	92	1.5	1.2	1.8	37	2.4	1.7	3.2	34	2.3	1.6	3.2	2	3.4	0.4	11.7	1	1.4	0.0	7.5
	Accident (10000369)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Accidental overdose (10000381)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acetabulum fracture (10000397)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anastomotic leak (10050456)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aneurysm perforation (10075395)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ankle fracture (10002544)	6	0.1	0.0	0.2	4	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Back injury (10003986)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bone fissure (10064210)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Burns second degree (10006802)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Burns third degree (10006803)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carbon monoxide poisoning (10007238)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cataract operation complication (10057419)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervical vertebral fracture (10049946)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chemical poisoning (10008428)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chest injury (10061386)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Clavicle fracture (10009245)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Comminuted fracture (10052614)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Compression fracture (10010214)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Concussion (10010254)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Contusion (10050584)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coronary artery reocclusion (10053261)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Craniocerebral injury (10070976)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Deep vein thrombosis postoperative (10066881)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Electrical burn (10069808)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eye penetration (10015960)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Face injury (10050392)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Facial bones fracture (10016042)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fall (10016173)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Femoral neck fracture (10016450)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Femur fracture (10016454)	5	0.1	0.0	0.2	2	0.0	0.0	0.1	5	0.1	0.0	0.2	14	0.2	0.1	0.4	3	0.2	0.0	0.6	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Fibula fracture (10016667)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Foot fracture (10016970)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Forearm fracture (10016997)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Foreign body (10070245)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fractured sacrum (10017308)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gun shot wound (10018794)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hand fracture (10019114)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Head injury (10019196)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hip fracture (10020100)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Humerus fracture (10020462)	0	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Incarcerated incisional hernia (10076387)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Incisional hernia (10021619)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint dislocation (10023204)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint injury (10060820)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Kidney contusion (10023413)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Laceration (10023572)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ligament rupture (10065433)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ligament sprain (10024453)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Limb crushing injury (10064031)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Limb injury (10061225)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lower limb fracture (10061599)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lumbar vertebral fracture (10049947)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meniscus injury (10072970)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Multiple fractures (10028200)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Multiple injuries (10028224)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle rupture (10028331)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle strain (10050031)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nerve root injury cervical (10029183)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Overdose (10033295)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Patella fracture (10034122)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pelvic fracture (10061161)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumothorax traumatic (10035765)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Poisoning (10061355)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post procedural complication (10058046)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post procedural haemorrhage (10051077)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post procedural pulmonary embolism (10063909)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Postoperative wound complication (10061468)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Procedural intestinal perforation (10074065)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Procedural pain (10064882)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pubis fracture (10070286)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Radius fracture (10037802)	4	0.1	0.0	0.2	5	0.1	0.0	0.2	8	0.1	0.1	0.3	6	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Respiratory fume inhalation disorder (10061485)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rib fracture (10039117)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	6	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Road traffic accident (10039203)	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Seroma (10040102)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin abrasion (10064990)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin wound (10072170)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skull fracture (10061365)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Snake bite (10041230)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal compression fracture (10041541)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Spinal cord injury (10041552)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal cord injury cervical (10041554)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal fracture (10041569)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Splenic rupture (10041658)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sternal fracture (10042015)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Subdural haematoma (10042361)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Synovial rupture (10042862)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tendon injury (10043242)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tendon rupture (10043248)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thermal burn (10053615)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thoracic vertebral fracture (10049948)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tibia fracture (10043827)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Toxicity to various agents (10070863)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Traumatic fracture (10049514)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Traumatic intracranial haemorrhage (10061387)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ulna fracture (10045375)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Upper limb fracture (10061394)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vascular graft occlusion (10049060)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vascular pseudoaneurysm (10048975)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Vascular pseudoaneurysm ruptured (10053949)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wound (10052428)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wound dehiscence (10048031)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Wrist fracture (10048049)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Investigations (10022891)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anticoagulation drug level above therapeutic (10060320)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood creatine phosphokinase increased (10005470)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood glucose fluctuation (10049803)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood heavy metal increased (10061718)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Blood pressure increased (10005750)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemoglobin decreased (10018884)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Heart rate decreased (10019301)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Liver function test abnormal (10024690)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Weight increased (10047899)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	At least one PT related to the corresponding SOC	7	0.1	0.0	0.2	8	0.1	0.1	0.3	32	0.5	0.4	0.7	26	0.4	0.3	0.6	12	0.8	0.4	1.3	19	1.3	0.8	2.0	0	0.0	0.0	6.1	1	1.4	0.0	7.5
Metabolism and nutrition disorders (10027433)	Cachexia (10006895)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Decreased appetite (10061428)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dehydration (10012174)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	6	0.1	0.0	0.2	1	0.0	0.0	0.1	3	0.2	0.0	0.6	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetes mellitus (10012601)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetes mellitus inadequate control (10012607)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Diabetic ketoacidosis (10012671)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Electrolyte imbalance (10014418)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gout (10018627)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperammonaemia (10020575)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperglycaemia (10020635)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperkalaemia (10020646)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperlipidaemia (10062060)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertriglyceridaemia (10020869)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypocalcaemia (10020947)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypoglycaemia (10020993)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	6	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypokalaemia (10021015)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hyponatraemia (10021036)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypophagia (10063743)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ketoacidosis (10023379)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lactic acidosis (10023676)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malnutrition (10061273)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Obesity (10029883)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Type 1 diabetes mellitus (10067584)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Type 2 diabetes mellitus (10067585)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	6	0.1	0.0	0.2	7	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Musculoskeletal and connective tissue disorders (10028395)	At least one PT related to the corresponding SOC	24	0.4	0.3	0.6	25	0.4	0.3	0.6	46	0.8	0.6	1.0	47	0.8	0.6	1.0	20	1.3	0.8	2.0	19	1.3	0.8	2.0	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Acquired claw toe (10057689)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthralgia (10003239)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthritis (10003246)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthrofibrosis (10058029)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arthropathy (10003285)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Back pain (10003988)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Bursitis (10006811)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervical spinal stenosis (10008313)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chondrocalcinosis (10061761)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chondropathy (10061762)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Costochondritis (10011219)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fasciitis (10016228)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Foot deformity (10061159)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gouty arthritis (10018634)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intervertebral disc disorder (10061521)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intervertebral disc protrusion (10050296)	1	0.0	0.0	0.1	7	0.1	0.0	0.3	4	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint destruction (10023203)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Joint effusion (10023215)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meniscal degeneration (10069364)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mixed connective tissue disease (10027754)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscle spasms (10028334)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Muscular weakness (10028372)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Musculoskeletal chest pain (10050819)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Musculoskeletal pain (10028391)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Myalgia (10028411)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myositis (10028653)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Neck pain (10028836)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteitis (10031149)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteoarthritis (10031161)	7	0.1	0.0	0.2	5	0.1	0.0	0.2	14	0.2	0.1	0.4	14	0.2	0.1	0.4	10	0.6	0.3	1.2	7	0.5	0.2	1.0	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteochondritis (10031230)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteochondrosis (10031233)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteolysis (10031248)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteonecrosis (10031264)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteoporosis (10031282)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Osteoporotic fracture (10031290)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pain in extremity (10033425)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pathological fracture (10034156)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Periarthritis (10034464)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polymyalgia rheumatica (10036099)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polymyositis (10036102)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pseudarthrosis (10048617)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rhabdomyolysis (10039020)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rheumatoid arthritis (10039073)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rotator cuff syndrome (10039227)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Soft tissue mass (10071051)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal column stenosis (10041540)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.1	0.0	0.2	4	0.3	0.1	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal disorder (10061368)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal osteoarthritis (10041591)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal pain (10072005)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spondyloarthropathy (10051265)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spondylolisthesis (10063550)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Still's disease adult onset (10064056)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Synovial cyst (10042858)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Synovitis (10042868)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Systemic lupus erythematosus (10042945)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tendonitis (10043255)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tenosynovitis (10043261)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Trigger finger (10044654)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	At least one PT related to the corresponding SOC	77	1.3	1.1	1.7	57	1.0	0.8	1.3	101	1.7	1.4	2.0	133	2.1	1.8	2.5	33	2.1	1.4	2.9	17	1.2	0.7	1.9	1	1.7	0.0	9.1	2	2.8	0.3	9.7
	Abdominal neoplasm (10060925)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acral lentiginous melanoma (10000583)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Acute monocytic leukaemia (10000871)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Acute myeloid leukaemia (10000880)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Acute promyelocytic leukaemia (10001019)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Adenocarcinoma (10001141)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Adenocarcinoma gastric (10001150)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Adenocarcinoma of colon (10001167)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Adenocarcinoma pancreas (10052747)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Adrenal adenoma (10001323)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Adrenal gland cancer (10073152)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Anaplastic astrocytoma (10002224)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	B-cell lymphoma (10003899)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Basal cell carcinoma (10004146)	4	0.1	0.0	0.2	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Benign neoplasm of bladder (10004302)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Benign neoplasm of orbit (10004355)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Benign neoplasm of thyroid gland (10004412)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Benign ovarian tumour (10004433)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Benign renal neoplasm (10061001)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Benign soft tissue neoplasm (10061004)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bile duct adenocarcinoma (10004585)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bile duct cancer (10004593)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bladder cancer (10005003)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	3	0.0	0.0	0.1	12	0.2	0.1	0.3	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bladder cancer recurrent (10005005)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bladder neoplasm (10005056)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bladder papilloma (10005064)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bladder transitional cell carcinoma (10005084)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bowen's disease (10006059)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Brain cancer metastatic (10055093)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Brain neoplasm benign (10006129)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Breast cancer (10006187)	7	0.1	0.0	0.2	3	0.1	0.0	0.2	2	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Breast cancer in situ (10006189)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Breast cancer metastatic (10055113)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bronchial carcinoma (10006417)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bronchial neoplasm (10052245)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Carcinoid tumour of the small bowel (10052819)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carcinoid tumour pulmonary (10007282)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervix carcinoma (10008342)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervix carcinoma recurrent (10008344)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholangiocarcinoma (10008593)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cholesteatoma (10008642)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic lymphocytic leukaemia (10008958)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic myeloid leukaemia (10009013)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colon adenoma (10048832)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colon cancer (10009944)	6	0.1	0.0	0.2	6	0.1	0.0	0.2	3	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colon neoplasm (10061045)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diffuse large b-cell lymphoma (10012818)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Endometrial adenocarcinoma (10014720)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Fallopian tube cancer (10016180)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric cancer (10017758)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal neoplasm (10061174)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal stromal tumour (10051066)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal tract adenoma (10051635)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glioblastoma multiforme (10018337)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glioma (10018338)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Glomus tumour (10018381)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic cancer (10073069)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic cancer metastatic (10055110)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatic neoplasm (10019695)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hepatocellular carcinoma (10073071)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypergammaglobulinaemia benign monoclonal (10020631)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypopharyngeal cancer (10021042)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal adenocarcinoma (10051925)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intraductal proliferative breast lesion (10073094)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Invasive ductal breast carcinoma (10073095)	4	0.1	0.0	0.2	3	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Invasive lobular breast carcinoma (10073096)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Invasive papillary breast carcinoma (10073098)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Large cell lung cancer (10023774)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Large intestine benign neoplasm (10073394)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Laryngeal cancer (10023825)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Laryngeal neoplasm (10023841)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Leukaemia (10024288)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip and/or oral cavity cancer (10061523)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lip squamous cell carcinoma (10064055)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lipoma (10024612)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung adenocarcinoma (10025031)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung adenocarcinoma metastatic (10064049)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung adenocarcinoma stage i (10025035)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung adenocarcinoma stage iii (10025037)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung cancer metastatic (10050017)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung neoplasm (10062042)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lung neoplasm malignant (10058467)	6	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	5	0.1	0.0	0.2	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lymphoma (10025310)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malignant mast cell neoplasm (10025638)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malignant melanoma (10025650)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malignant melanoma in situ (10025652)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malignant neoplasm of unknown primary site (10073059)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malignant palate neoplasm (10026663)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Malignant pleural effusion (10026673)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Melanocytic naevus (10027145)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meningioma (10027191)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Meningioma benign (10027192)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Mesothelioma (10027406)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Metastases to adrenals (10027451)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Metastases to bone (10027452)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Metastases to central nervous system (10059282)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Metastases to liver (10027457)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Metastases to lung (10027458)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Metastases to lymph nodes (10027459)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Metastases to peritoneum (10051676)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Metastases to stomach (10049718)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Metastatic carcinoma of the bladder (10057352)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Metastatic malignant melanoma (10027480)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Metastatic neoplasm (10061289)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Metastatic renal cell carcinoma (10050513)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Metastatic squamous cell carcinoma (10063569)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Myelodysplastic syndrome (10028533)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Nasopharyngeal cancer (10061306)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Neoplasm malignant (10028997)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Neoplasm skin (10029098)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Non-hodgkin's lymphoma (10029547)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Non-small cell lung cancer (10061873)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Non-small cell lung cancer stage iv (10029522)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Oesophageal adenocarcinoma (10030137)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Oesophageal carcinoma (10030155)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Oesophageal squamous cell carcinoma (10061534)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Ovarian cancer (10033128)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Ovarian cancer recurrent (10066697)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Ovarian epithelial cancer (10061328)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Ovarian fibroma (10064257)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Ovarian germ cell teratoma benign (10033236)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Ovarian neoplasm (10061535)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Pancreatic carcinoma (10033609)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	1.4	0.0	7.5
	Pancreatic carcinoma metastatic (10033610)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Pancreatic neoplasm (10061902)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Pancreatic neuroendocrine tumour (10067517)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Papillary thyroid cancer (10033701)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Paraganglion neoplasm (10061332)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Parathyroid tumour benign (10033964)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Phaeochromocytoma (10034800)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Pituitary tumour benign (10061538)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Plasma cell myeloma (10035226)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Pleural mesothelioma (10035603)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Prostate cancer (10060862)	7	0.1	0.0	0.2	9	0.2	0.1	0.3	16	0.3	0.2	0.4	8	0.1	0.1	0.3	1	0.1	0.0	0.4	4	0.3	0.1	0.7	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Prostate cancer metastatic (10036909)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Prostate cancer recurrent (10036911)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Prostatic adenoma (10036940)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Rectal adenocarcinoma (10038019)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Rectal adenoma (10048829)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Rectal cancer (10038038)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Rectal cancer recurrent (10038046)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Renal cancer (10038389)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Renal cancer metastatic (10050018)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Renal cell carcinoma (10067946)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	1.4	0.0	7.5
	Renal cell carcinoma recurrent (10038410)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Renal neoplasm (10061482)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Renal oncocytoma (10050176)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Salivary gland cancer (10061934)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Sarcoma (10039491)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Skin cancer (10040808)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Small cell lung cancer (10041067)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Small intestine adenocarcinoma (10073373)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Spinal cord neoplasm (10062261)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Squamous cell carcinoma (10041823)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Squamous cell carcinoma of lung (10041826)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Squamous cell carcinoma of skin (10041834)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Squamous cell carcinoma of the oral cavity (10041857)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sweat gland tumour (10042658)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Testicular neoplasm (10061379)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thyroid adenoma (10043688)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thyroid cancer (10066474)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thyroid neoplasm (10043744)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue neoplasm malignant stage unspecified (10043966)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Transitional cell carcinoma (10044412)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tumour haemorrhage (10049750)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urethral neoplasm (10062223)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Uterine cancer (10046766)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Uterine leiomyoma (10046798)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vulval cancer (10047741)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	32	0.6	0.4	0.8	34	0.6	0.4	0.8	89	1.5	1.2	1.8	95	1.5	1.2	1.9	44	2.8	2.0	3.7	53	3.6	2.7	4.7	2	3.4	0.4	11.7	0	0.0	0.0	5.0
	Amnesia (10001949)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Amyotrophic lateral sclerosis (10002026)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aphasia (10002948)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ataxia (10003591)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Balance disorder (10049848)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Basal ganglia haemorrhage (10067057)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Basal ganglia infarction (10069020)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Basilar artery thrombosis (10063093)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Brain injury (10067967)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Brain stem infarction (10006147)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Brain stem syndrome (10063292)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carotid artery disease (10061744)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carotid artery occlusion (10048964)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carotid artery stenosis (10007687)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carotid artery thrombosis (10007688)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carotid sinus syndrome (10050202)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Carpal tunnel syndrome (10007697)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Central nervous system lesion (10051290)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebellar haemorrhage (10008030)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebellar ischaemia (10068621)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral artery embolism (10008088)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral artery thrombosis (10008092)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral atrophy (10008096)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral haemorrhage (10008111)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral infarction (10008118)	6	0.1	0.0	0.2	2	0.0	0.0	0.1	10	0.2	0.1	0.3	12	0.2	0.1	0.3	1	0.1	0.0	0.4	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral ischaemia (10008120)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebrospinal fluid leakage (10008164)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebrovascular accident (10008190)	6	0.1	0.0	0.2	6	0.1	0.0	0.2	20	0.3	0.2	0.5	13	0.2	0.1	0.4	10	0.6	0.3	1.2	6	0.4	0.2	0.9	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Cerebrovascular disorder (10008196)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervical myelopathy (10008289)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cervicobrachial syndrome (10008334)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cognitive disorder (10057668)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Dementia (10012267)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dementia alzheimer's type (10012271)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dementia with lewy bodies (10067889)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic neuropathy (10012680)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dizziness (10013573)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Drop attacks (10013643)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dural arteriovenous fistula (10074462)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Encephalopathy (10014625)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Epilepsy (10015037)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Generalised tonic-clonic seizure (10018100)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Guillain-barre syndrome (10018767)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhage intracranial (10018985)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhagic stroke (10019016)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Haemorrhagic transformation stroke (10055677)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Headache (10019211)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hemiparesis (10019465)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hemiplegia (10019468)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hydrocephalus (10020508)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertonia (10020852)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypoaesthesia (10020937)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hypoxic-ischaemic encephalopathy (10070511)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intracranial aneurysm (10022758)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intraventricular haemorrhage (10022840)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ischaemic stroke (10061256)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lacunar infarction (10051078)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Loss of consciousness (10024855)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lumbar radiculopathy (10050219)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Memory impairment (10027175)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metabolic encephalopathy (10062190)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Migraine (10027599)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mixed dementia (10075174)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mononeuritis (10027910)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myelopathy (10028570)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myoclonus (10028622)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nerve compression (10029174)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nervous system disorder (10029202)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neuralgia (10029223)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neuritis cranial (10029244)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neuropathy peripheral (10029331)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Paraesthesia (10033775)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Parkinsonism (10034010)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Partial seizures (10061334)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Post polio syndrome (10036239)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Presyncope (10036653)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Radiculopathy (10037779)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Restless legs syndrome (10058920)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Reversible ischaemic neurological deficit (10050496)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ruptured cerebral aneurysm (10039330)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Sciatica (10039674)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Seizure (10039906)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Senile dementia (10039966)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Somnolence (10041349)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spinal claudication (10041539)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Spondylitic myelopathy (10041670)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Subarachnoid haemorrhage (10042316)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Syncope (10042772)	4	0.1	0.0	0.2	4	0.1	0.0	0.2	9	0.1	0.1	0.3	12	0.2	0.1	0.3	2	0.1	0.0	0.5	9	0.6	0.3	1.2	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Thalamic infarction (10064961)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Thrombotic cerebral infarction (10067347)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Transient global amnesia (10044380)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Transient ischaemic attack (10044390)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	17	0.3	0.2	0.4	9	0.1	0.1	0.3	6	0.4	0.1	0.8	7	0.5	0.2	1.0	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Trigeminal neuralgia (10044652)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Vascular dementia (10057678)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Vascular encephalopathy (10063661)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Vertebrobasilar insufficiency (10047334)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Viith nerve paralysis (10050040)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
Psychiatric disorders (10037175)	At least one PT related to the corresponding SOC	3	0.1	0.0	0.2	8	0.1	0.1	0.3	15	0.2	0.1	0.4	14	0.2	0.1	0.4	6	0.4	0.1	0.8	4	0.3	0.1	0.7	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Acute psychosis (10001022)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Adjustment disorder (10061621)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Affective disorder (10001443)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Alcohol withdrawal syndrome (10053164)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Anxiety disorder (10057666)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Breathing-related sleep disorder (10006344)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Completed suicide (10010144)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Confusional state (10010305)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Delirium (10012218)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Delirium febrile (10059267)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Depressed mood (10012374)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Depression (10012378)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	5	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Disorientation (10013395)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Generalised anxiety disorder (10018075)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Hallucination (10019063)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Korsakoff's syndrome (10070997)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Major depression (10057840)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Mental disorder (10061284)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Mental disorder due to a general medical condition (10061285)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Primary System Organ Class	Panic attack (10033664)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Panic disorder (10033666)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Psychotic disorder (10061920)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Schizoaffective disorder bipolar type (10068889)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Schizophrenia (10039626)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Somatoform disorder (10054153)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Suicidal ideation (10042458)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Suicide attempt (10042464)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
Renal and urinary disorders (10038359)	At least one PT related to the corresponding SOC	12	0.2	0.1	0.4	7	0.1	0.0	0.3	21	0.3	0.2	0.5	37	0.6	0.4	0.8	22	1.4	0.9	2.1	21	1.4	0.9	2.2	0	0.0	0.0	0.1	1	1.4	0.0	7.5
	Acute kidney injury (10069339)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	6	0.1	0.0	0.2	8	0.1	0.1	0.3	5	0.3	0.1	0.7	6	0.4	0.2	0.9	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Acute prerenal failure (10001017)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Azotaemia (10003885)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bladder neck obstruction (10005053)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bladder perforation (10063575)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bladder prolapse (10048475)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Calculus bladder (10006987)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Calculus ureteric (10007025)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Calculus urinary (10007027)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Chronic kidney disease (10064848)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	6	0.4	0.2	0.9	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cystitis interstitial (10011796)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Diabetic nephropathy (10061835)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Dysuria (10013990)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Haematuria (10018867)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Hydronephrosis (10020524)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Nephroangiosclerosis (10052242)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Nephrolithiasis (10029148)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Nephropathy toxic (10029155)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	1.4	0.0	7.5
	Neurogenic bladder (10029279)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Prerenal failure (10072370)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Renal artery arteriosclerosis (10065561)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Renal artery occlusion (10048988)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Renal colic (10038419)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Renal cyst (10038423)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Renal failure (10038435)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.1	0.0	0.2	3	0.2	0.0	0.6	3	0.2	0.0	0.6	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Renal hypertension (10038464)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Renal impairment (10062237)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Stress urinary incontinence (10066218)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Tubulointerstitial nephritis (10048302)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Urethral meatus stenosis (10058463)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Urethral polyp (10051507)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Urethral stenosis (10065584)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Urinary incontinence (10046543)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Urinary retention (10046555)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Urinary tract disorder (10046566)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
Reproductive system and breast disorders (10038604)	At least one PT related to the corresponding SOC	11	0.2	0.1	0.3	7	0.1	0.0	0.3	8	0.1	0.1	0.3	12	0.2	0.1	0.3	4	0.3	0.1	0.6	3	0.2	0.0	0.6	0	0.0	0.0	0.1	1	1.4	0.0	7.5
	Atrophic vulvovaginitis (10003693)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Benign prostatic hyperplasia (10004446)	5	0.1	0.0	0.2	3	0.1	0.0	0.2	4	0.1	0.0	0.2	5	0.1	0.0	0.2	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Breast dysplasia (10006237)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Cystocele (10011803)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Endometrial hypertrophy (10014756)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Fibrocystic breast disease (10016621)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Ovarian cyst (10033132)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Postmenopausal haemorrhage (10055870)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Prostatic obstruction (10055026)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Prostatitis (10036978)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Prostatomegaly (10051482)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Rectocele (10038084)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Uterine enlargement (10046782)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Uterine polyp (10046811)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Uterine prolapse (10046814)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	1.4	0.0	7.5
	Uterovaginal prolapse (10046830)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Vaginal haemorrhage (10046910)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Vaginal prolapse (10046940)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Vaginal ulceration (10046943)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
Respiratory, thoracic and mediastinal disorders (10038738)	At least one PT related to the corresponding SOC	11	0.2	0.1	0.3	12	0.2	0.1	0.4	41	0.7	0.5	0.9	55	0.9	0.7	1.1	34	2.2	1.5	3.0	26	1.8	1.2	2.6	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Acute pulmonary oedema (10001029)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Acute respiratory failure (10001053)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Asthma (10003553)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	6	0.1	0.0	0.2	3	0.2	0.0	0.6	3	0.2	0.0	0.6	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Atelectasis (10003598)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Bronchiectasis (10006445)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bronchitis chronic (10006458)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Bronchospasm (10006482)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Chronic obstructive pulmonary disease (10009033)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	9	0.1	0.1	0.3	6	0.1	0.0	0.2	11	0.7	0.3	1.2	9	0.6	0.3	1.2	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Diaphragmatic disorder (10061106)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Dyspnoea (10013968)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Epistaxis (10015090)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Haemoptysis (10018964)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Haemothorax (10019027)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Hyperventilation (10020910)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Hypoxia (10021143)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Idiopathic pulmonary fibrosis (10021240)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Lung disorder (10025082)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Nasal polyps (10028756)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Nasal septum deviation (10028762)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Nasal turbinate hypertrophy (10028779)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Paranasal cyst (10062321)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pickwickian syndrome (10035004)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pleural calcification (10035592)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pleural effusion (10035598)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	8	0.1	0.1	0.3	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pleuritic pain (10035623)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pneumonia aspiration (10035669)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pneumothorax (10035759)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pulmonary bulla (10051688)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pulmonary cavitation (10051738)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pulmonary congestion (10037368)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pulmonary embolism (10037377)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	8	0.1	0.1	0.3	16	0.3	0.1	0.4	4	0.3	0.1	0.6	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pulmonary fibrosis (10037383)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pulmonary mass (10056342)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Pulmonary oedema (10037423)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Respiratory acidosis (10038661)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Respiratory distress (10038687)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Respiratory failure (10038695)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	3	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.3	0.1	0.6	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	0.5
	Sleep apnoea syndrome (10040979)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	0.5

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Skin and subcutaneous tissue disorders (10040785)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	4	0.1	0.0	0.2	6	0.1	0.0	0.2	4	0.1	0.0	0.2	6	0.4	0.1	0.8	9	0.6	0.3	1.2	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Actinic keratosis (10000614)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Angioedema (10002424)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Decubitus ulcer (10011985)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermal cyst (10012426)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatitis (10012431)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatitis allergic (10012434)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatitis contact (10012442)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Dermatomyositis (10012503)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diabetic foot (10060734)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Drug eruption (10013687)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Eczema (10014184)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Erythema multiforme (10015218)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperkeratosis (10020649)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Leukoplakia (10062037)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Lichen planus (10024429)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin necrosis (10040893)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin ulcer (10040943)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Stasis dermatitis (10041955)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Urticaria (10046735)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Surgical and medical procedures (10042613)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac pacemaker replacement (10049434)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hospitalisation (10054112)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal polypectomy (10038075)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	18	0.3	0.2	0.5	15	0.3	0.1	0.4	42	0.7	0.5	0.9	61	1.0	0.8	1.3	30	1.9	1.3	2.7	41	2.8	2.0	3.8	0	0.0	0.0	6.1	3	4.2	0.9	11.7
	Aneurysm (10002329)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aneurysm ruptured (10048380)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Angiodysplasia (10061636)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic aneurysm (10002882)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic aneurysm rupture (10002886)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic arteriosclerosis (10065558)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic dilatation (10057453)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic dissection (10002895)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic rupture (10060874)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Aortic stenosis (10002906)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Arterial thrombosis (10003178)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Arteriosclerosis (10003210)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Arteriovenous fistula (10003226)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Bleeding varicose vein (10005144)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Blood pressure inadequately controlled (10051128)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Circulatory collapse (10009192)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Deep vein thrombosis (10051055)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	3	0.0	0.0	0.1	5	0.1	0.0	0.2	5	0.3	0.1	0.7	3	0.2	0.0	0.6	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Diabetic vascular disorder (10061815)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Embolism (10061169)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Essential hypertension (10015488)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Femoral artery aneurysm (10016427)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Femoral artery occlusion (10052019)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Haematoma (10018852)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	4	0.3	0.1	0.7	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Haemodynamic instability (10052076)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Haemorrhage (10055798)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Hypertension (10020772)	5	0.1	0.0	0.2	4	0.1	0.0	0.2	14	0.2	0.1	0.4	16	0.3	0.1	0.4	5	0.3	0.1	0.7	14	1.0	0.5	1.6	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Hypertensive crisis (10020802)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	7	0.1	0.0	0.2	4	0.3	0.1	0.6	0	0.0	0.0	0.3	0	0.0	0.0	0.1	1	1.4	0.0	7.5
	Hypertensive emergency (10058179)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Hypotension (10021097)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.2	0.0	0.6	4	0.3	0.1	0.7	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Inferior vena caval occlusion (10058987)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Intermittent claudication (10022562)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Internal haemorrhage (10075192)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Labile hypertension (10049079)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Orthostatic hypertension (10065508)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Orthostatic hypotension (10031127)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Peripheral arterial occlusive disease (10062585)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	0.1	2	2.8	0.3	9.7
	Peripheral artery aneurysm (10057521)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Peripheral artery stenosis (10072563)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Peripheral artery thrombosis (10072564)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Peripheral embolism (10061340)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Peripheral ischaemia (10034576)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Peripheral vascular disorder (10034636)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0

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		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Peripheral venous disease (10075049)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Polyarteritis nodosa (10036024)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Shock haemorrhagic (10049771)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Temporal arteritis (10043207)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombophlebitis (10043570)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombosis (10043607)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Varicose ulceration (10046995)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Varicose vein (10046996)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Venous thrombosis limb (10061408)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects reporting the symptom at least once

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 14.3.1.37 Global Summary of serious adverse events reported from first vaccination up to month 14 post first vaccination by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	357	328	697	751	293	332	8	10	1355	1421
Number of doses followed by at least one unsolicited symptom	365	330	719	780	311	349	8	11	1403	1470
Number of unsolicited symptoms classified by MedDRA Preferred Term*	501	465	1075	1248	531	617	9	16	2116	2346
Number of unsolicited symptoms reported**	501	466	1090	1266	547	637	9	16	2147	2385

Non-Frail = Subjects with frailty index score ≤ 0.08

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Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

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Table 14.3.1.38 Percentage of subjects reporting the occurrence of serious adverse events classified by MedDRA Primary System Organ Class from first vaccination up to month 14 post first vaccination by frailty status (Total Vaccinated Cohort)

	Non-Frail								Pre-Frail								Frail								Unknown							
	HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
	95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom	357	6.2	5.6	6.8	328	5.7	5.1	6.4	697	11.5	10.7	12.3	751	12.1	11.3	12.9	293	18.6	16.7	20.6	332	22.7	20.6	24.9	8	13.6	6.0	25.0	10	13.9	6.9	24.1
Blood and lymphatic system disorders (10005329)	7	0.1	0.0	0.2	2	0.0	0.0	0.1	14	0.2	0.1	0.4	21	0.3	0.2	0.5	7	0.4	0.2	0.9	10	0.7	0.3	1.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Cardiac disorders (10007541)	54	0.9	0.7	1.2	46	0.8	0.6	1.1	138	2.3	1.9	2.7	157	2.5	2.1	2.9	75	4.8	3.8	5.9	98	6.7	5.5	8.1	1	1.7	0.0	9.1	2	2.8	0.3	9.7
Congenital, familial and genetic disorders (10010331)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Ear and labyrinth disorders (10013993)	1	0.0	0.0	0.1	7	0.1	0.0	0.3	4	0.1	0.0	0.2	6	0.1	0.0	0.2	3	0.2	0.0	0.6	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Endocrine disorders (10014698)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	3	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Eye disorders (10015919)	2	0.0	0.0	0.1	10	0.2	0.1	0.3	12	0.2	0.1	0.3	12	0.2	0.1	0.3	2	0.1	0.0	0.5	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Gastrointestinal disorders (10017947)	27	0.5	0.3	0.7	42	0.7	0.5	1.0	81	1.3	1.1	1.7	89	1.4	1.2	1.8	26	1.7	1.1	2.4	39	2.7	1.9	3.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
General disorders and administration site conditions (10018065)	14	0.2	0.1	0.4	12	0.2	0.1	0.4	31	0.5	0.3	0.7	34	0.5	0.4	0.8	15	1.0	0.5	1.6	19	1.3	0.8	2.0	0	0.0	0.0	6.1	1	1.4	0.0	7.5
Hepatobiliary disorders (10019805)	18	0.3	0.2	0.5	11	0.2	0.1	0.3	21	0.3	0.2	0.5	36	0.6	0.4	0.8	5	0.3	0.1	0.7	15	1.0	0.6	1.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Immune system disorders (10021428)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	1	1.7	0.0	9.1	0	0.0	0.0	5.0
Infections and infestations (10021881)	69	1.2	0.9	1.5	54	0.9	0.7	1.2	132	2.2	1.8	2.6	137	2.2	1.9	2.6	68	4.3	3.4	5.4	91	6.2	5.0	7.6	1	1.7	0.0	9.1	1	1.4	0.0	7.5
Injury, poisoning and procedural complications (10022117)	54	0.9	0.7	1.2	49	0.9	0.6	1.1	101	1.7	1.4	2.0	92	1.5	1.2	1.8	37	2.4	1.7	3.2	34	2.3	1.6	3.2	2	3.4	0.4	11.7	1	1.4	0.0	7.5
Investigations (10022891)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Metabolism and nutrition disorders (10027433)	7	0.1	0.0	0.2	8	0.1	0.1	0.3	32	0.5	0.4	0.7	26	0.4	0.3	0.6	12	0.8	0.4	1.3	19	1.3	0.8	2.0	0	0.0	0.0	6.1	1	1.4	0.0	7.5
Musculoskeletal and connective tissue disorders (10028395)	24	0.4	0.3	0.6	25	0.4	0.3	0.6	46	0.8	0.6	1.0	47	0.8	0.6	1.0	20	1.3	0.8	2.0	19	1.3	0.8	2.0	0	0.0	0.0	6.1	1	1.4	0.0	7.5
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	77	1.3	1.1	1.7	57	1.0	0.8	1.3	101	1.7	1.4	2.0	133	2.1	1.8	2.5	33	2.1	1.4	2.9	17	1.2	0.7	1.9	1	1.7	0.0	9.1	2	2.8	0.3	9.7
Nervous system disorders (10029205)	32	0.6	0.4	0.8	34	0.6	0.4	0.8	89	1.5	1.2	1.8	95	1.5	1.2	1.9	44	2.8	2.0	3.7	53	3.6	2.7	4.7	2	3.4	0.4	11.7	0	0.0	0.0	5.0
Psychiatric disorders (10037175)	3	0.1	0.0	0.2	8	0.1	0.1	0.3	15	0.2	0.1	0.4	14	0.2	0.1	0.4	6	0.4	0.1	0.8	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Renal and urinary disorders (10038359)	12	0.2	0.1	0.4	7	0.1	0.0	0.3	21	0.3	0.2	0.5	37	0.6	0.4	0.8	22	1.4	0.9	2.1	21	1.4	0.9	2.2	0	0.0	0.0	6.1	1	1.4	0.0	7.5
Reproductive system and breast disorders (10038604)	11	0.2	0.1	0.3	7	0.1	0.0	0.3	8	0.1	0.1	0.3	12	0.2	0.1	0.3	4	0.3	0.1	0.6	3	0.2	0.0	0.6	0	0.0	0.0	6.1	1	1.4	0.0	7.5
Respiratory, thoracic and mediastinal disorders (10038738)	11	0.2	0.1	0.3	12	0.2	0.1	0.4	41	0.7	0.5	0.9	55	0.9	0.7	1.1	34	2.2	1.5	3.0	26	1.8	1.2	2.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Skin and subcutaneous tissue disorders (10040785)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	6	0.1	0.0	0.2	4	0.1	0.0	0.2	6	0.4	0.1	0.8	9	0.6	0.3	1.2	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Surgical and medical procedures (10042613)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Vascular disorders (10047065)	18	0.3	0.2	0.5	15	0.3	0.1	0.4	42	0.7	0.5	0.9	61	1.0	0.8	1.3	30	1.9	1.3	2.7	41	2.8	2.0	3.8	0	0.0	0.0	6.1	3	4.2	0.9	11.7

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N = number of subjects with at least one administered dose
n/% = number/percentage of subjects reporting the symptom at least once
95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 14.3.1.39 Percentage of subjects reporting the occurrence of serious adverse events classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination from first vaccination up to month 14 post first vaccination by frailty status (Total Vaccinated Cohort)

		Non-Frail						Pre-Frail						Frail						Unknown					
		HZ/su N = 5784			Placebo N = 5734			HZ/su N = 6071			Placebo N = 6219			HZ/su N = 1573			Placebo N = 1464			HZ/su N = 59			Placebo N = 72		
		95% CI			95% CI			95% CI			95% CI			95% CI			95% CI			95% CI			95% CI		
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		6	0.1	0.0	0.2	2	0.0	0.0	0.1	6	0.1	0.0	0.2	8	0.1	0.1	0.3	2	0.1	0.0	0.5	0	0.0	0.0	0.3
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3
	Immune thrombocytopenic purpura (10074667)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3
	Lymphadenitis (10025188)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
Cardiac disorders (10007541)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Acute myocardial infarction (10000891)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
Ear and labyrinth disorders (10013993)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Deafness neurosensory (10011891)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
Gastrointestinal disorders (10017947)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Pancreatitis acute (10033647)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
General disorders and administration site conditions (10018065)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Administration site erythema (10074796)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Administration site pain (10058049)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Chills (10008531)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Pyrexia (10037660)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
Immune system disorders (10021428)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Allergic granulomatous angiitis (10048594)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3
	Arthritis bacterial (10053555)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Erysipelas (10015145)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Herpes zoster oticus (10063491)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Neutropenic sepsis (10049151)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3
Musculoskeletal and connective tissue disorders (10028395)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3
	Musculoskeletal chest pain (10050819)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3

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		Non-Frail						Pre-Frail						Frail						Unknown					
		HZ/su N = 5784			Placebo N = 5734			HZ/su N = 6071			Placebo N = 6219			HZ/su N = 1573			Placebo N = 1464			HZ/su N = 59			Placebo N = 72		
		95% CI			95% CI			95% CI			95% CI			95% CI			95% CI			95% CI			95% CI		
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Polymyalgia rheumatica (10036099)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Rheumatoid arthritis (10039073)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	5.0
	Acute myeloid leukaemia (10000880)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	5.0
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Cerebral infarction (10008118)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Cerebrovascular accident (10008190)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Guillain-Barre syndrome (10018767)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Loss of consciousness (10024855)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Mononeuritis (10027910)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Nervous system disorder (10029202)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Syncope (10042772)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
Skin and subcutaneous tissue disorders (10040785)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Eczema (10014184)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Hypotension (10021097)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects reporting the symptom at least once

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

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Table 14.3.1.40 Percentage of subjects reporting the occurrence of serious adverse events classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, from first vaccination until study end by frailty status (Total Vaccinated Cohort)

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		6	0.1	0.0	0.2	3	0.1	0.0	0.2	9	0.1	0.1	0.3	2	0.1	0.0	0.5
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Immune thrombocytopenic purpura (10074667)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Lymphadenitis (10025188)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
Cardiac disorders (10007541)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Acute myocardial infarction (10000891)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
Ear and labyrinth disorders (10013993)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Deafness neurosensory (10011891)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
Gastrointestinal disorders (10017947)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pancreatitis acute (10033647)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
General disorders and administration site conditions (10018065)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Administration site erythema (10074796)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Administration site pain (10058049)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Chills (10008531)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Pyrexia (10037660)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
Immune system disorders (10021428)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Allergic granulomatous angiitis (10048594)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3
	Arthritis bacterial (10053555)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Erysipelas (10015145)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Herpes zoster oticus (10063491)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Neutropenic sepsis (10049151)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
Musculoskeletal and connective tissue disorders (10028395)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.3
	Musculoskeletal chest pain (10050819)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3

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		Non-Frail						Pre-Frail						Frail						Unknown					
		HZ/su N = 5784			Placebo N = 5734			HZ/su N = 6071			Placebo N = 6219			HZ/su N = 1573			Placebo N = 1464			HZ/su N = 59			Placebo N = 72		
		95% CI			95% CI			95% CI			95% CI			95% CI			95% CI			95% CI			95% CI		
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Polymyalgia rheumatica (10036099)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Rheumatoid arthritis (10039073)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	5.0
	Acute myeloid leukaemia (10000880)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	5.0
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Cerebral infarction (10008118)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Cerebrovascular accident (10008190)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Guillain-barre syndrome (10018767)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Loss of consciousness (10024855)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Mononeuritis (10027910)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Nervous system disorder (10029202)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Syncope (10042772)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
Renal and urinary disorders (10038359)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Glomerulonephritis (10018364)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
Skin and subcutaneous tissue disorders (10040785)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Eczema (10014184)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Hypotension (10021097)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	5.0

Non-Frail = Subjects with frailty index score ≤0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects reporting the symptom at least once

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 14.3.1.41 Global Summary of serious adverse events reported with causal relationship to vaccination, from first vaccination until study end by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	6	3	6	9	2	0	0	0	14	12
Number of doses followed by at least one unsolicited symptom	6	3	6	9	2	0	0	0	14	12
Number of unsolicited symptoms classified by MedDRA Preferred Term*	9	3	6	10	3	0	0	0	18	13
Number of unsolicited symptoms reported**	9	3	6	10	3	0	0	0	18	13

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

Table 14.3.1.42 Percentage of subjects reporting the occurrence of fatal serious adverse events classified by MedDRA Primary System Organ Class and Preferred Term from first vaccination until study end by frailty status (Total Vaccinated Cohort)

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		124	2.1	1.8	2.6	109	1.9	1.6	2.3	299	4.9	4.4	5.5	343	5.5	5.0	6.1	174	11.1	9.6	12.7	182	12.4	10.8	14.2	2	3.4	0.4	11.7	6	8.3	3.1	17.3
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Anaemia (10002034)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Disseminated intravascular coagulation (10013442)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombocytopenia (10043554)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Cardiac disorders (10007541)	At least one PT related to the corresponding SOC	25	0.4	0.3	0.6	18	0.3	0.2	0.5	87	1.4	1.1	1.8	91	1.5	1.2	1.8	50	3.2	2.4	4.2	71	4.8	3.8	6.1	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Acute coronary syndrome (10051592)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute left ventricular failure (10063081)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Acute myocardial infarction (10000891)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	9	0.1	0.1	0.3	13	0.2	0.1	0.4	1	0.1	0.0	0.4	9	0.6	0.3	1.2	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic valve disease (10061589)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Aortic valve stenosis (10002918)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arrhythmia (10003119)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Arteriosclerosis coronary artery (10003211)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrial fibrillation (10003658)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.2	0.0	0.6	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrial flutter (10003662)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrioventricular block (10003671)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Atrioventricular block complete (10003673)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac arrest (10007515)	4	0.1	0.0	0.2	1	0.0	0.0	0.1	14	0.2	0.1	0.4	16	0.3	0.1	0.4	8	0.5	0.2	1.0	5	0.3	0.1	0.8	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac disorder (10061024)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac failure (10007554)	5	0.1	0.0	0.2	3	0.1	0.0	0.2	23	0.4	0.2	0.6	25	0.4	0.3	0.6	13	0.8	0.4	1.4	22	1.5	0.9	2.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac failure acute (10007556)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac failure chronic (10007558)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac failure congestive (10007559)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	4	0.1	0.0	0.2	3	0.0	0.0	0.1	6	0.4	0.1	0.8	6	0.4	0.2	0.9	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac tamponade (10007610)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardio-respiratory arrest (10007617)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiogenic shock (10007625)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiomegaly (10007632)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiomyopathy (10007636)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Cardiomyopathy alcoholic (10007637)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiopulmonary failure (10051093)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiovascular insufficiency (10065929)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Congestive cardiomyopathy (10056370)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coronary artery disease (10011078)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coronary artery insufficiency (10052895)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ischaemic cardiomyopathy (10048858)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Left ventricular failure (10024119)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Left ventricular hypertrophy (10049773)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myocardial infarction (10028596)	4	0.1	0.0	0.2	6	0.1	0.0	0.2	17	0.3	0.2	0.4	19	0.3	0.2	0.5	12	0.8	0.4	1.3	12	0.8	0.4	1.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Myocardial ischaemia (10028600)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pericardial effusion (10034474)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pericarditis (10034484)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Right ventricular failure (10039163)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tachycardia (10043071)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ventricular fibrillation (10047290)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ventricular tachycardia (10047302)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Congenital, familial and genetic disorders (10010331)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cystic fibrosis (10011762)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypertrophic cardiomyopathy (10020871)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal dysplasia (10038433)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Gastrointestinal disorders (10017947)	At least one PT related to the corresponding SOC	3	0.1	0.0	0.2	4	0.1	0.0	0.2	11	0.2	0.1	0.3	11	0.2	0.1	0.3	7	0.4	0.2	0.9	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Abdominal adhesions (10000050)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ascites (10003445)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diarrhoea (10012735)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Diverticulum intestinal haemorrhagic (10013560)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Duodenal ulcer (10013836)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Duodenal ulcer haemorrhage (10013839)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Duodenal ulcer perforation (10013849)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastric ulcer (10017822)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Gastric ulcer perforation (10017835)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Gastrointestinal haemorrhage (10017955)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ileus (10021328)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal infarction (10022657)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal ischaemia (10022680)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal obstruction (10022687)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Intestinal perforation (10022694)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Large intestinal obstruction (10062062)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Large intestine perforation (10023804)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mesenteric artery embolism (10027395)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Mesenteric artery thrombosis (10027397)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Nausea (10028813)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal ulcer (10030201)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal varices haemorrhage (10030210)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatitis (10033645)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatitis acute (10033647)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pneumoperitoneum (10048299)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Retroperitoneal haemorrhage (10038980)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Small intestinal obstruction (10041101)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombosis mesenteric vessel (10043626)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Upper gastrointestinal haemorrhage (10046274)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Volvulus (10047697)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
General disorders and administration site conditions (10018065)	At least one PT related to the corresponding SOC	12	0.2	0.1	0.4	14	0.2	0.1	0.4	37	0.6	0.4	0.8	33	0.5	0.4	0.7	18	1.1	0.7	1.8	25	1.7	1.1	2.5	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Accidental death (10063746)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Asthenia (10003549)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cardiac death (10049993)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Death (10011906)	5	0.1	0.0	0.2	8	0.1	0.1	0.3	14	0.2	0.1	0.4	20	0.3	0.2	0.5	8	0.5	0.2	1.0	14	1.0	0.5	1.6	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Device failure (10056871)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Drowning (10013647)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	General physical health deterioration (10049438)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Multi-organ failure (10028154)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	9	0.1	0.1	0.3	3	0.0	0.0	0.1	3	0.2	0.0	0.6	7	0.5	0.2	1.0	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Organ failure (10053159)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Pyrexia (10037660)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Sudden cardiac death (10049418)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Sudden death (10042434)	4	0.1	0.0	0.2	2	0.0	0.0	0.1	8	0.1	0.1	0.3	5	0.1	0.0	0.2	4	0.3	0.1	0.6	3	0.2	0.0	0.6	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Systemic inflammatory response syndrome (10051379)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
Hepatobiliary disorders (10019805)	At least one PT related to the corresponding SOC	4	0.1	0.0	0.2	1	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.2	5	0.3	0.1	0.7	3	0.2	0.0	0.6	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Acute hepatic failure (10000804)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Cholangitis (10008604)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Cholecystitis (10008612)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Cholecystitis acute (10008614)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Cholelithiasis (10008629)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Cholestasis (10008635)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Drug-induced liver injury (10072268)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Fatty liver alcoholic (10016262)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Gallbladder perforation (10017639)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Hepatic cirrhosis (10019641)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Hepatic failure (10019663)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Hepatitis alcoholic (10019728)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Ischaemic hepatitis (10023025)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Jaundice cholestatic (10023129)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	14	0.2	0.1	0.4	15	0.3	0.1	0.4	45	0.7	0.5	1.0	49	0.8	0.6	1.0	40	2.5	1.8	3.4	37	2.5	1.8	3.5	1	1.7	0.0	9.1	0	0.0	0.0	5.0
	Abdominal infection (10056519)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Abdominal sepsis (10058040)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Atypical pneumonia (10003757)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Bacterial infection (10060945)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Bacterial sepsis (10053840)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Bronchitis (10006451)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Bronchopneumonia (10006469)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Candida sepsis (10053166)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Cellulitis (10007882)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Clostridium difficile colitis (10009657)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Clostridium difficile infection (10054236)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Colonic abscess (10073573)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Cystitis klebsiella (10011797)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown								
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72				
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI								
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	
	Diverticulitis (10013538)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Endocarditis (10014665)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Erysipelas (10015145)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Escherichia sepsis (10015296)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Gangrene (10017711)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Gastroenteritis (10017888)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Gastroenteritis clostridial (10017898)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Gastroenteritis norovirus (10068189)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Gastrointestinal infection (10017964)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Infected skin ulcer (10021784)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Infection (10021789)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Influenza (10022000)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Intestinal gangrene (10022651)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Klebsiella sepsis (10054160)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Lobar pneumonia (10024738)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Lower respiratory tract infection (10024968)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Lung infection (10061229)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Mycobacterial infection (10062207)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Nasopharyngitis (10028810)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Necrotising fasciitis (10028885)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Necrotising fasciitis streptococcal (10028888)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Neutropenic sepsis (10049151)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Osteomyelitis (10031252)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Peritonitis (10034674)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.2	0.0	0.6	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Pharyngotonsillitis (10049140)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Pneumonia (10035664)	5	0.1	0.0	0.2	7	0.1	0.0	0.3	22	0.4	0.2	0.5	24	0.4	0.2	0.6	10	0.6	0.3	1.2	13	0.9	0.5	1.5	1	1.7	0.0	9.1	0	0.0	0.0	5.0	
	Pneumonia bacterial (10060946)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Pneumonia influenzal (10035714)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Pneumonia klebsiella (10035717)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Pneumonia pneumococcal (10035728)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Post procedural infection (10067268)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Pseudomembranous colitis (10037128)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Psittacosis (10037151)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Pulmonary tuberculosis (10037440)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Pyelonephritis (10037596)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Respiratory tract infection (10062352)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Sepsis (10040047)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	7	0.1	0.0	0.2	9	0.1	0.1	0.3	12	0.8	0.4	1.3	9	0.6	0.3	1.2	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Primary System Organ Class (CODE)	Septic shock (10040070)	2	0.0	0.0	0.1	5	0.1	0.0	0.2	3	0.0	0.0	0.1	5	0.1	0.0	0.2	5	0.3	0.1	0.7	3	0.2	0.0	0.6	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Serratia infection (10061512)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Soft tissue infection (10062255)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Staphylococcal infection (10058080)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Toxic shock syndrome (10044248)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Urinary tract infection (10046571)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.1	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Urosepsis (10048709)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Viral infection (10047461)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Wound infection pseudomonas (10059444)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
Injury, poisoning and procedural complications (10022117)	At least one PT related to the corresponding SOC	4	0.1	0.0	0.2	7	0.1	0.0	0.3	14	0.2	0.1	0.4	11	0.2	0.1	0.3	5	0.3	0.1	0.7	5	0.3	0.1	0.8	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Accident (10000369)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Aneurysm perforation (10075395)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Carbon monoxide poisoning (10007238)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Cervical vertebral fracture (10049946)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Facial bones fracture (10016042)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Fall (10016173)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Femoral neck fracture (10016450)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Femur fracture (10016454)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Head injury (10019196)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Hip fracture (10020100)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Injury (10022116)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Laceration (10023572)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Multiple injuries (10028224)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Overdose (10033295)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Post procedural complication (10058046)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Respiratory fume inhalation disorder (10061485)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Road traffic accident (10039203)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Skull fracture (10061365)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Spinal cord injury (10041552)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Spinal cord injury cervical (10041554)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Splenic rupture (10041658)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Subdural haematoma (10042361)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Subdural haemorrhage (10042364)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0
	Toxicity to various agents (10070863)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Traumatic intracranial haemorrhage (10061387)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Traumatic shock (10044541)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Wound evisceration (10054108)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	1	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4
Metabolism and nutrition disorders (10027433)	Cachexia (10006895)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Dehydration (10012174)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2
	Electrolyte imbalance (10014418)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Failure to thrive (10016165)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Hyperkalaemia (10020646)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Hypovolaemia (10021137)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Malnutrition (10061273)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Marasmus (10026820)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Metabolic acidosis (10027417)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
Musculoskeletal and connective tissue disorders (10028395)	Fasciitis (10016228)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Polymyositis (10036102)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Rhabdomyolysis (10039020)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	At least one PT related to the corresponding SOC	54	0.9	0.7	1.2	43	0.7	0.5	1.0	86	1.4	1.1	1.7	100	1.6	1.3	2.0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	Abdominal neoplasm (10060925)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Acute leukaemia (10000830)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Acute monocytic leukaemia (10000871)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Acute myeloid leukaemia (10000880)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Adenocarcinoma (10001141)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Adenocarcinoma gastric (10001150)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4
	Adenocarcinoma of colon (10001167)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Adenocarcinoma pancreas (10052747)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4
	Adult t-cell lymphoma/leukaemia (10001413)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Anaplastic astrocytoma (10002224)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Anaplastic thyroid cancer (10002240)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Angioimmunoblastic t-cell lymphoma (10002449)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	B precursor type acute leukaemia (10003890)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	At least one PT related to the corresponding SOC	54	0.9	0.7	1.2	43	0.7	0.5	1.0	86	1.4	1.1	1.7	100	1.6	1.3	2.0
	Abdominal neoplasm (10060925)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Acute leukaemia (10000830)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Acute monocytic leukaemia (10000871)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Acute myeloid leukaemia (10000880)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Adenocarcinoma (10001141)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Adenocarcinoma gastric (10001150)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4
	Adenocarcinoma of colon (10001167)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Adenocarcinoma pancreas (10052747)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4
	Adult t-cell lymphoma/leukaemia (10001413)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Anaplastic astrocytoma (10002224)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Anaplastic thyroid cancer (10002240)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	Angioimmunoblastic t-cell lymphoma (10002449)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2
	B precursor type acute leukaemia (10003890)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	B-cell lymphoma (10003899)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Bile duct cancer (10004593)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Bladder cancer (10005003)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Bladder neoplasm (10005056)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Bladder transitional cell carcinoma recurrent (10066750)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Bone cancer (10005949)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Brain cancer metastatic (10055093)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Brain neoplasm (10061019)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Brain neoplasm malignant (1006131)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Breast cancer (10006187)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Breast cancer metastatic (10055113)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Bronchial carcinoma (10006417)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Bronchial neoplasm (10052245)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Carcinoid tumour pulmonary (10007282)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Central nervous system neoplasm (10007958)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Cholangiocarcinoma (10008593)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4
	Chronic lymphocytic leukaemia (10008958)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Chronic myeloid leukaemia (10009013)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Colon cancer (10009944)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.1	0.0	0.4
	Colon cancer metastatic (10055114)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Colon neoplasm (10061045)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Diffuse large b-cell lymphoma (10012818)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Diffuse large b-cell lymphoma stage iv (10012826)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Endometrial adenocarcinoma (10014720)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Gallbladder cancer (10017614)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Gastric cancer (10017758)	2	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.1	0.0	0.2	1	0.1	0.0	0.4
	Gastrointestinal carcinoma (10017940)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Gastrointestinal neoplasm (10061174)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Glioblastoma (10018336)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Glioblastoma multiforme (10018337)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Glioma (10018338)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Hepatic cancer (10073069)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.2

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Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Hepatic cancer metastatic (10055110)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Hepatic neoplasm (10019695)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Hepatocellular carcinoma (10073071)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Hypopharyngeal cancer (10021042)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Large cell lung cancer (10023774)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Laryngeal cancer (10023825)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Laryngeal neoplasm (10023841)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Leukaemia (10024288)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Lip and/or oral cavity cancer (10061523)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Lung adenocarcinoma (10025031)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	6	0.1	0.0	0.2	0	0.0	0.0	0.3
	Lung adenocarcinoma metastatic (10064049)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.3
	Lung cancer metastatic (10050017)	4	0.1	0.0	0.2	0	0.0	0.0	0.1	4	0.1	0.0	0.2	1	0.1	0.0	0.4
	Lung neoplasm (10062042)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Lung neoplasm malignant (10058467)	6	0.1	0.0	0.2	2	0.0	0.0	0.1	15	0.2	0.1	0.4	8	0.1	0.1	0.3
	Lymphoma (10025310)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1
	Malignant fibrous histiocytoma of bone (10025557)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Malignant mast cell neoplasm (10025638)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Malignant melanoma (10025650)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Malignant neoplasm of ampulla of vater (10025697)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Malignant neoplasm of unknown primary site (10073059)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4
	Meningioma (10027191)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Metastases to adrenals (10027451)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Metastases to bone (10027452)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Metastases to central nervous system (10059282)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	0	0.0	0.0	0.3
	Metastases to gastrointestinal tract (10062196)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Metastases to liver (10027457)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.1	0.0	0.5
	Metastases to lung (10027458)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Metastases to peritoneum (10051676)	4	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Metastases to pleura (10027463)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Metastases to stomach (10049718)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Metastasis (10062194)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1

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Report Final

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Metastatic carcinoma of the bladder (10057352)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastatic gastric cancer (10063916)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastatic malignant melanoma (10027480)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastatic neoplasm (10061289)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastatic renal cell carcinoma (10050513)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Metastatic squamous cell carcinoma (10063569)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Myelodysplastic syndrome (10028533)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neoplasm malignant (10028997)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neoplasm prostate (10029096)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Neuroendocrine carcinoma (10057270)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Non-hodgkin's lymphoma (10029547)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Non-small cell lung cancer (10061873)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Non-small cell lung cancer stage iv (10029522)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal adenocarcinoma (10030137)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal adenocarcinoma metastatic (10058526)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal cancer metastatic (10055102)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal carcinoma (10030155)	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oesophageal squamous cell carcinoma (10061534)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ovarian cancer (10033128)	3	0.1	0.0	0.2	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ovarian cancer recurrent (10066697)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatic carcinoma (10033609)	4	0.1	0.0	0.2	7	0.1	0.0	0.3	5	0.1	0.0	0.2	8	0.1	0.1	0.3	2	0.1	0.0	0.5	2	0.1	0.0	0.5	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Pancreatic carcinoma metastatic (10033610)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatic neoplasm (10061902)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Plasma cell myeloma (10035226)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pleural mesothelioma (10035603)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostate cancer (10060862)	1	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostate cancer metastatic (10036909)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Prostate cancer recurrent (10036911)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Rectal adenocarcinoma (10038019)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	1	1.7	0.0	9.1	0	0.0	0.0	5.0

CONFIDENTIAL

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Report Final

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		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Primary System Organ Class (CODE)	Rectal cancer (10038038)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal cancer (10038389)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal cancer metastatic (10050018)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Renal cell carcinoma (10067946)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Salivary gland cancer (10061934)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Skin cancer (10040808)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Small cell lung cancer (10041067)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Small cell lung cancer metastatic (10059514)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Small intestine adenocarcinoma (10073373)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Squamous cell carcinoma (10041823)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Squamous cell carcinoma of lung (10041826)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Squamous cell carcinoma of the oral cavity (10041857)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	T-cell lymphoma (10042971)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Throat cancer (10043515)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Tongue neoplasm malignant stage unspecified (10043966)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Transitional cell carcinoma metastatic (10071080)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Uterine cancer (10046766)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Vulval cancer (10047741)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	7	0.1	0.0	0.2	8	0.1	0.1	0.3	29	0.5	0.3	0.7	41	0.7	0.5	0.9	20	1.3	0.8	2.0	12	0.8	0.4	1.4	0	0.0	0.0	6.1	1	1.4	0.0	7.5
	Amyotrophic lateral sclerosis (10002026)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Basal ganglia haemorrhage (10067057)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Brain injury (10067967)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebellar haemorrhage (10008030)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral artery thrombosis (10008092)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral haemorrhage (10008111)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	4	0.1	0.0	0.2	8	0.1	0.1	0.3	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral infarction (10008118)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	5	0.1	0.0	0.2	7	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebral ischaemia (10008120)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebrovascular accident (10008190)	1	0.0	0.0	0.1	5	0.1	0.0	0.2	10	0.2	0.1	0.3	12	0.2	0.1	0.3	8	0.5	0.2	1.0	4	0.3	0.1	0.7	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebrovascular disorder (10008196)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Cerebrovascular insufficiency (10058842)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Coma (10010071)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Dementia (10012267)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Dementia alzheimer's type (10012271)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2
	Diabetic coma (10012650)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Dyspraxia (10013976)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Epilepsy (10015037)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Guillain-barre syndrome (10018767)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Haemorrhage intracranial (10018985)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Haemorrhagic stroke (10019016)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.4
	Hypoxic-ischaemic encephalopathy (10070511)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.4
	Intraventricular haemorrhage (10022840)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Ischaemic stroke (10061256)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Loss of consciousness (10024855)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Metabolic encephalopathy (10062190)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Mixed dementia (10075174)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Progressive supranuclear palsy (10036813)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.4
	Ruptured cerebral aneurysm (10039330)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Seizure (10039906)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Senile dementia (10039966)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Status epilepticus (10041962)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Subarachnoid haemorrhage (10042316)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Syncope (10042772)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.4
	Thalamus haemorrhage (10058939)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Thrombotic cerebral infarction (10067347)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
Psychiatric disorders (10037175)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	5	0.1	0.0	0.2
	Completed suicide (10010144)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	4	0.1	0.0	0.2
	Delirium (10012218)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
Renal and urinary disorders (10038359)	At least one PT related to the corresponding SOC	4	0.1	0.0	0.2	2	0.0	0.0	0.1	12	0.2	0.1	0.3	10	0.2	0.1	0.3
	Acute kidney injury (10069339)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	9	0.1	0.1	0.3	3	0.0	0.0	0.1
	Azotaemia (10003885)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.3
	Chronic kidney disease (10064848)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.4

CONFIDENTIAL

204878 (ZOSTER-064)

Report Final

		Non-Frail								Pre-Frail								Frail								Unknown								
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72				
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI								
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	
Respiratory, thoracic and mediastinal disorders (10038738)	Cystitis haemorrhagic (10011793)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Renal failure (10038435)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	4	0.1	0.0	0.2	4	0.3	0.1	0.6	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Urethral haemorrhage (10049710)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Urinary incontinence (10046543)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	At least one PT related to the corresponding SOC	6	0.1	0.0	0.2	10	0.2	0.1	0.3	29	0.5	0.3	0.7	27	0.4	0.3	0.6	23	1.5	0.9	2.2	24	1.6	1.1	2.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Acute pulmonary oedema (10001029)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	3	0.2	0.0	0.6	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Acute respiratory failure (10001053)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	3	0.2	0.0	0.6	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Aspiration (10003504)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Asthma (10003553)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Bronchitis chronic (10006458)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Chronic obstructive pulmonary disease (10009033)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	6	0.4	0.1	0.8	8	0.5	0.2	1.1	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Dyspnoea (10013968)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Emphysema (10014561)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Interstitial lung disease (10022611)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Lung disorder (10025082)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Pleural effusion (10035598)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Pneumonia aspiration (10035669)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.2	0.0	0.6	3	0.2	0.0	0.6	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Pulmonary embolism (10037377)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	5	0.1	0.0	0.2	8	0.1	0.1	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Pulmonary fibrosis (10037383)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Pulmonary oedema (10037423)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
Respiratory acidosis (10038661)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0	
Respiratory arrest (10038669)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0	
Respiratory distress (10038687)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.1	0.0	0.5	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0	
Respiratory failure (10038695)	0	0.0	0.0	0.1	3	0.1	0.0	0.2	8	0.1	0.1	0.3	10	0.2	0.1	0.3	7	0.4	0.2	0.9	4	0.3	0.1	0.7	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0	
Skin and subcutaneous tissue disorders (10040785)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Decubitus ulcer (10011985)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Diabetic foot (10060734)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	10	0.2	0.1	0.3	5	0.1	0.0	0.2	8	0.1	0.1	0.3	15	0.2	0.1	0.4	7	0.4	0.2	0.9	7	0.5	0.2	1.0	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Aneurysm ruptured (10048380)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Aortic aneurysm (10002882)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Aortic aneurysm rupture (10002886)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Aortic dissection (10002895)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Aortic occlusion (10058178)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Aortic rupture (10060874)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Aortic stenosis (10002906)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0

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		Non-Frail								Pre-Frail								Frail								Unknown								
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72				
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI								
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	
	Arterial disorder (10060963)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Arteriosclerosis (10003210)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Bleeding varicose vein (10005144)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Circulatory collapse (10009192)	3	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Deep vein thrombosis (10051055)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Embolism (10061169)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Haematoma (10018852)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Haemodynamic instability (10052076)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Haemorrhage (10055798)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Hypertension (10020772)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Hypotension (10021097)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Hypovolaemic shock (10021138)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Internal haemorrhage (10075192)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Peripheral arterial occlusive disease (10062585)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Peripheral vascular disorder (10034636)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Shock haemorrhagic (10049771)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Superior vena cava syndrome (10042569)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0
	Vasculitis (10047115)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.6	1	0	0.0	0.0	5.0

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects reporting the symptom at least once

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 14.3.1.43 Global Summary of fatal serious adverse events reported from first vaccination until study end by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	124	109	299	343	174	182	2	6	599	640
Number of doses followed by at least one unsolicited symptom	124	109	300	343	174	182	2	6	600	640
Number of unsolicited symptoms classified by MedDRA Preferred Term*	167	147	401	434	245	242	3	6	816	829
Number of unsolicited symptoms reported**	168	147	401	434	245	243	3	6	817	830

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

Table 14.3.1.44 Percentage of subjects reporting the occurrence of fatal serious adverse events classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, from first vaccination until study end by frailty status (Total Vaccinated Cohort)

		Non-Frail						Pre-Frail						Frail						Unknown					
		HZ/su N = 5784			Placebo N = 5734			HZ/su N = 6071			Placebo N = 6219			HZ/su N = 1573			Placebo N = 1464			HZ/su N = 59			Placebo N = 72		
		95% CI			95% CI			95% CI			95% CI			95% CI			95% CI			95% CI			95% CI		
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	5.0
Infections and infestations (10021881)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	5.0
	Neutropenic sepsis (10049151)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	5.0

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects reporting the symptom at least once

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 14.3.1.45 Global Summary of fatal serious adverse events reported with causal relationship to vaccination, from first vaccination until study end by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	0	0	0	0	1	0	0	0	1	0
Number of doses followed by at least one unsolicited symptom	0	0	0	0	1	0	0	0	1	0
Number of unsolicited symptoms classified by MedDRA Preferred Term*	0	0	0	0	1	0	0	0	1	0
Number of unsolicited symptoms reported**	0	0	0	0	1	0	0	0	1	0

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

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Table 14.3.1.46 Percentage of subjects reporting the occurrence of potential Immune-Mediated Diseases classified by MedDRA Primary System Organ Class and Preferred Term from first vaccination until study end by frailty status (Total Vaccinated Cohort)

		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		74	1.3	1.0	1.6	69	1.2	0.9	1.5	76	1.3	1.0	1.6	90	1.4	1.2	1.8	15	1.0	0.5	1.6	27	1.8	1.2	2.7	1	1.7	0.0	9.1	0	0.0	0.0	5.0
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Immune thrombocytopenic purpura (10074667)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.1	0.0	0.4	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pernicious anaemia (10034695)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Thrombocytopenia (10043554)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Ear and labyrinth disorders (10013993)	Vestibular disorder (10047386)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	At least one PT related to the corresponding SOC	12	0.2	0.1	0.4	8	0.1	0.1	0.3	6	0.1	0.0	0.2	8	0.1	0.1	0.3	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Endocrine disorders (10014698)	Autoimmune thyroiditis (10049046)	8	0.1	0.1	0.3	3	0.1	0.0	0.2	4	0.1	0.0	0.2	6	0.1	0.0	0.2	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Basedow's disease (10004161)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hyperthyroidism (10020850)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Hypothyroidism (10021114)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Eye disorders (10015919)	Autoimmune uveitis (10075690)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Ocular myasthenia (10049168)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Uveitis (10046851)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	At least one PT related to the corresponding SOC	6	0.1	0.0	0.2	7	0.1	0.0	0.3	3	0.0	0.0	0.1	5	0.1	0.0	0.2	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Autoimmune pancreatitis (10069002)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
Gastrointestinal disorders (10017947)	Chronic gastritis (10008882)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Coeliac disease (10009839)	3	0.1	0.0	0.2	2	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colitis microscopic (10056979)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Colitis ulcerative (10009900)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Crohn's disease (10011401)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Oral lichen planus (10030983)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Pancreatitis acute (10033647)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Proctitis ulcerative (10036783)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Autoimmune pancreatitis (10069002)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Chronic gastritis (10008882)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

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204878 (ZOSTER-064)

Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Hepatobiliary disorders (10019805)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Biliary cirrhosis primary (10004661)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
Immune system disorders (10021428)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Allergic granulomatous angitis (10048594)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Sarcoidosis (10039486)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
Infections and infestations (10021881)	Encephalitis (10014581)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Encephalomyelitis (10014619)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Vestibular neuronitis (10047393)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Diabetes mellitus (10012601)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
Metabolism and nutrition disorders (10027433)	Type 1 diabetes mellitus (10067584)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	At least one PT related to the corresponding SOC	25	0.4	0.3	0.6	20	0.3	0.2	0.5	33	0.5	0.4	0.8	35	0.6	0.4	0.8
	Arthritis reactive (10003267)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
Musculoskeletal and connective tissue disorders (10028395)	Crest syndrome (10011380)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Inclusion body myositis (10066407)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Mixed connective tissue disease (10027754)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Polyarthritis (10036030)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Polymyalgia rheumatica (10036099)	10	0.2	0.1	0.3	5	0.1	0.0	0.2	17	0.3	0.2	0.4	19	0.3	0.2	0.5
	Polymyositis (10036102)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Psoriatic arthropathy (10037162)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Rheumatoid arthritis (10039073)	9	0.2	0.1	0.3	8	0.1	0.1	0.3	11	0.2	0.1	0.3	1	0.0	0.0	0.1
	Seronegative arthritis (10062164)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Sjogren's syndrome (10040767)	2	0.0	0.0	0.1	3	0.1	0.0	0.2	4	0.1	0.0	0.2	2	0.1	0.0	0.2
	Spondyloarthropathy (10051265)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	2	0.1	0.0	0.2
	Still's disease adult onset (10064056)	2	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Systemic lupus erythematosus (10042945)	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (10029104)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Plasma cell myeloma (10035226)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	10	0.2	0.1	0.3	5	0.1	0.0	0.2	11	0.2	0.1	0.3	14	0.2	0.1	0.4
	Demyelinating polyneuropathy (10061811)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1

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Report Final

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784		Placebo N = 5734		HZ/su N = 6071		Placebo N = 6219		HZ/su N = 1573		Placebo N = 1464		HZ/su N = 59		Placebo N = 72	
		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI		95% CI	
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Demyelination (10012305)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Facial paresis (10051267)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Guillain-Barre syndrome (10018767)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Miller Fisher syndrome (10049567)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Mononeuritis (10027910)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Multiple sclerosis (10028245)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Myasthenia gravis (10028417)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Myasthenic syndrome (10028424)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Neuritis (10029240)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Neuritis cranial (10029244)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Parkinson's disease (10061536)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Parkinsonism (10034010)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Polyneuropathy (10036105)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Radiculitis brachial (10037778)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Trigeminal nerve paresis (10068008)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Trigeminal neuralgia (10044652)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Vasculitis cerebral (10047119)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Viiith nerve lesion (10062177)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Viiith nerve paralysis (10050040)	3	0.1	0.0	0.2	3	0.1	0.0	0.2	3	0.0	0.0	0.1	2	0.1	0.0	0.5
Renal and urinary disorders (10038359)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Glomerulonephritis (10018364)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Iga nephropathy (10021263)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
Respiratory, thoracic and mediastinal disorders (10038738)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	5	0.1	0.0	0.2
	Idiopathic pulmonary fibrosis (10021240)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	3	0.0	0.0	0.1	0	0.0	0.0	0.1
	Pulmonary fibrosis (10037383)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4
Skin and subcutaneous tissue disorders (10040785)	At least one PT related to the corresponding SOC	11	0.2	0.1	0.3	18	0.3	0.2	0.5	11	0.2	0.1	0.3	16	0.3	0.1	0.4
	Alopecia areata (10001761)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Dermatitis exfoliative (10012455)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Dermatitis psoriasiform (10058675)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Dermatomyositis (10012503)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Eczema (10014184)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Erythema multiforme (10015218)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Erythema nodosum (10015226)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Hypersensitivity vasculitis (10020764)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4
	Lichen planus (10024429)	2	0.0	0.0	0.1	4	0.1	0.0	0.2	2	0.0	0.0	0.1	3	0.1	0.0	0.4
	Lichen sclerosus (10024434)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1

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		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
	Pemphigoid (10034277)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Pemphigus (10034280)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Psoriasis (10037153)	6	0.1	0.0	0.2	6	0.1	0.0	0.2	4	0.1	0.0	0.2	7	0.1	0.0	0.2	2	0.1	0.0	0.5	3	0.2	0.0	0.6	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Pustular psoriasis (10037575)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Subacute cutaneous lupus erythematosus (10057903)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Vitiligo (10047642)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	6	0.1	0.0	0.2	5	0.1	0.0	0.2	3	0.0	0.0	0.1	6	0.1	0.0	0.2	1	0.1	0.0	0.4	2	0.1	0.0	0.5	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Behcet's syndrome (10004213)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Microscopic polyangiitis (10063344)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Polyarteritis nodosa (10036024)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Raynaud's phenomenon (10037912)	1	0.0	0.0	0.1	3	0.1	0.0	0.2	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.1	0.0	0.4	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Temporal arteritis (10043207)	5	0.1	0.0	0.2	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Thromboangiitis obliterans (10043540)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	1	0.1	0.0	0.4	0	0.0	0.0	0.1	0	0.0	0.0	5.0
	Vasculitis (10047115)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	0.1	0	0.0	0.0	5.0

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects reporting the symptom at least once

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 14.3.1.47 Global Summary of potential Immune-Mediated Diseases reported from first vaccination until study end by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	74	69	76	90	15	27	1	0	166	186
Number of doses followed by at least one unsolicited symptom	74	70	76	91	15	27	1	0	166	188
Number of unsolicited symptoms classified by MedDRA Preferred Term*	75	72	77	99	15	27	1	0	168	198
Number of unsolicited symptoms reported**	75	73	77	99	15	27	1	0	168	199

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

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Table 14.3.1.48 Percentage of subjects reporting the occurrence of potential Immune-Mediated Diseases classified by MedDRA Primary System Organ Class and Preferred Term with causal relationship to vaccination, from first vaccination until study end by frailty status (Total Vaccinated Cohort)

		Non-Frail				Pre-Frail				Frail				Unknown			
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219			
		95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
At least one symptom		4	0.1	0.0	0.2	7	0.1	0.0	0.3	9	0.1	0.1	0.3	6	0.1	0.0	0.2
Blood and lymphatic system disorders (10005329)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Immune thrombocytopenic purpura (10074667)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Thrombocytopenia (10043554)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
Gastrointestinal disorders (10017947)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Colitis ulcerative (10009900)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Pancreatitis acute (10033647)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
Immune system disorders (10021428)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Allergic granulomatous angiitis (10048594)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
Musculoskeletal and connective tissue disorders (10028395)	At least one PT related to the corresponding SOC	2	0.0	0.0	0.1	3	0.1	0.0	0.2	2	0.0	0.0	0.1	4	0.1	0.0	0.2
	Arthritis reactive (10003267)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Inclusion body myositis (10066407)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Polymyalgia rheumatica (10036099)	1	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	0	0.0	0.0	0.1
	Rheumatoid arthritis (10039073)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1
	Sjogren's syndrome (10040767)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
Nervous system disorders (10029205)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	1	0.0	0.0	0.1	2	0.0	0.0	0.1	1	0.0	0.0	0.1
	Guillain-Barre syndrome (10018767)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Mononeuritis (10027910)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Myasthenic syndrome (10028424)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
Renal and urinary disorders (10038359)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Glomerulonephritis (10018364)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
Skin and subcutaneous tissue disorders (10040785)	At least one PT related to the corresponding SOC	1	0.0	0.0	0.1	1	0.0	0.0	0.1	3	0.0	0.0	0.1	1	0.1	0.0	0.4
	Alopecia areata (10001761)	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Dermatitis exfoliative (10012455)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Erythema nodosum (10015226)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1
	Hypersensitivity vasculitis (10020764)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1
	Psoriasis (10037153)	0	0.0	0.0	0.1	0	0.0	0.0	0.1	1	0.0	0.0	0.1	1	0.1	0.0	0.4

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		Non-Frail								Pre-Frail								Frail								Unknown							
		HZ/su N = 5784				Placebo N = 5734				HZ/su N = 6071				Placebo N = 6219				HZ/su N = 1573				Placebo N = 1464				HZ/su N = 59				Placebo N = 72			
		95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI				95% CI			
Primary System Organ Class (CODE)	Preferred Term (CODE)	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL	n	%	LL	UL
Vascular disorders (10047065)	At least one PT related to the corresponding SOC	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0
	Behcet's syndrome (10004213)	0	0.0	0.0	0.1	1	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.1	0	0.0	0.0	0.2	0	0.0	0.0	0.3	0	0.0	0.0	6.1	0	0.0	0.0	5.0

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

At least one symptom = at least one symptom experienced (regardless of the MedDRA Preferred Term)

N = number of subjects with at least one administered dose

n/% = number/percentage of subjects reporting the symptom at least once

95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Table 14.3.1.49 Global Summary of potential Immune Mediated Diseases reported with causal relationship to vaccination, from first vaccination until study end by frailty status (Total Vaccinated Cohort)

	Group									
	Non-Frail		Pre-Frail		Frail		Unknown		All	
	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo	HZ/su	Placebo
Number of subjects with at least one unsolicited symptom reported	4	7	9	6	2	1	0	0	15	14
Number of doses followed by at least one unsolicited symptom	4	7	9	6	2	1	0	0	15	14
Number of unsolicited symptoms classified by MedDRA Preferred Term*	4	7	9	6	2	1	0	0	15	14
Number of unsolicited symptoms reported**	4	7	9	6	2	1	0	0	15	14

Non-Frail = Subjects with frailty index score ≤ 0.08

Pre-Frail = Subjects with frailty index score > 0.08 and ≤ 0.25

Frail = Subjects with frailty index score > 0.25

Unknown = Subjects who were not assigned a Frailty category

HZ/su = Herpes Zoster subunit vaccine

Placebo = Placebo

* Symptoms reported by a subject after a given dose and classified by the same Preferred Term are counted once

** Symptoms reported by a subject after a given dose and classified by the same Preferred Term and the same start date of the event, are counted once

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16. APPENDICES

16.1. Study Information

16.1.1. Protocol and protocol amendments

**Study Protocol**

Sponsor:

GlaxoSmithKline Biologicals SA

Rue de l'Institut 89, 1330 Rixensart, Belgium

eTrack study number and Abbreviated Title	204878 (ZOSTER-064)
Investigational New Drug (IND) number	BB-IND-13857
Date of protocol	Final: 29 January 2018
Date of protocol amendment	Amendment 1 Final: 17 October 2018
Date of protocol administrative change	Administrative Change 1 Final 27 March 2018 Administrative Change 2 Final: 13 November 2018 Administrative Change 3 Final 11 February 2019
Title	Observational study to assess frailty of subjects during ZOSTER-006 and ZOSTER-022.
Detailed Title	Observational study to assess frailty of subjects during ZOSTER-006 and ZOSTER-022 and HZ efficacy, immunogenicity and safety of HZ/su by frailty status.
Co-ordinating author(s)	• PPD [REDACTED], Lead Scientific Writer • PPD [REDACTED], Senior Scientific Writer • PPD [REDACTED], Scientific Writer, XPE Pharma & Science for GSK Biologicals • PPD [REDACTED], Scientific Writer, XPE Pharma & Science for GSK Biologicals (Administrative Change 3, 11 Feb 2019)
Contributing authors	• PPD [REDACTED], Clinical Research and Development Lead • PPD [REDACTED], Study Delivery Lead • PPD [REDACTED], Lead Statistician • PPD [REDACTED], Lead Statistician • PPD [REDACTED], Oversight Data Management

eTrack study number and Abbreviated Title	204878 (ZOSTER-064)
Investigational New Drug (IND) number	BB-IND-13857
Detailed Title	Observational study to assess frailty of subjects during ZOSTER-006 and ZOSTER-022 and HZ efficacy, immunogenicity and safety of HZ/su by frailty status.
Contributing authors (cont.)	• PPD [REDACTED], Director Value Evidence • PPD [REDACTED], Health Economics Biostatistician • PPD [REDACTED], Global Regulatory Affairs (Administrative Change 3, 11 Feb 2019) • PPD [REDACTED], Clinical and Epidemiology Project Lead (CEPL) for Zoster, US RDC

GSK Biologicals' protocol template for observational studies and interventional studies without administration of medicinal products as described in a research protocol based on the Protocol Document Standard version 15.0

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Protocol Administrative Change 3 Sponsor Signatory Approval

eTrack study number and Abbreviated Title	204878 (ZOSTER-064)
IND number	BB-IND-13857
Date of protocol administrative change	Administrative Change 3 Final: 11 February 2019
Detailed Title	Observational study to assess frailty of subjects during ZOSTER-006 and ZOSTER-022 and HZ efficacy, immunogenicity and safety of HZ/su by frailty status.
Sponsor signatory	Anne Schuind, Clinical and Epidemiology Project Lead for Zoster, GlaxoSmithKline Biologicals, US RDC

Signature

Date

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Protocol Administrative Change 3 Rationale

Amendment number:	Administrative Change 3
Rationale/background for changes: • The Japan Vaccine Company will no longer be in operation as of 01 April 2019. Therefore, the reference to “Japan Vaccine Co., Ltd.” has been changed to “GSK Japan”.	

Protocol Administrative Change 3 Investigator Agreement

I agree:

- To conduct the study in compliance with this protocol, any mutually agreed future protocol amendments or protocol administrative changes, with the terms of the study agreement and with any other study conduct procedures and/or study conduct documents provided by GlaxoSmithKline (GSK) Biologicals.
- To assume responsibility for the proper conduct of the study at this site.
- That I am aware of, and will comply with, 'Good Clinical Practice' (GCP) and all applicable regulatory requirements.
- To ensure that all persons assisting me with the study are adequately informed about study-related duties and functions as described in the protocol.
- To co-operate with a representative of GSK Biologicals in the monitoring process of the study and in resolution of queries about the data.
- That I have been informed that certain regulatory authorities require the sponsor to obtain and supply, as necessary, details about the investigator's ownership interest in the sponsor, and more generally about his/her financial ties with the sponsor. GSK Biologicals will use and disclose the information solely for the purpose of complying with regulatory requirements.

Hence, I:

- Agree to supply GSK Biologicals with any necessary information regarding ownership interest and financial ties (including those of my spouse and dependent children).
- Agree to promptly update this information if any relevant changes occur during the course of the study and for one year following completion of the study.
- Agree that GSK Biologicals may disclose any information it has about such ownership interests and financial ties to regulatory authorities.
- Agree to provide GSK Biologicals with an updated Curriculum Vitae and other documents required by regulatory agencies for this study.

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204878 (ZOSTER-064)
Protocol Administrative Change 3 Final

**eTrack study number and
Abbreviated Title**

204878 (ZOSTER-064)

IND number

BB-IND-13857

**Date of protocol
administrative change**

Administrative Change 3 Final: 11 February 2019

Detailed Title

Observational study to assess frailty of subjects
during ZOSTER-006 and ZOSTER-022 and HZ
efficacy, immunogenicity and safety of HZ/su by
frailty status.

Investigator name

Signature

Date

**Leiter der klinischen
Prüfung name, function and
title**

Signature

Date

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204878 (ZOSTER-064)
Protocol Administrative Change 3 Final

**eTrack study number and
Abbreviated Title**

204878 (ZOSTER-064)

IND number

BB-IND-13857

**Date of protocol
administrative change**

Administrative Change 3 Final: 11 February 2019

Detailed Title

Observational study to assess frailty of subjects
during ZOSTER-006 and ZOSTER-022 and HZ
efficacy, immunogenicity and safety of HZ/su by
frailty status.

***GSK Japan** study
representative name,
function and title**

Signature

Date

***(Administrative Change 3, 11 February 2019)**

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Sponsor Information

1. Sponsor

GlaxoSmithKline Biologicals

Rue de l'Institut 89, 1330 Rixensart, Belgium

2. Sponsor Medical Expert for the Study

Refer to the local study contact information document.

3. Sponsor Study Monitor

Refer to the local study contact information document.

SYNOPSIS

Detailed Title	Observational study to assess frailty of subjects during ZOSTER-006 and ZOSTER-022 and HZ efficacy, immunogenicity and safety of HZ/su by frailty status.
Objective(s)	Primary - To assess the baseline frailty of subjects enrolled in ZOSTER-006 and ZOSTER-022. Secondary - To present the distribution of <i>SF-36</i> and <i>EQ-5D</i> scores in subjects included in ZOSTER-006 and ZOSTER-022 at baseline by country to allow comparison with normative values for those questionnaires in the general population of the countries participating in the study. - To assess vaccine efficacy against HZ by frailty status. - To assess HZ burden of illness (BOI) by frailty status. - To identify predictive factors for individuals developing HZ. - To describe safety per frailty status. - To assess humoral immunogenicity by frailty status. Tertiary - To describe CMI by frailty status of subjects enrolled in ZOSTER-006 only.
Rationale for the study	In the course of ZOSTER-006 and ZOSTER-022, QoL questionnaires were encoded into the respective trial database only for subjects who developed a suspected HZ episode during the study. This was done to assess the QoL of subjects who developed suspected cases of HZ between the vaccine group and the placebo group. The remaining subjects who did not develop suspected cases of HZ completed the questionnaires; however, these questionnaires were never encoded or analysed as part of ZOSTER-006 and ZOSTER-022. The purpose of this study is to allow for the encoding and analysis of all questionnaires for subjects enrolled in ZOSTER-006 and ZOSTER-022. The aim is to assess the baseline frailty of subjects enrolled in ZOSTER-006 and ZOSTER-022 and to investigate the representativeness of the study population to the general population. Additionally, analysis of efficacy, safety and immunogenicity will be performed by frailty status. The study will also explore if quality of life data and subject characteristics reported by the subjects before the onset of HZ would be predictive of HZ.

This should help confirm previously hypothesized predictive factors such as age, stress or functional status, and also to assess other potential risk factors such as frailty, fatigue or emotional and mental health.

Study design

- A multi-country, observational, retrospective study.
- Study population: All subjects enrolled in ZOSTER-006 and ZOSTER-022.
- Type of study: Data to be analysed in this study have been collected in the ZOSTER-006 (eTrack 110390) and ZOSTER-022 (eTrack 113077) and will be combined for assessment of primary, secondary and tertiary objectives.
- Data collection: QoL questionnaires and the year of birth of subjects enrolled in ZOSTER-006 and ZOSTER-022.
 - QoL questionnaires: The *SF-36* is a multi-purpose health survey with 36 questions. The *EQ-5D* is a questionnaire with 5 questions designed as a generic measure of health status that provides a simple descriptive profile and a single index value. The *EQ-5D* defines health in terms of mobility, self-care, usual activities, pain/discomfort and anxiety/depression.
- Method: Frailty scores for study subjects in ZOSTER-006 and ZOSTER-022 will be calculated by incorporating the subject's medical history and items from the *SF-36* and *EQ-5D* questionnaires.

Discussion of study design

This is a retrospective, observational study of subjects previously enrolled in ZOSTER-006 and ZOSTER-022, therefore no new subjects will be enrolled in this study and no new ICF will be required from study subjects.

Number of subjects

Approximately 30,000 subjects who were enrolled in ZOSTER-006 and ZOSTER-022

Endpoints

Primary

- Baseline Frailty Status:
 - Frailty Status pre-vaccination dose 1 as defined by responses to components of the *SF-36* and *EQ-5D* questionnaire at vaccination day 0 and the subjects coded medical history.

Secondary

- SF-36 and *EQ-5D* scale scores:
 - At months 0, 14, 26 and 38.
- Confirmed HZ cases:
 - Incidence of HZ cases during ZOSTER-006 and ZOSTER-022 for subjects in the modified Total Vaccinated Cohort (mTVC).
- HZ Burden of Illness:
 - HZ Burden of Illness score for subjects in both ZOSTER-006 and ZOSTER-022 as calculated from the Zoster Brief Pain Inventory (ZBPI).
- Solicited local and general symptoms from ZOSTER-006 and ZOSTER-022:
 - Occurrence, intensity of each solicited local symptom within 7 days (Days 0-6) after each vaccination, in subjects included in the 7-day diary card subset;
 - Occurrence, intensity and relationship to vaccination of each solicited general symptom within 7 days (Days 0-6) after each vaccination, in subjects included in the 7-day diary card subset.
- Unsolicited adverse events (AEs) from ZOSTER-006 and ZOSTER-022:
 - Occurrence, intensity and relationship to vaccination of unsolicited AEs during 30 days (Days 0 - 29) after each vaccination, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification in all subjects.
- Serious Adverse Events (SAEs) from ZOSTER-006 and ZOSTER-022.
 - Occurrence and relationship to vaccination of all SAEs from Month 0 to Month 14 in all subjects;
 - Occurrence of SAEs related to study participation or to a concurrent GSK medication/vaccine during the entire study period in all subjects;
 - Occurrence of any fatal SAEs during the entire study period in all subjects.

- Occurrence of pre-defined AEs
 - Occurrence and relationship to vaccination of any pIMDs during the entire study period in all subjects.
- Humoral Immunogenicity of the study vaccine in subset of subjects from ZOSTER-006 and ZOSTER-022.
 - Anti-gE and *anti-VZV Ab* concentrations as determined by Enzyme-linked Immunosorbent Assay (ELISA), in a subset of subjects at Months 0, 3, 14, 26 and 38.

Tertiary

- Cell-mediated immunogenicity (CMI) of the study vaccine in subsets of subjects from ZOSTER-006 only.
 - CMI in terms of frequencies of antigen-specific CD4 T cells at Months 0, 3, 14, 26 and 38
 - Frequencies of CD4 T cells with antigen-specific Interferon gamma (IFN- γ) and/or Interleukin-2 (IL-2) and/or Tumour Necrosis Factor alpha (TNF- α) and/or CD40 Ligand (CD40L) secretion/expression to glycoprotein E (gE) and VZV as determined by intracellular cytokine staining (ICS) in a subset of subjects at Months 0, 3, 14, 26 and 38.

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LIST OF ABBREVIATIONS

ATP	According to protocol
BOI	Burden of illness
EQ-5D	EuroQol 5D questionnaire
GCP	Good Clinical Practice
GSK	GlaxoSmithKline
HZ	Herpes Zoster
HZ/su	Herpes Zoster Subunit Vaccine (50µg gE/AS01B)
HZAC	Herpes Zoster Ascertainment Committee
ICH	International Conference on Harmonisation
IEC	Independent Ethics Committee
IND	Investigational New Drug
IRB	Institutional Review Board
mTVC	modified Total Vaccinated Cohort
PCR	Polymerase Chain Reaction
PHN	Postherpetic Neuralgia
QoL	Quality of Life
SDV	Source Document Verification
SF-36	Short Form 36 Questionnaire
TTO	Time-Trade-Off
TVC	Total Vaccinated Cohort
VZV	Varicella-Zoster Virus
YOA	Years of Age
ZBPI	Zoster Brief Pain Inventory

GLOSSARY OF TERMS

According to Protocol (ATP)	In ZOSTER-006 and ZOSTER-022, the ATP cohort included all evaluable subjects meeting all eligibility criteria, complying with the procedures and intervals allowed for the analysis, with no elimination criteria during the study.
Case-control study:	A form of epidemiological study where the study population is selected on the basis of whether the subjects do (cases) or do not (controls) have the particular outcome (disease) under study. The groups are then compared with respect to exposure/ characteristic of interest.
Coded:	Data from which personal identifier information has been removed and replaced by a key. These data are not anonymised since a decode listing exists and it is therefore possible to identify the patient under certain circumstances by an authorised or legally appointed third party data custodian, or by the original holder of the data.
Eligible:	Qualified for enrolment into the study based upon strict adherence to inclusion/exclusion criteria.
Epidemiological study:	An observational or interventional study without administration of medicinal product(s) as described in a research protocol.
Epoch:	An epoch is a self-contained set of consecutive timepoints or a single timepoint from a single protocol. Self-contained means that data collected for all subjects at all-timepoints within that epoch allows to draw a complete conclusion. Typical examples of epochs are retrospective data collection and prospective data collection, etc.
eTrack:	GSK Biologicals' tracking tool for clinical/ epidemiological trials.
modified Total Vaccinated cohort (mTVC)	The mTVC will include only subjects from centres that participate in ZOSTER-064, which will exclude subjects in the TVC who were not administered the second vaccination or who developed a confirmed case of HZ prior to 1 month after the second vaccination (i.e. these subjects that were included in the mTVC of ZOSTER-006 and ZOSTER-022.

Non-interventional (observational) Human Subject Research:	Studies where medicinal products, should they be administered, are prescribed in normal (routine) medical practice. No medical care or medical/scientific procedures as required in a research protocol are administered to participants except as part of routine medical care.
Quality of Life (QoL)	Quality of life is measured, using two questionnaires (<i>EQ-5D</i> and <i>SF-36</i>) that were completed by the subject. <i>EQ-5D</i> and <i>SF-36</i> provide multi-dimensional evaluation of the health status.
Research protocol:	A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a study. The protocol usually also gives the background and rationale for the study, but these could be provided in other protocol referenced documents.
Retrospective study:	A study that looks backward in time (e.g., at events that occurred in the past; outcomes and exposure can no longer be influenced), usually using medical records, databases or interviews in order to address one or more study objectives.
Study population:	Sample of population of interest.
Subject:	Term used throughout the protocol to denote an individual who has been contacted in order to participate or participates in the epidemiological study or a person about whom some medical information has been recorded in a database.
Subject number:	A unique number identifying a subject, assigned to each subject consenting to participate in the study.
Total Vaccinated cohort (TVC)	The TVC will include all subjects from centres that participate in ZOSTER-064 and all subjects who had a HZ suspected case in either the ZOSTER-006 or ZOSTER-022 studies. Subjects enrolled in ZOSTER-064 need to have been part of the TVC in ZOSTER-006 or ZOSTER-022.

1. INTRODUCTION

1.1. Background

Varicella-Zoster Virus (VZV) causes two distinct diseases. Varicella (chickenpox) shortly occurs after primary VZV infection and is characterised by systemic illness and a widely disseminated rash. Herpes Zoster (HZ, shingles) occurs when VZV reactivates from latency and typically manifests as a localised, dermatomal rash. The typical HZ rash usually lasts 2 to 4 weeks and is usually accompanied by pain; that is often described as burning, shooting, or stabbing, and pruritus, which can also be severe, may be as common as pain. In some patients, even touching the affected area lightly may cause severe pain, a phenomenon known as allodynia. The most common complication of HZ is postherpetic neuralgia (PHN), defined as pain that persists after the resolution of the HZ rash. Patients affected by PHN typically report constant burning, throbbing, intermittent sharp or electric shock-like pain, or allodynia. PHN tends to improve over a period of months and about 70-80% of cases resolve within 1 year. However, in some persons PHN persists for many years [Dworkin, 2007].

Inclusion of subjects in clinical trials may be biased for various reasons, e.g. inclusion/exclusion criteria, selection of patients by investigators, self-selection of patients. As such, the aim of this study is to explore if the subjects in the ZOSTER-006 and ZOSTER-022 studies were representative of an older adult population. This will be done by exploring the baseline frailty status and quality of life scores of subjects within the studies.

Several studies have demonstrated that the incidence and severity of HZ increases with age [CDC, 2008]. It is also likely that the incidence and severity of HZ is higher in frail subjects. However, as with age vaccine efficacy may somewhat lower in frail subjects. This study will therefore allow a synthesis of the benefit of vaccination in frail subjects, i.e. in terms of increased incidence, vaccine efficacy, safety and immunogenicity.

1.1.1. Risk factors for herpes zoster

Several risk factors for developing HZ have previously been identified, amongst which the age of the individual is the most common. The incidence of HZ is relatively constant at 2-3 cases per 1000 persons per year until age 40, and then increases progressively with age: At 50-59 years of age (YOA) the incidence is about 5 cases per 1000 persons per year, and it increases to 10 cases per 1000 persons per year in people ≥ 60 YOA [CDC, 2008]. Half of all HZ cases occur in subjects over the age of 60, and individuals who reach 85 years old have a 50% chance of having HZ during their lifetime [Oxman, 2005]. Age has also been demonstrated to be a risk factor for the development of PHN amongst patients with HZ [Oxman, 2005; Scott, 2006; Kanbayashi, 2012; Kawai, 2015].

A second factor that has been consistently related to HZ development is the presence of immunosuppressive conditions [Cohen, 2007; Buchbinder, 1992; Langan, 2013]. Other factors have been suggested to be associated with an increase of HZ incidence, including female gender [Fleming, 2004; Jung, 2004; Liu, 2015], race [Fleming, 2004; Schmader, 1998], psychological symptoms such as stress and depression [Irwin, 1998; Schmader, 1998; Lasserre, 2012], or impaired functional status [Wolfe, 2006; Liu, 2015].

Some factors have also been associated with greater incidence of PHN among patients with HZ: psychological symptoms [Clark, 2000; Volpi, 2008], impaired physical and social functional status [Katz, 2005; Drolet, 2010; Kawai, 2015] and severity of the HZ rash and associated pain [Whitley, 1999; Jung, 2004; Opstelten, 2007; Drolet, 2010; Kanbayashi, 2012].

1.1.2 ZOSTER-006 and ZOSTER-022

Two GSK-sponsored Phase III studies investigated the effect of GSK's candidate HZ/su vaccine on the incidence of the disease in subjects 50 YOA and older (ZOSTER-006, eTrack number 110390, NCT01165177, started in 2010) [Lal, 2015] and in subjects 70 YOA and older (ZOSTER-022, eTrack number 113077, NCT01165229, started in 2010), respectively [Cunningham, 2016].

An indication in adults ≥ 50 YOA was filed for registration. HZ/su (trade name *Shingrix*) was first approved in Canada and the United States in October 2017.

As part of the study procedures, each subject enrolled in one of these two studies was asked to complete two quality of life (QoL) questionnaires named respectively *SF-36* and *EQ-5D* at predefined timepoints. These questionnaires were to be completed independently from the fact that subjects had HZ or not and provide relevant information about the QoL (functional status, ability to socialize, mental health, etc.) of subjects before they develop HZ (see APPENDIX A and APPENDIX B for samples of the *SF-36* and *EQ-5D* questionnaires).

1.2. Rationale for the study

In the course of ZOSTER-006 and ZOSTER-022, Quality of Life questionnaires (QoL), *EQ-5D* and *SF-36*, were completed by all study subjects at baseline. Extracting some elements of these questionnaires and combining them with other medical history data allows attributing of frailty scores.

As these questionnaires were encoded into the respective trial databases only for subjects who developed a suspected Herpes Zoster (HZ) episode during the studies, as per the original study protocols, the purpose of ZOSTER-064 is to allow for the encoding of remaining questionnaires of the subjects and analysis of all questionnaires together. This will allow classification in different levels of frailty and therefore will allow baseline frailty assessment of subjects that took part in the ZOSTER-006 and ZOSTER-022 studies. This will inform the representativeness of the study sample to the general population in older adults, i.e. in terms of the proportion of subjects who are pre-frail and frail. In addition, a comparison of the *SF-36* and *EQ-5D* scores in subjects at baseline

with normative values for those questionnaires in the general population of the countries participating in the study (where these values are available) will also provide further insight in the study population and allow to better understand the study population compared to the overall target population for the vaccine.

Analyses pertaining to efficacy, safety and immunogenicity as per frailty score might then also be performed according to the methodology used in the ZOSTER-006 and ZOSTER-022 studies.

Additionally, the data collected can be used to assess if some physical, physiological and/or psychological characteristics reported by the subjects before the onset of HZ would be predictive of HZ. This will help understand the previously hypothesized predictive factors such as stress or functional status, and also to assess other potential risk factors such as frailty, fatigue or emotional and mental health.

2. BENEFIT: RISK ASSESSMENT

ZOSTER-064 study will use data collected as part of the *SF-36* and *EQ-5D* QoL questionnaires completed by subjects in ZOSTER-006 and ZOSTER-022 studies. There are no risks or benefits to subjects in this study because this is a retrospective observational study.

3. OBJECTIVES

3.1. Primary Objective

- To assess the baseline frailty of subjects enrolled in ZOSTER-006 and ZOSTER-022.

3.2. Secondary Objectives

- To present the distribution of *SF-36* and *EQ-5D* scores in subjects included in ZOSTER-006 and ZOSTER-022 at baseline by country to allow comparison with normative values for those questionnaires in the general population of the countries participating in the study.
- To assess vaccine efficacy against HZ by frailty status.
- To assess HZ burden of illness (BOI) by frailty status.
- To identify predictive factors for individuals developing HZ.
- To describe safety per frailty status.
- To assess humoral immunogenicity by frailty status.

3.3. Tertiary Objectives

- To describe CMI by frailty status of subjects enrolled in ZOSTER-006 only.

4. STUDY DESIGN OVERVIEW

Protocol waivers or exemptions are not allowed. Therefore, adherence to the study design requirements, including those specified in the outline of study procedures (Section 8), are essential and required for study conduct.

- Type of design: Observational, retrospective study.
- Study population: Adults aged ≥ 50 years of age who participated in either ZOSTER-006 or ZOSTER-022.
- Type of study: to be combined with other protocols for analysis: data to be analysed in this study have been collected in ZOSTER-006 (eTrack 110390) and ZOSTER-022 (eTrack 113077).
- Data collection: CRF/eCRF
- Duration of the study: The time between the first and the last information to be encoded will be approximately 8 months.

4.1. Discussion of study design

This is a retrospective, observational study, therefore no new subjects will be enrolled in this study and no new ICF will be required from study subjects (see Section 7.2). In ZOSTER-006 and ZOSTER-022, encoding of QoL questionnaires (*SF-36*, *EQ-5D*) was only performed for subjects who developed a suspected HZ episode during the study. This was done to assess the QoL of subjects who developed suspected cases of HZ between the vaccine group and the placebo group. The remaining study subjects who did not develop suspected cases of HZ completed the questionnaires; however, these questionnaires were never encoded or analysed as part of ZOSTER-006 and ZOSTER-022. The purpose of ZOSTER-064 is to allow for the encoding of the remaining questionnaires to assess the baseline frailty of all the subjects in ZOSTER-006 and ZOSTER-022.

5. HZ CASE DEFINITION

Classification as a HZ confirmed case was done during ZOSTER-006 and ZOSTER-022, after confirmation of all suspected HZ cases by either of the two following ways:

- Polymerase Chain Reaction (PCR):
Rash lesion samples were collected from subjects clinically diagnosed as having a suspected case of HZ. The samples were transferred to GSK Biologicals or a validated laboratory designated by GSK Biologicals using standardised and validated procedures for laboratory diagnosis of HZ by PCR. For more information, please refer to Appendix B of the ZOSTER-006 protocol.
- The HZ Ascertainment Committee:

All suspected HZ cases were referred to the HZ Adjudication Committee (HZAC). The HZAC classified all referred cases as either “HZ”, “not HZ”, or “not able to decide”. However, the HZAC classification was to serve as the final case definition only when the case could not be confirmed or excluded by PCR, e.g., when all samples from a given subject were inadequate (as when both VZV and β -actin PCR results were negative), or when no samples were available for a given subject. If the case could not be confirmed or excluded by PCR and the HZAC final outcome was ‘not able to decide’, the overall final outcome was “No possible classification”; for analysis the categories “not HZ” and “No possible classification” were considered as “not HZ”.

6. STUDY POPULATION

6.1. Number of subjects/ centres

Approximately 30,000 subjects enrolled in ZOSTER-006 and ZOSTER-022

There will be no new subjects enrolled in the ZOSTER-064 study. The protocol is developed to allow for the encoding into the eCRF of all QoL questionnaires of subjects enrolled in ZOSTER-006 and ZOSTER-022 and analysing frailty status.

6.2. Inclusion criteria for the study

Deviations from inclusion criteria are not allowed because they can potentially jeopardise the scientific integrity of the study. Therefore, adherence to the criteria as specified in the protocol is essential.

All subjects must satisfy ALL the following criteria at study entry:

- All subjects enrolled in ZOSTER-006 and ZOSTER-022 (See Section [7.2](#) and [8.3.1](#))

6.2.1. Inclusion criteria for the study data encoding

- All subjects enrolled in ZOSTER-006 and ZOSTER-022 (See Section [7.2](#) and [8.3.1](#))
- Subjects who died or were lost to follow-up during ZOSTER-006 and ZOSTER-022 will be considered for enrolment in ZOSTER-064 and their data/questionnaires up to that point will be used.

See Section [8.1](#) for site specific subject lists.

6.3. Exclusion criteria for the study

Deviations from exclusion criteria are not allowed because they can potentially jeopardise the scientific integrity of the study. Therefore, adherence to the criteria as specified in the protocol is essential.

The following criteria should be checked at the time of study entry. If the exclusion criterion applies, the subject must not be included in the study:

- Subjects who were excluded from all analyses from ZOSTER-006 and ZOSTER-022. This will include any subject eliminated following deviations from GCP compliance.

6.3.1. Exclusion criteria for data encoding

- Subjects who developed a suspected HZ case during ZOSTER-006 and ZOSTER-022 (since their QoL questionnaires were encoded in the eCRF for ZOSTER-006 and ZOSTER-022).

7. CONDUCT OF THE STUDY

7.1. Regulatory and ethical considerations

The study will be conducted in accordance with the ICH Guideline for Good Clinical Practice (GCP), all applicable subject privacy requirements and the guiding principles of the Declaration of Helsinki.

Conduct of the study includes, but is not limited to, the following:

- Institutional Review Board (IRB)/Independent Ethics Committee (IEC) review and favourable opinion/approval of study protocol and any subsequent amendments.
- Investigator reporting requirements as stated in the protocol.

GSK Biologicals will provide full details of the above procedures to the investigator, either verbally, in writing, or both.

7.2. Informed consent

ZOSTER-064 is a study related to ZOSTER-006 and ZOSTER-022 that allows for encoding and analysis of questionnaires already completed by the subjects who were part of those earlier studies. Not all of the previously completed questionnaires have been encoded and analysed yet. As such, ZOSTER-064 will provide an opportunity to assess the frailty index of all subjects enrolled in ZOSTER-006 and ZOSTER-022.

Every subject considered for inclusion in this study has previously signed an ICF from the investigational sites of ZOSTER-006 or ZOSTER-022. The ICF signed by the patients in ZOSTER-006 and ZOSTER-022 allows for the use of all collected information in new studies. In these ICFs, it was specified that:

“The coded information collected by the study doctor will be sent to GSK, who may:

- Keep it and analyse it by computer to find out what this study is telling us.
- Share it with agencies that approve new vaccines / products / medicines, or with groups that check that research is done properly.
- Write up the study results for medical journals (this will not include any information that directly identifies you).
- Share it with other companies or universities to better understand the disease / or develop this vaccine. If the information is sent to another country, GSK will apply the same level of protection to your information, to the extent permitted by local law.
- Use it to plan new studies, other types of research or other medical purposes.

Information regarding the study and coded results will be publicly available on the internet. Information from this study may also be combined with the data from other studies in future.”

Since consent has been obtained in the prior studies (ZOSTER-006 and ZOSTER-022), it is the Sponsor’s request to obtain a waiver of informed consent from subjects to be enrolled in ZOSTER-064.

8. DETAILED STUDY PROCEDURES

8.1. Subject identification

Subjects will be identified by the same subject identification number as in ZOSTER-006 and ZOSTER-022, but a prefix will be added to the original subject identification number. Prefix will be “6” for subjects enrolled in ZOSTER-006, and will be “2” for subjects enrolled in ZOSTER-022. This will prevent from the possibility of having two subjects enrolled in two different studies with the same identification number.

Sites will be provided with a list of subjects for whom questionnaires and data should be encoded. To help the investigator/delegate identify subjects for which data and QoL questionnaires are to be encoded, the list will include (but may not be limited to) the following information for each subject:

- Subject identification number in ZOSTER-006 or ZOSTER-022
- New subject identification number to be used in ZOSTER-064
- Site number
- Date of birth (year)
- Date of subject’s consent withdrawal, when applicable
- Occurrence of suspected HZ episode in ZOSTER-006 and ZOSTER-022

8.2. Outline of study procedures

Table 1 List of study procedures

Activity	Epoch-001
Check inclusion/exclusion criteria*	○
Encoding of subject's year of birth**	●
Encoding of QoL questionnaires**	●
Study conclusion (Investigator's signature)**	●

QoL: quality of life

● is used to indicate a study procedure that requires documentation in the individual eCRF.

○ is used to indicate a study procedure performed by GSK and not documented in the eCRF.

* To be performed by GSK.

** Procedure to be performed for subjects with no suspected HZ episode during ZOSTER-006 and ZOSTER-022.

Refer to Section 8.3 for details about the study procedures.

8.3. Detailed description of study procedures

8.3.1. Check inclusion and exclusion criteria

Check all applicable inclusion and exclusion criteria as described in Sections 6.2 and 6.3, respectively, before encoding of subject data.

Checking of the eligibility criteria will be performed centrally. Sites will receive a list of subjects for which data and QoL questionnaires should be encoded (see Section 8.1).

8.3.2. Encoding of data in the ZOSTER-064 eCRF

A new eCRF database (using the Inform system) will be created for ZOSTER-064.

8.3.2.1. Demographic characteristics

The list of subjects for which demographic characteristics need to be encoded in the ZOSTER-064 eCRF will be provided to the sites (see Section 8.1).

Demographic characteristics to be encoded in the ZOSTER-064 eCRF include:

- the subject identification number to be used in ZOSTER-064
- the site number,
- the date of birth (year).

These data will be provided in the list of subjects that will be sent to the sites.

To note: Additional subject's information related to (but not limited to) medical history, development of an immune-compromising condition or taking immune-suppressive treatments will be used to perform the analysis. These data **do not** need to be encoded on the ZOSTER-064 eCRF, but will be retrieved centrally from the ZOSTER-006 and ZOSTER-022 databases and linked to perform the required analyses.

8.3.3. Encoding of QoL questionnaires

The list of subjects for which QoL questionnaires (*SF-36* and *EQ-5D*) need to be encoded in the ZOSTER-064 eCRF will be provided to the sites (see Section 8.1).

Reminder: Eligible subject for this study, for which QoL questionnaires and the year of birth should be encoded, were those enrolled in ZOSTER-006 and ZOSTER-022. This includes any subjects that completed the study, data collected up to withdraw of consent for subjects who withdrew from the study, or data collected up to date of death for subjects who died (as documented in the database for ZOSTER-006 and ZOSTER-022), and whose questionnaires were not previously encoded into the eCRF during these studies (subjects who did not have suspected HZ).

8.3.4. Study conclusion

The investigator/delegate will:

- review all the data encoded in eCRF to ensure accuracy and completeness,
- sign the eCRF.

8.4. Biological sample handling and analysis

No samples will be collected as part of this study.

9. SAFETY

Not applicable.

10. DATA EVALUATION: CRITERIA FOR EVALUATION OF OBJECTIVES

10.1. Primary endpoint

- Baseline Frailty Status:
 - Frailty Status pre-vaccination dose 1 as defined by responses to components of the *SF-36* and *EQ-5D* questionnaire at vaccination day 0 and the subjects coded medical history.

10.2. Secondary endpoints

- *SF-36* and *EQ-5D* scale scores:
 - At months 0, 14, 26 and 38.
- Confirmed HZ cases:
 - Incidence of HZ cases during the ZOSTER-006 and ZOSTER-022 studies for subjects in the mTVC.

- HZ Burden of Illness
 - HZ Burden of Illness score for subjects in both the ZOSTER-006 and -022 studies as calculated from the ZBPI.
- Solicited local and general symptoms from ZOSTER-006 and ZOSTER-022:
 - Occurrence, intensity of each solicited local symptom within 7 days (Days 0-6) after each vaccination, in subjects included in the 7-day diary card subset;
 - Occurrence, intensity and relationship to vaccination of each solicited general symptom within 7 days (Days 0-6) after each vaccination, in subjects included in the 7-day diary card subset.
- Unsolicited adverse events (AEs) from ZOSTER-006 and ZOSTER-022:
 - Occurrence, intensity and relationship to vaccination of unsolicited AEs during 30 days (Days 0 - 29) after each vaccination, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification in all subjects.
- Serious Adverse Events (SAEs) from ZOSTER-006 and ZOSTER-022.
 - Occurrence and relationship to vaccination of all SAEs from Month 0 to Month 14 in all subjects;
 - Occurrence of SAEs related to study participation or to a concurrent GSK medication/vaccine during the entire study period in all subjects;
 - Occurrence of any fatal SAEs during the entire study period in all subjects.
- Occurrence of pre-defined AEs
 - Occurrence and relationship to vaccination of any pIMDs during the entire study period in all subjects.
- Humoral Immunogenicity of the study vaccine in subset of subjects from ZOSTER-006 and ZOSTER-022.
 - Anti-gE and anti-VZV Ab concentrations as determined by Enzyme-linked Immunosorbent Assay (ELISA), in a subset of subjects at Months 0, 3, 14, 26 and 38.

10.3. Tertiary endpoints

- Cell-mediated immunogenicity (CMI) of the study vaccine in subsets of subjects from ZOSTER-006 only.
 - CMI in terms of frequencies of antigen-specific CD4 T cells at Months 0, 3, 14, 26 and 38;
 - Frequencies of CD4 T cells with antigen-specific Interferon gamma (IFN- γ) and/or Interleukin-2 (IL-2) and/or Tumour Necrosis Factor alpha (TNF- α) and/or CD40 Ligand (CD40L) secretion/expression to glycoprotein E (gE) and VZV as determined by intracellular cytokine staining (ICS) in a subset of subjects at Months 0, 3, 14, 26 and 38.

10.4. Determination of sample size

Approximately 30,000 subjects were enrolled in ZOSTER-006 and ZOSTER-022. Out of these, approximately 1000 subjects will have developed suspected HZ cases over the course of the studies and their QoL questionnaires were encoded in the eCRF for ZOSTER-006 and ZOSTER-022, according to the protocols of those studies, respectively. Therefore approximately 29,000 subjects whose QoL questionnaires were completed and collected but not encoded in the earlier studies, will be encoded in the ZOSTER-064 study. Data encoded as part of the 064 study will be combined with data from the ZOSTER-006 and ZOSTER-022 studies to ensure that subjects data are available for analysis, as appropriate taking into account inclusion/exclusion criteria (see section 6) and cohorts for analysis (see section 10.5).

10.4.1. Number of subjects in the CMI subset

The CMI analyses was performed for ZOSTER-006 only in the Immunogenicity subset in three countries (Czech Republic, Japan and United States) at designated sites that had access to a PBMC processing facility within the acceptable time window from sample collection to PBMC processing. The CMI subset contained approximately 350 subjects. As a consequence, analysis of CMI by frailty status is expected to be limited.

10.4.2. Number of subjects in the Humoral subset

The analysis of humoral immunogenicity was performed in both the ZOSTER-006 and ZOSTER-022 studies. The Humoral subset contained approximately 2800 subjects in total between ZOSTER-006 and ZOSTER-022.

10.5. Cohorts for Analysis

10.5.1. Total Vaccinated cohort

The primary analysis of EQ-5D and SF-36 questionnaires will be performed on the TVC. The TVC will include all subjects from centres that participated in ZOSTER-064 and all subjects who had a HZ suspected event in either the ZOSTER-006 or ZOSTER-022 studies.

Subjects enrolled in ZOSTER-064 need to have been part of the TVC in ZOSTER-006 or ZOSTER-022. Refer to the glossary of terms for the definition of TVC.

The TVC for analysis of safety will include all subjects with at least one vaccine administration documented.

10.5.2. modified Total Vaccinated Cohort

The mTVC will include only subjects from centres that participate in ZOSTER-064 (i.e. these subjects that were included in the mTVC of ZOSTER-006 and ZOSTER-022), which will exclude subjects in the TVC who were not administered the second vaccination or who developed a confirmed case of HZ prior to 1 month after the second vaccination.

10.5.3. According to Protocol cohort for analysis of immunogenicity

The analysis of the immunogenicity data from the ZOSTER-064 (i.e. combined immunogenicity data from ZOSTER-006 and ZOSTER-022) will be performed on the ATP cohort for analysis of immunogenicity

In ZOSTER-006 and ZOSTER-022, the ATP cohort for analysis of immunogenicity included all evaluable subjects from the ATP cohort for analysis of safety (i.e., those meeting all eligibility criteria, complying with the procedures and intervals allowed for the analysis, with no elimination criteria during the study) for whom data concerning immunogenicity endpoint measures were available.

For the immunogenicity tables where different timepoints were presented, the concept of “**Adapted ATP cohort for immunogenicity**” was used to denote that for each timepoint, the corresponding ATP cohort for immunogenicity was used.

More specifically,

- The analyses on the timepoints Month 0 and Month 3 were based on the ATP cohort for immunogenicity Month 3;
- The analysis on the timepoint Month 14 was based on the ATP cohort for immunogenicity Month 14;
- The analysis on the timepoint Month 26 was based on the ATP cohort for immunogenicity Month 26;
- The analysis on the timepoint Month 38 was based on the ATP cohort for immunogenicity Month 38;

The goal was to include all evaluable subjects in the statistical analysis at a specific timepoint, i.e., by including all the subjects not impacted by the elimination code for a specific Adapted ATP cohort for immunogenicity. For the criterion impacted only a specified timepoint (specified blood sampling interval), the subject was excluded from the analysis at that timepoint. For the criteria impacting a specified timepoint and the subsequent ones (e.g., medication forbidden by the protocol), the subject was excluded from the analyses performed at that timepoint onwards. For the criteria impacting all timepoints (e.g., not received two doses), the subject was excluded from the analyses at all-timepoints.

For the analysis of humoral immunogenicity, ATP cohort was further defined as ATP cohort for immunogenicity – Humoral.

For CMI the analysis will be performed on all the samples available (TVC) due to low number of samples.

Compared to the criteria applicable for the ATP cohort for analysis of safety, additional criteria for the ATP cohort for immunogenicity were the following:

- Administration of any medication forbidden by the protocol
- Underlying medical condition forbidden by the protocol
- Concomitant infection related to the disease under study (VZV) which might have influenced immune response
- Concomitant infection not related to the disease under study (VZV) which might have influenced immune response
- Vaccination done but not compliant with Dose 1- Dose 2 vaccination schedules (dates of vaccination not corresponding to protocol intervals or unknown vaccination dates)
- Blood sample taken but not compliant with blood sampling schedules (dates of BS not corresponding to adapted protocol intervals or unknown BS/vaccination dates)
- Serological results not available for antigens POST vaccination (including lost samples, not done, unable to test, absence of parallelism)
- Subject did not belong to the specified Immunogenicity subset
- The subject did not receive two doses

10.6. Derived and transformed data

10.6.1. Handling of missing data

For a given subject and a given measurement, missing or non-evaluable measurements will not be imputed for the analysis. The missing endpoint and censoring are supposed to occur independently, and the pattern of the missingness being either Completely At Random (MCAR) or Missing At Random (MAR) only.

For the analysis of solicited symptoms, missing or non-evaluable measurements will not be replaced. Therefore, the analysis of the solicited symptoms based on the TVC will include only subjects/doses with documented safety data (i.e., symptom screen/sheet completed).

For the analysis of unsolicited AEs/SAEs/concomitant medication, all vaccinated subjects will be considered and subjects who did not report an event will be considered as subjects without an event.

For a given subject and a given immunogenicity measurement, missing or non-evaluable measurements will not be replaced. Therefore, an analysis will exclude subjects with missing or non-evaluable measurements.

10.6.2. Humoral and CMI immune response

The derivation of data transformed variables for humoral immunogenicity and CMI will be consistent with the derivation provided in the Zoster-006 and Zoster-022 protocols, and the details will be included in the statistical analysis plan.

10.7. Statistical methods

Age in years will be computed as the difference between the date of completion of the QoL questionnaire collected at Month 0 and the date of birth.

As this is an exploratory analysis, no adjustment will be done for multiple comparisons (i.e. a 2-sided significance level of 0.05 will be used).

Spearman correlations coefficients will be presented to display the relationships between pairs of variables. In addition, particularly for the QoL variables, the variance inflation factor and the condition indices for testing multicollinearity will be estimated.

A bootstrap analysis will be carried out to evaluate the robustness of the results with respect to the selection of variables in the final multivariate model.

All analyses will be carried out using SAS Version 9.1.3 or later.

GSK vaccines will be responsible for performing the statistical analysis.

10.7.1. Quality of Life Questionnaires

The *EQ-5D* and *SF-36* QoL questionnaires have been completed by subjects enrolled in ZOSTER-006 and ZOSTER-022. Questionnaires were completed by all subjects to assess the frailty of subjects enrolled in ZOSTER-006 and ZOSTER-022 and also the existence of predictive factors for the development of HZ. Both the *EQ-5D* and *SF-36* questionnaires are international standards and have been appropriately validated.

10.7.2. SF-36 questionnaire

The *SF-36* is a multi-purpose health survey with 36 questions underlying the construction of 8 scales [Ware, 2001]. All but one of the 36 items (self-reported health transition) are used to score the eight *SF-36* scales (see Table 2). Each item is used in scoring only one scale. Scale scores are to be constructed following the summated ratings and standardized *SF-36* scoring algorithms. See APPENDIX A for a sample of *SF-36* questionnaire.

Table 2 Construction of the eight scales generated from the SF-36

Scale	Items	Response Categories Per Item
Physical Functioning (PF)	3a, 3b, 3c, 3d, 3e, 3f, 3g, 3h, 3i, 3j	3
Role Physical (RP)	4a, 4b, 4c, 4d	5
Bodily Pain (BP)	7*, 8*	6, 5
General Health (GH)	1*, 11a, 11b*, 11c, 11d*	5
Vitality (VT)	9a*, 9e*, 9g, 9i	5
Social functioning (SF)	6*, 10	5
Role Emotional (RE)	5a, 5b, 5c	5
Mental Health (MH)	9b, 9c, 9d*, 9f, 9h*	5

* Item Reversed

10.7.3. EQ-5D questionnaire

The *EQ-5D* questionnaire is a generic measure of health status that provides a simple descriptive profile and a single index value [Kind, 1996]. The *EQ-5D* defines health in terms of mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The 5 items are combined to generate health profiles, i.e. a respondent who responds 1 (no problem/no symptom) to all 5 items has a profile “11111” and similarly a subject who responds with the highest level of difficulty or symptom to all items has a profile “33333”. These profiles are subsequently converted to a continuous single index utility score using a one to one matching, e.g. “11111”=1.00, “22222”=0.52 and “33333”= -0.59, using value sets (i.e. matching profiles to single index utility scores). As suggested by the developers, for international studies, the United Kingdom Time-Trade-Off (TTO) value set is to be used for the main analysis. Note: higher scores represent a better QoL. See [APPENDIX B](#) for a sample of *EQ-5D* questionnaire.

10.7.4. Definition of Frailty

Frailty status will be measured in relation to the accumulation of deficits using a frailty index (FI) adapted from the model proposed by Mitnitski et al. [Mitnitski, 2001]. The different aspects of frailty composing the FI will be assessed through the medical history and *SF-36* and *EQ-5D* questionnaires recorded pre-vaccination dose 1. The frailty index will be a score between 0 and 41 as detailed in [Table 3](#).

Table 3 Detail of frailty components

Item	Scoring method based on response to question	Max Contribution to Frailty Index
SF-36 Q1	Poor=1, Fair=0.5 Good=0, Very good=0 Excellent=0	1
SF-36 Q11A-11D	Q11A, Q11C Definitely true=1 Mostly true=0.5 Don't know=0 Mostly false=0 Definitely false=0	4

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Item	Scoring method based on response to question	Max Contribution to Frailty Index
	Q11B, Q11D Definitely true=0 Mostly true=0 Don't know=0 Mostly false=0.5 Definitely false=1	
SF-36 Q3I - Q3J	Limited a lot=1 Limited a little=0.5 Not limited at all=0	10
SF-36 Q9A - Q9I	Q9A, Q9D, Q9E, Q9H: All of the Time=0 Most of the time=0 Some of the time=0 A little of the time=0.5 None of the time=1 Q9B, Q9C, Q9F, Q9G, Q9I : All of the Time=1 Most of the time=0.5 Some of the time=0 A little of the time=0 None of the time=0	9
SF-36 Q2 Compared to one week before, how did the subject rate his / her health in general?	Much worse=1, Somewhat worse=0.5, Same=0 Somewhat better=0 Better=0	1
EQ-5D Mobility	No Problems=0 Some Problems=0.5 Confined to bed=1	1
EQ-5D Anxiety	No Anxiety=0 Moderate Anxiety=0.5 Extreme Anxiety=1	1
EQ-5D Self care	No Problems=0 Some Problems=0.5 Inability to wash or dress himself /herself=1	1
EQ-5D Usual activities	No Problems=0 Some Problems=0.5 Inability to perform usual activities=1	1
Medical history	Cancer	1
	Diabetes Mellitus	1
	High Blood Pressure	1
	Heart Attack	1
	Congestive Heart Failure	1
	Cerebrovascular Disease	1
	Arthritis	1
	Chronic Lung Disease	1
	Stomach or Intestinal Ulcers	1
	Migraine	1
	Cataract	1
	Glaucoma	1
Total		41

The medical history is divided into 12 categories; each category will contribute a score of 0 or 1 to the frailty index. The coded medical history database will be searched and subjects with the relevant preferred terms will be assigned to 1 or more of the above categories. A frailty index will be defined by combining all 41 items into a score from 0 to 1 whereby: frailty index = (accumulation of deficits) / (number of items).

Each subject will then be assigned to one of three categories, Non-Frail, Pre-Frail and Frail.

If the frailty index is less than or equal to 0.08 then the subject is classified as Non-Frail. If the score is greater than 0.08 but less than or equal to 0.25 then the subject is classified as pre-frail. If the score is greater than 0.25 then the subject is classified as Frail.

Further details of the calculation of the frailty index will be provided in the statistical analysis plan (SAP).

10.7.5. HZ burden-of-illness score

For each confirmed case of HZ in ZOSTER-006 and ZOSTER-022, responses to the “worst pain” question in the ZBPI were used to calculate a “HZ burden-of-illness” score, defined as the area under the curve (AUC) of HZ-associated pain plotted against time during the 182-day period after the onset of the case. Subjects who developed HZ presented “burden-of-illness” scores ranging from 0 up to, theoretically, 1820. A score of 0 is recorded for subjects in whom HZ did not develop during the study period.

10.7.6. Analysis of Frailty

10.7.6.1. Analysis of primary objective

The number and percentage of subjects in each of the frailty status categories (non-frail, pre-frail and frail) pre-vaccination dose 1 will be presented by vaccination group, overall by age and the following age strata: 50-59, 60-69, 70-79 and ≥ 80 YOA.

10.7.6.2. Analysis of secondary objectives

Descriptive statistics of the 8 derived scales of the *SF-36* and the *EQ-5D* Utility is presented at vaccination day 0 and post-vaccination months 14, 26 and 38.

The analyses will also be presented by country to allow comparison with normative values for those questionnaires in the general population of the countries participating in the study.

10.7.6.2.1. Vaccine efficacy against HZ by frailty status

The primary efficacy endpoint in ZOSTER-006 and ZOSTER-022, vaccine efficacy against HZ, will be summarised by baseline frailty status (non-frail, pre-frail, frail) for subjects in the modified Total Vaccinated cohort.

10.7.6.2.2. Vaccine efficacy against HZ BOI by frailty status

Vaccine efficacy against HZ BOI will be analysed by frailty status (non-frail, pre-frail, frail) for subjects in the modified Total Vaccinated cohort.

10.7.6.3. Predictive factors for individuals developing HZ

Only subjects in the placebo vaccination group will be included in the analysis of potential predictive factors. A Cox proportional hazards regression model allowing for time-dependent covariates will be fitted to identify which factors are predictive of developing HZ. The model will include time to HZ as the outcome variable and as potential predictors: demographic and clinical characteristics, *SF-36* variables and *EQ-5D* variables. Subjects who did not develop HZ will be censored at the time of their last study visit. The proportional hazards regression model will be used for both minimally adjusted analyses and multivariate analyses. All factors will initially be examined in an age- and sex-adjusted model with stratification for the clinical trial (i.e. ZOSTER-006 and ZOSTER-022). Factors will be included in the multivariate model if they are associated ($P < 0.05$ using a two-sided test) with HZ in the minimally adjusted model. The multivariate model will also include age and gender with stratification for the clinical trial (i.e. ZOSTER-006 and ZOSTER-022). A step-down (backward) variable selection procedure will be used to fit the final multivariate model. This model will be fitted using the PHREG procedure of the *SAS/STAT* package.

Spearman correlations coefficients will be presented to display the relationships between pairs of variables. In addition, particularly for the quality of life variables, the variance inflation factor and the condition indices for testing multicollinearity will be estimated.

In the analysis, the impact of excluding “suspected but not confirmed cases” of HZ will be explored. Three analyses will be performed whereby it will be assumed that “suspected but not confirmed cases” are (1) “Not in at risk group” (2) “In at risk group” and event=0, (3) “In at risk group” and event=1.

Due to the multiple measurements of the *EQ-5D* and *SF-36* over time, repartition in the HZ positive or HZ negative will be dynamic. Subjects who did not develop a confirmed HZ before one-timepoint (Day 0, Month 14, Month 26 and Month 38) will be considered HZ negative at that timepoint, and the characteristics and QoL scores reported for this subject at the previous timepoint will be considered as **not leading** to HZ.

Subjects who developed a confirmed HZ during the interval between two timepoints will be considered HZ+ at the later timepoint. Characteristics and QoL scores reported for this subject at the last timepoint before onset of HZ will be considered **leading** to HZ.

Example: A subject developed a confirmed HZ episode on Month 22:

- Subject’s characteristics and QoL scores reported at Day 0 will be considered as **not leading** to HZ.
- Subject’s characteristics and QoL scores reported at Month 14 will be considered as **leading** to HZ.

- Subject's characteristics and QoL scores reported at timepoints posterior to onset of HZ (Month 26 and Month 38) will be censored.

Further, details regarding the analysis will be provided in the statistical analysis plan.

10.7.6.4. Analysis of safety by frailty status

This analysis of the safety data from the ZOSTER-064 population will be based on the Total Vaccinated cohort for safety. Solicited, unsolicited and serious adverse events will be analysed by baseline frailty status.

Incidences of SAEs during the 30-day (Days 0 – 29) follow-up period after each vaccination, up to 8 months and during any time during the study classified according to the MedDRA System Organ Class and Preferred Terms will be tabulated by frailty status.

10.7.7. Analysis of immunogenicity

The analysis will be based on the immunogenicity data from the ZOSTER-064 population for subjects in the adapted ATP for analysis of humoral immunogenicity, and for subjects in the TVC for analysis of CMI, respectively (Section 10.5.3).

10.7.7.1. Humoral immune response

Humoral immune response will be assessed and analysed by frailty status in the Humoral Immunogenicity subset.

Descriptive statistics:

If the data allows the following parameters will be tabulated by vaccination group and frailty status at Month 0, Month 3, Month 14, Month 26 and Month 38:

- Geometric mean concentrations (GMCs) of anti-gE/anti-VZV Ab with 95% CIs;
- Humoral seropositivity rates with exact 95% CIs;
- Vaccine response rates with 95% CIs.

10.7.7.2. Cell-mediated immune response

CMI response will only be assessed and analysed in the CMI component of the Immunogenicity subset for subjects in the ZOSTER-006 study.

Descriptive statistics:

For CMI response; provided the data allows, the following parameters will be tabulated by vaccination group and frailty status at Months 0, 3, 14, 26 and 38:

- descriptive statistics of the frequency of CD4 T cell secreting at least two different cytokines (IFN- γ , IL-2, TNF- α , CD40L) to both VZV and gE antigens;

- descriptive statistics of the frequency of CD4 T cell secreting at least IFN- γ and another cytokine (IL-2, TNF- α , CD40L) to both VZV and gE antigens;
- descriptive statistics of the frequency of CD4 T cell secreting at least IL-2 and another cytokine (IFN- γ , TNF- α , CD40L) to both VZV and gE antigens;
- descriptive statistics of the frequency of CD4 T cell secreting at least TNF- α and another cytokine (IFN- γ , IL-2, CD40L) to both VZV and gE antigens;
- descriptive statistics of the frequency of CD4 T cell secreting at least CD40L and another cytokine (IFN- γ , IL-2, TNF- α) to both VZV and gE antigens;
- proportion of responders with exact 95% CI.

10.8. Interpretation of analyses

Comparative analyses will be descriptive with the aim to characterise the difference between groups in the endpoint related to the objective. These descriptive analyses should be interpreted with caution.

10.9. Conduct of analyses

Any deviation(s) or change(s) from the original statistical plan outlined in this protocol will be described and justified in the final study report.

10.9.1. Sequence of analyses

There will be one analysis (final analysis) after completion of the data encoding.

10.9.2. Statistical considerations for interim analyses

All analyses will be conducted on final data and therefore no statistical adjustment for interim analyses is required.

11. ADMINISTRATIVE MATTERS

To comply with ICH GCP or other applicable guidelines, administrative obligations relating to data collection, monitoring, archiving data, audits, confidentiality, ownership and publications must be met.

11.1. Electronic Case Report Form instructions

A validated GSK defined electronic data collection tool will be used as the method for data collection.

In all cases, subject initials will not be collected nor transmitted to GSK. Subject data necessary for analysis and reporting will be entered/transmitted into a validated database or data system. Clinical data management will be performed in accordance with applicable GSK standards and data cleaning procedures.

While completed eCRFs are reviewed by a GSK Biologicals' Site Monitor, omissions or inconsistencies detected by subsequent eCRF (specifically the QoL questionnaires) review may necessitate clarification or correction of omissions or inconsistencies with documentation and approval by the investigator or appropriately qualified designee. In all cases, the investigator remains accountable for the study data.

Once the database is archived and the clinical study report is complete and approved by all parties, each participating investigator will be provided with a CD-ROM of the final version of the data generated at his/her investigational site.

11.2. Study monitoring by GSK Biologicals

GSK will monitor the study to verify that, amongst others, the:

- Data are authentic, accurate, and complete.
- Safety and rights of subjects are being protected.
- Study is conducted in accordance with the currently approved protocol, any other study agreements, GCP and all applicable regulatory requirements.

The investigator and the head of the medical institution (where applicable) agrees to allow the monitor direct access to all relevant documents.

The investigator must ensure provision of reasonable time, space and qualified personnel for monitoring visits.

Direct access to all study-site related and source data (QoL questionnaires) is mandatory for the purpose of monitoring review. The monitor will perform eCRF review and a Source Document Verification (SDV). By SDV we understand verifying eCRF entries by comparing them with the source data that will be made available by the investigator for this purpose.

The Source Documentation Agreement Form describes the source data for the different data in the eCRF. This document should be completed and signed by the site monitor and investigator and should be filed in the monitor's and investigator's study file. Any data item for which the eCRF will serve as the source must be identified, agreed and documented in the source documentation agreement form.

For eCRF, the monitor will mark completed and approved screens at each visit.

Upon completion or premature discontinuation of the study, the monitor will conduct site closure activities with the investigator or site staff, as appropriate, in accordance with applicable regulations, GCP, and GSK procedures.

11.3. Record retention

Following closure of the study, the investigator must maintain all site study records (except for those required by local regulations to be maintained elsewhere) in a safe and secure location. The records must be easily accessible, when needed (e.g., audit or inspection), and must be available for review in conjunction with assessment of the facility, supporting systems, and staff. Where permitted by applicable laws/regulations or institutional policy, some or all of these records can be maintained in a validated format other than hard copy (e.g., microfiche, scanned, electronic); however, caution needs to be exercised before such action is taken. The investigator must ensure that all reproductions are legible and are a true and accurate copy of the original and meet accessibility and retrieval standards, including re-generating a hard copy, if required. Furthermore, the investigator must ensure that an acceptable back-up of the reproductions exists and that there is an acceptable quality control procedure in place for making these reproductions.

GSK will inform the investigator/institution of the time period for retaining these records to comply with all applicable regulatory requirements. However, the investigator/institution should seek the written approval of the sponsor before proceeding with the disposal of these records. The minimum retention time will meet the strictest standard applicable to a particular site, as dictated by ICH GCP or other applicable guidelines, any institutional requirements or applicable laws or regulations, or GSK standards/procedures. The source documents (QoL questionnaires) completed during ZOSTER-006 and ZOSTER-022 will be retained according to what was agreed for these studies.

The investigator/institution must notify GSK of any changes in the archival arrangements, including, but not limited to, archival at an off-site facility and transfer of ownership of the records in the event the investigator leaves the site.

11.4. Quality assurance

To ensure compliance with GCP or other applicable guidelines and all applicable regulatory requirements, GSK may conduct a quality assurance audit. Regulatory agencies may also conduct a regulatory inspection of this study. Such audits/inspections can occur at any time during or after completion of the study. If an audit or inspection occurs, the investigator and institution agree to allow the auditor/inspector direct access to all relevant documents and to allocate his/her time and the time of his/her staff to the auditor/inspector to discuss findings and any relevant issues.

11.5. Posting of information on publicly available registers and publication policy

Results of research studies, utilizing data or biological samples from previous GSK clinical studies that do not evaluate GSK (or other) vaccines/products are progressed for publication in the scientific literature when the results provide important scientific or medical knowledge.

11.6. Provision of study results to investigators

Where required by applicable regulatory requirements, an investigator signatory will be identified for the approval of the study report. The investigator will be provided reasonable access to statistical tables, figures, and relevant reports and will have the opportunity to review the complete study results at a GSK Biologicals site or other mutually-agreed location.

GSK Biologicals will also provide the investigator with the full summary of the study results. The investigator is encouraged to share the summary results with the study subjects, as appropriate.

12. COUNTRY SPECIFIC REQUIREMENTS

12.1. Requirements for Japan

12.1.1. Regulatory and Ethical Considerations

The study will be conducted in accordance with “the Ministerial Ordinance on the Standards for the Conduct of Clinical Trials of Medicinal Products (Ministry of Health and Welfare [MHW] No.28 dated 27th March, 1997)” and Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices.

The statement “I acknowledge that I am responsible for the overall study conduct.” on the Investigator Protocol Agreement Page means the investigator’s responsibility as defined by Japanese GCP.

Study Monitoring

Direct access to essential documents by monitors, the scope of those documents, and collection of information on safety according to the Japanese local regulation for the post-marketing clinical study will be specified separately in the written procedures for monitoring prepared for this study.

12.1.2. Study period

Study period is included in the Japanese specific exhibit document.

12.1.3. Study administrative structure

Sponsor information and List of Medical Institutions and Investigators are included in the Japanese specific exhibit document.

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APPENDIX C AMENDMENTS AND ADMINISTRATIVE CHANGES TO THE PROTOCOL

GlaxoSmithKline Biologicals SA Vaccines R &D Protocol Administrative Change 1	
eTrack study number and Abbreviated Title	204878 (ZOSTER-064)
IND number	BB-IND-13857
Administrative change number:	Administrative change 1
Administrative change date:	27 March 2018
Co-ordinating author:	PPD, Scientific Writer
Rationale/background for changes: • Trademark table updated to include <i>Shingrix</i> • Updated background text to include clinical indication • Updated study personnel • Additional spelling and grammar changes were made throughout for clarification. • The Sample <i>EQ-5D</i> questionnaire in Appendix B of the protocol was missing the Visual Analogue Scale (VAS). Images of pages from a sample <i>EQ-5D</i> questionnaire, including the VAS, are now provided to replace the <i>EQ-5D</i> questionnaire text, to better represent the appearance of the <i>EQ-5D</i> questionnaire used in the study. • To complement the images of an <i>EQ-5D</i> sample questionnaire in APPENDIX B, images of pages from a sample <i>SF-36</i> questionnaire are now provided to replace the <i>SF-36</i> questionnaire text in APPENDIX A, to better represent the appearance of the <i>SF-36</i> questionnaire used in this study.	

Amended text has been included in ***bold italics*** and deleted text in ~~strikethrough~~ in the following sections:

Synopsis

Secondary Endpoints

- Solicited local and general symptoms from ZOSTER-006 and ***ZOSTER-022***:

Tertiary Endpoints

- Frequencies of CD4 T cells with antigen-specific Interferon gamma (*IFN- γ*) and/or Interleukin-2 (IL-2) and/or Tumour Necrosis Factor alpha (*TNF- α*) and/or CD40 Ligand (CD40L) secretion/expression to glycoprotein E (gE) and VZV as determined by intracellular cytokine staining (ICS) in a subset of subjects at Months 0, 3, 14, 26 and 38.

Trademark Section

Trademarks owned by the GlaxoSmithKline group of companies	Generic description
<i>Shingrix</i>	<i>Herpes Zoster vaccine non-live recombinant AS01_a adjuvanted</i>

An indication in adults ≥ 50 YOA was filed for registration. HZ/su (trade name Shingrix) was first approved in the United States and Canada in October 2017.

Secondary Endpoint (body of text)

- Solicited local and general symptoms from ZOSTER-006 and **ZOSTER-022**:

Tertiary Endpoints (body of text)

- Frequencies of CD4 T cells with antigen-specific Interferon gamma (*IFN- γ*) and/or Interleukin-2 (IL-2) and/or Tumour Necrosis Factor alpha (*TNF- α*) and/or CD40 Ligand (CD40L) secretion/expression to glycoprotein E (gE) and VZV as determined by intracellular cytokine staining (ICS) in a subset of subjects at Months 0, 3, 14, 26 and 38.

GlaxoSmithKline Biologicals SA	
Vaccines R &D	
Protocol Amendment 1	
eTrack study number and Abbreviated Title	204878 (ZOSTER-064)
IND number	BB-IND-13857
Amendment number:	Amendment 1
Amendment date:	17 October 2018
Co-ordinating author:	PPD [REDACTED], Lead Scientific Writer
Rationale/background for changes: • This protocol is amended to include the specific requirements of the Japanese Ministry of Health and Welfare, Labour Ministerial Ordinance on the Standards for Conduct of Clinical Trials of Medicinal Products, dated 27 March 1997. (country specific). • The list of medical conditions used to build the Frailty Index, which is based on the comorbidities terminology of Zoster 063 study, has been clarified. • Updates to the definition of Cohorts for Analysis. • Additional typographical changes were made throughout for clarification.	

Amended text has been included in ***bold italics*** and deleted text in ~~strikethrough~~ in the following sections:

Title Page	
Co-ordinating author(s)	• PPD [REDACTED], Lead Scientific Writer • PPD [REDACTED] Lead Scientific Writer
Contributing authors	• PPD [REDACTED] Clinical Research and Development Lead • PPD [REDACTED] Clinical Research and Development Lead • PPD [REDACTED], Clinical Research and Development Lead • PPD [REDACTED], Study Delivery Lead • PPD [REDACTED] Study Delivery Lead • PPD [REDACTED], Study Delivery Lead • PPD [REDACTED], Lead Statistician

- PPD [REDACTED], Study Delivery Lead
- PPD [REDACTED] Lead Statistician
- PPD [REDACTED], Oversight Data Management
- PPD [REDACTED], Director Value Evidence
- PPD [REDACTED], Health Economics Biostatistician
- PPD [REDACTED], Global Regulatory Affairs
- PPD [REDACTED], Global Regulatory Affairs
- PPD [REDACTED] Clinical and Epidemiology
Project Lead (CEPL) for Zoster, Belgian US RDC

GLOSSARY OF TERMS

modified Total Vaccinated Cohort (mTVC)

~~In the~~ *The mTVC will include only subjects from centres that participate in ZOSTER-064-006 and ZOSTER-022 studies, the mTVC was the primary population for efficacy analysis, which excluded* *will exclude* subjects in the TVC for efficacy analysis who were not administered with the second vaccination or who developed a confirmed case of HZ prior to 1 month after the second vaccination (*i.e. these subjects that were included in the mTVC of ZOSTER-006 and ZOSTER-022.*

Total Vaccinated cohort (TVC)

~~In the ZOSTER-006 and ZOSTER-022 studies, the TVC included all subjects who received at least one dose of study product (vaccine or placebo) and were not withdrawn due to GCP issues.~~ *The TVC will include all subjects from centres that participate in ZOSTER-064 and all subjects who had a HZ suspected case in either the ZOSTER-006 or ZOSTER-022 studies. Subjects enrolled in ZOSTER-064 need to have been part of the TVC in ZOSTER-006 or ZOSTER-022.*

1.1.2 ZOSTER-006 and ZOSTER-022

An indication in adults ≥ 50 YOA was filed for registration. HZ/su (trade name *Shingrix*) was first approved in **Canada and** the United States ~~and Canada~~ in October 2017.

8.3.2 Encoding of data in the Zoster-064 eCRF

A new eCRF database ~~study~~ (using the Inform system) will be created for ZOSTER-064.

10.5 Cohorts for Analysis

10.5.1 Total Vaccinated cohort - ZOSTER-006 and ZOSTER-022

The primary analysis of *EQ-5D* and *SF-36* questionnaires will be performed on the TVC. The TVC will include all subjects ~~analysed~~ *from centres that participated* in ZOSTER-064 *and all subjects who had a HZ suspected event in either the ZOSTER-006 or ZOSTER-022 studies.*

10.5.2 ~~Modified~~ Total Vaccinated Cohort

The mTVC will ~~be the population~~ *include only subjects* from *centres that participate in* ZOSTER-064 (i.e. these subjects that were included in the mTVC of ZOSTER-006 and ZOSTER-022), which will exclude subjects in the TVC who were not administered the second vaccination or who developed a confirmed case of HZ prior to 1 month after the second vaccination.

10.7.4 Definition of Frailty

Table 3 Detail of frailty components

Item	Scoring method based on response to question	Max Contribution to Frailty Index
Medical history	Cancer	1
	Diabetes <i>Mellitus</i>	1
	High Blood Pressure	1
	Myocardial Infarction <i>Heart Attack</i>	1
	CHF	1
	Cerebrovascular <i>Disease</i>	1
	Arthritis	1
	<i>Chronic</i> Lung Disease	1
	<i>Stomach or</i> Intestinal disorders <i>Ulcers</i>	1
	Migraine	1
	Cataract	1
	Glaucoma	1
Total		41

If the frailty index is *less than or equal to* 0.08 then the subject is classified as Non-Frail. If the score is greater than 0.08 but less than **or equal to** 0.25 then the subject is classified as pre-frail. If the score is greater than ~~or equal to~~ 0.25 then the subject is classified as Frail.

10.7.7.2 Cell Mediated Response

~~If data allows,~~ CMI response will only be assessed and analysed in the CMI component of the Immunogenicity subset for subjects in the ZOSTER-006 study.

12. COUNTRY SPECIFIC REQUIREMENTS

12.1 Requirements for Japan

12.1.1 Regulatory and Ethical Considerations

The study will be conducted in accordance with “the Ministerial Ordinance on the Standards for the Conduct of Clinical Trials of Medicinal Products (Ministry of Health and Welfare [MHW] No.28 dated 27th March 1997)” and, Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices.

The statement “I acknowledge that I am responsible for the overall study conduct.” on the Investigator Protocol Agreement Page means the investigator’s responsibility as defined by Japanese GCP.

Study Monitoring

Direct access to essential documents by monitors, the scope of those documents, and collection of information on safety according to the Japanese local regulation for the post-marketing clinical study will be specified separately in the written procedures for monitoring prepared for this study.

12.1.2 Study period

Study period is included in the Exhibit.

12.1.3 Study administrative structure

Sponsor information and List of Medical Institutions and Investigators are included in the Exhibit.

GlaxoSmithKline Biologicals SA Vaccines R &D Protocol Administrative Change 2	
eTrack study number and Abbreviated Title	204878 (ZOSTER-064)
IND number	BB-IND-13857
Administrative change number:	Administrative change 2
Administrative change date:	13 November 2018
Co-ordinating author:	PPD, Lead Scientific Writer
Rationale/background for changes: • Typographical errors corrected	

Amended text has been included in ***bold italics*** and deleted text in ~~strikethrough~~ in the following sections:

Synopsis

Endpoints

Secondary

- *SF-36* and *EQ-5D* scale scores:
 - At months 0, 14, 26 and 38.
- Confirmed HZ cases:
 - Incidence of HZ cases during ZOSTER-006 and ZOSTER-022 ***for subjects in the modified Total Vaccinated Cohort (mTVC).***
- Humoral Immunogenicity of the study vaccine in subset of subjects from ZOSTER-006 and ZOSTER-022.
 - Anti-gE ~~Ab~~ and ***anti-VZV Ab*** concentrations as determined by Enzyme-linked Immunosorbent Assay (ELISA), in a subset of subjects at Months 0, 3, 14, 26 and 38.

Section 4: Study Design Overview

- Type of study: *to be combined with other protocols for analysis* ~~to be combined with other protocols for analysis to be combined with other protocols for analysis:~~ data to be analysed in this study have been collected in ZOSTER-006 (eTrack 110390) and ZOSTER-022 (eTrack 113077).
- Data collection: *CRF/eCRF* ~~CRF/eCRF CRF/eCRF CRF/eCRF~~

Section 8.3.1: Check inclusion and exclusion criteria

- Check all applicable inclusion and exclusion criteria as described in Sections ~~0~~ 6.2 and 6.3, respectively, before encoding of subject data.
- Checking of the eligibility criteria will be performed centrally. Sites will receive a list of subjects for which data and QoL questionnaires should be encoded (see Section 8.1).

Section 10.5.2 *modified* Total Vaccinated Cohort

GlaxoSmithKline Biologicals SA Vaccines R & D Protocol Administrative Change 3	
eTrack study number and Abbreviated Title	204878 (ZOSTER-064)
IND number	BB-IND-13857
Administrative change number:	Administrative Change 3
Administrative change date:	11 February 2019
Co-ordinating author:	PPD [REDACTED], Scientific Writer, XPE Pharma & Science for GSK Biologicals
Rationale/background for changes: The Japan Vaccine Company will no longer be in operation as of 01 April 2019. Therefore, the reference to “Japan Vaccine Co., Ltd.” has been changed to “GSK Japan”.	

Amended text has been included in ***bold italics*** and deleted text in ~~strikethrough~~ in the following sections:

Added to authors:

- PPD [REDACTED], Scientific Writer, XPE Pharma & Science for GSK Biologicals
- PPD [REDACTED], Global Regulatory Affairs

On page 2 changed copyright date: © ~~2018~~***2019*** GSK group of companies or its licensor.

On page 7 Signature page for Japan representative: ***GSK Japan*** ~~Japan Vaccine Co~~
representative name, function and title

Section 8.1 Subject Identification: Date of subject's consent

16.1.2. Sample case report form (unique pages only)

Annotated Study Book for Study Design: ZOSTER-064 (204878)

Study Design Version: 0.0

Sponsor: GlaxoSmithKline

Protocol: ZOSTER-064 (204878)

Generic Drug Name: NA

Observational study to assess frailty of subjects during ZOSTER-006 and ZOSTER-022 and HZ efficacy, immunogenicity and safety of HZ/su by frailty status.

Generated by Central Designer TM

October 31, 2018 3:59PM

ZOSTER-064 (204878): SCREENING (Screening) [frmSCREENING]	
SCREENING [sctSCR]	
1.	Initials: [hidden] [Initials] [txtScrSINIT: Not submitted - for internal use] A3★
2.*	Please tick box to confirm CRF creation: [itmCRF_FLG: Not submitted - for internal use] ☐
Key: [*] = Item is required [★] = ASCII Only Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

ZOSTER-064 (204878): ENROLLMENT (Enrollment) [frmENROLLMENT]		
ENROLLMENT [sctENROLLMENT]		
1.*	Type of data	[itmSUB_TYPE : Not submitted - for internal use] ☐ [itmSUB_NUM : Not submitted - for internal use] Subject Number N10
2.	Subject Number: [hidden] [Subj Nr]	[itmPID : Not submitted - for internal use] N9
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

ZOSTER-064 (204878): DEMOGRAPHY (Demography) [frmDEMOGRAPHY]	
PREVIOUS STUDY [sctPREVIOUSSTUDY]	
1.* Previous study number: [Previous Study Nr]	[DMPRVS: PREVINFO.PR_ST_ID] ☐ 110390 (Zoster-006) ☐ 113077 (Zoster-022)
2.* Previous Subject number: [Previous Subject Nr]	[DMPRPID: PREVINFO.PR_PID] N9
DEMOGRAPHY [sctDEMOGRAPHY]	
3.* Date of birth: [DOB]	[itmDOB_RAW: DM.BRTHDAT] ☐ Req ☐ (1900-1967)
4. Weight for Safety DB (Do not delete) [hidden]	[itmWEIGHT_HID: Not submitted - for internal use] XXXX.
PATIENT IDENTIFICATION [sctPATIENTIDENTIFICATION]	
Only to be used during the study conduct in case the existing subject number needs to be changed	
5.* Please enter new subject number [Changed subject number]	[itmNEW_PID: Not submitted - for internal use] N10
6. Subject Number: [hidden] [Subj Nr]	[itmPID: Not submitted - for internal use] N9
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.	

ZOSTER-064 (204878): EQ-5D / SF-36 FLAG (eq-5d / sf-36 flag) [frmEQ5DSF36FLAG]		
EQ-5D FLAG [sctEQ5DFLAG]		
1.*	Has the EQ-5D questionnaire been filled in by the subject at this visit? [Has the EQ-5D questionnaire been filled in by the subject at this visit?]	[QSEQYN : QSFLAG.EQ_FLG] ☐ No ☐ Yes -> Please complete the corresponding form
SF-36 FLAG [sctSF36FLAG]		
2.*	Has SF-36 questionnaire been filled in by the subject at this visit? [Has SF-36 questionnaire been filled in by the subject at this visit?]	[QSSFYN : QSFLAG.SF_FLG] ☐ No ☐ Yes -> Please complete the corresponding form
Key: [*] = Item is required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

ZOSTER-064 (204878): EQ-5D QUESTIONNAIRE (eq-5d questionnaire) [frmEQ5DQUESTIONNAIRE]**HEALTH (EQ-5D) QUESTIONNAIRE [sctHEALTHEQ5D]**

By placing a checkmark in one box in each group below, please indicate which statements best describe the subject's health state.

1.*	Date when the questionnaire was filled in: [Date when the questionnaire was filled in]	[EQ_DT: HEALTH.EQ_DAT] ☐ Req ☐ / ☐ Req ☐ / ☐ Req ☐ (2010-2015)
2.*	Mobility [Mobility]	[MOBILITY: HEALTH.MOBILITY] ☐ The subject had no problems in walking about ☐ The subject had some problems in walking about ☐ The subject was confined to bed
3.*	Self-Care [Self-Care]	[CARE: HEALTH.CARE] ☐ The subject had no problems with self-care ☐ The subject had some problems washing or dressing himself/herself ☐ The subject was unable to wash or dress himself/herself
4.*	Usual Activities (e.g. work, study, housework, family or leisure activities) [Usual Activities (e.g. work, study, housework, family or leisure activities)]	[USUAL_ACT: HEALTH.USUAL_AC] ☐ The subject had no problems with performing his/her usual activities ☐ The subject had some problems with performing his/her usual activities ☐ The subject was unable to perform his/her usual activities
5.*	Pain/Discomfort [Pain/Discomfort]	[PAIN_DIS: HEALTH.PAIN_DIS] ☐ The subject had no pain or discomfort ☐ The subject had moderate pain or discomfort ☐ The subject had extreme pain or discomfort
6.*	Anxiety/Depression [Anxiety/Depression]	[ANXIETY_DEP: HEALTH.ANXIETY] ☐ The subject was not anxious or depressed ☐ The subject was moderately anxious or depressed ☐ The subject was extremely anxious or depressed
7.*	VAS score [VAS score]	[VAS_SCORE: HEALTH.SCORE] N3

Key: [*] = Item is required

Note: Source verification critical settings made in InForm will override any settings made in Central Designer.

ZOSTER-064 (204878): SF-36 QUESTIONNAIRE (sf-36 questionnaire) [frmSF36QUESTIONNAIRE]**QUESTIONS 1 & 2 [sctHEALTHQ1]**

This survey asked for the subject's views about his / her health. This information will help keep track of how the subject felt and how well the subject was able to do his / her usual activities.

1.*	Date when the questionnaire was filled in: [Date when the questionnaire was filled in]	[SF_DT: HW_SF36.SF_DAT] ☐ Req ☐ / ☐ Req ☐ / ☐ Req ☐ (2010-2015)
2.*	1. In general, what did the subject say his / her health was? [In general, what did the subject say his / her health was?]	[HEALTH01: HW_SF36.HW1_Q1] ☐ Excellent ☐ Very good ☐ Good ☐ Fair ☐ Poor
3.*	2. Compared to one week before, how did the subject rate his /her health in general? [Compared to one week before, how did the subject rate his /her health in general?]	[HEALTH02: HW_SF36.HW2_Q1] ☐ Much better now than one week ago ☐ Somewhat better now than one week ago ☐ About the same as one week ago ☐ Somewhat worse now than one week ago ☐ Much worse now than one week ago

QUESTIONS 3 [sctHEALTHQ3]

3.The following questions are about activities the subject might have done during a typical day.
Did the subject's health now limit the subject in these activities? If so, how much?

4.*	3a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports [Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports]	[HEALTH03: HW_SF36.HW3_QA] ☐ Yes, limited a lot ☐ Yes, limited a little ☐ No, not limited at all
5.*	3b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf [Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf]	[HEALTH04: HW_SF36.HW3_QB] ☐ Yes, limited a lot ☐ Yes, limited a little ☐ No, not limited at all
6.*	3c. Lifting or carrying groceries [Lifting or carrying groceries]	[HEALTH05: HW_SF36.HW3_QC] ☐ Yes, limited a lot ☐ Yes, limited a little ☐ No, not limited at all
7.*	3d. Climbing several flights of stairs [Climbing several flights of stairs]	[HEALTH06: HW_SF36.HW3_QD] ☐ Yes, limited a lot ☐ Yes, limited a little ☐ No, not limited at all
8.*	3e. Climbing one flight of stairs [Climbing one flight of stairs]	[HEALTH07: HW_SF36.HW3_QE] ☐ Yes, limited a lot ☐ Yes, limited a little ☐ No, not limited at all
9.*	3f. Bending, kneeling, or stooping [Bending, kneeling, or stooping]	[HEALTH08: HW_SF36.HW3_QF] ☐ Yes, limited a lot ☐ Yes, limited a little ☐ No, not limited at all
10.*	3g. Walking more than a mile [Walking more than a mile]	[HEALTH09: HW_SF36.HW3_QG] ☐ Yes, limited a lot ☐ Yes, limited a little ☐ No, not limited at all
11.*	3h. Walking several hundred yards [Walking several hundred yards]	[HEALTH10: HW_SF36.HW3_QH] ☐ Yes, limited a lot ☐ Yes, limited a little ☐ No, not limited at all
12.*	3i. Walking one hundred yards [Walking one hundred yards]	[HEALTH11: HW_SF36.HW3_QI] ☐ Yes, limited a lot ☐ Yes, limited a little ☐ No, not limited at all

13.*	3j. Bathing or dressing himself / herself [Bathing or dressing himself / herself]	[HEALTH12 : HW_SF36.HW3_QJ] ☐ Yes, limited a lot ☐ Yes, limited a little ☐ No, not limited at all
QUESTIONS 4 [sctHEALTHQ4]		
4. During the past week, how much of the time did the subject have any of the following problems with the subject's work or other regular daily activities as a result of the subject's physical health?		
14.*	4a. Cut down on the amount of time the subject spent on work or other activities [Cut down on the amount of time the subject spent on work or other activities]	[HEALTH13 : HW_SF36.HW4_QA] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
15.*	4b. Accomplished less than the subject would like [Accomplished less than the subject would like]	[HEALTH14 : HW_SF36.HW4_QB] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
16.*	4c. Were limited in the kind of work or other activities [Were limited in the kind of work or other activities]	[HEALTH15 : HW_SF36.HW4_QC] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
17.*	4d. Had difficulty performing the work or other activities (for example, it took extra effort) [Had difficulty performing the work or other activities (for example, it took extra effort)]	[HEALTH16 : HW_SF36.HW4_QD] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
QUESTIONS 5 [sctHEALTHQ5]		
5. During the past week, how much of the time did the subject have any of the following problems with the subject's work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?		
18.*	5a. Cut down on the amount of time the subject spent on work or other activities [Cut down on the amount of time the subject spent on work or other activities]	[HEALTH17 : HW_SF36.HW5_QA] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
19.*	5b. Accomplished less than the subject would like [Accomplished less than the subject would like]	[HEALTH18 : HW_SF36.HW5_QB] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
20.*	5c. Did work or other activities less carefully than usual [Did work or other activities less carefully than usual]	[HEALTH19 : HW_SF36.HW5_QC] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
QUESTIONS 6 / 7 / 8 [sctHEALTHQ6]		
21.*	6. During the past week, to what extent did the subject's physical health or emotional problems interfere with the subject's normal social activities with family, friends, neighbors, or groups? [During the past week, to what extent did the subject's physical health or emotional problems interfere with the subject's normal social activities with family, friends, neighbors, or groups?]	[HEALTH20 : HW_SF36.HW6_Q1] ☐ Not at all ☐ Slightly ☐ Moderately ☐ Quite a bit ☐ Extremely

22.*	7. How much bodily pain did the subject have during the past week? [How much bodily pain did the subject have during the past week?]	[HEALTH21 : HW_SF36.HW7_Q1] ☐ None ☐ Very mild ☐ Mild ☐ Moderate ☐ Severe ☐ Very severe
23.*	8. During the past week, how much did pain interfere with the subject's normal work (including both work outside the home and housework)? [During the past week, how much did pain interfere with the subject's normal work (including both work outside the home and housework)?]	[HEALTH22 : HW_SF36.HW8_Q1] ☐ Not at all ☐ A little bit ☐ Moderately ☐ Quite a bit ☐ Extremely
QUESTIONS 9 / 10 [setHEALTHQ9]		
9. These questions are about how the subject felt and how things had been with the subject during the past week. For each question, please give the one answer that comes closest to the way the subject had been feeling. How much of the time during the past week...		
24.*	9a. Did the subject feel full of life? [Did the subject feel full of life?]	[HEALTH23 : HW_SF36.HW9_QA] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
25.*	9b. Had the subject been very nervous? [Had the subject been very nervous?]	[HEALTH24 : HW_SF36.HW9_QB] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
26.*	9c. Had the subject felt so down in the dumps that nothing could cheer the subject up? [Had the subject felt so down in the dumps that nothing could cheer the subject up?]	[HEALTH25 : HW_SF36.HW9_QC] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
27.*	9d. Had the subject felt calm and peaceful? [Had the subject felt calm and peaceful?]	[HEALTH26 : HW_SF36.HW9_QD] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
28.*	9e. Did the subject have a lot of energy? [Did the subject have a lot of energy?]	[HEALTH27 : HW_SF36.HW9_QE] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
29.*	9f. Had the subject felt downhearted and depressed? [Had the subject felt downhearted and depressed?]	[HEALTH28 : HW_SF36.HW9_QF] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
30.*	9g. Did the subject feel worn out? [Did the subject feel worn out?]	[HEALTH29 : HW_SF36.HW9_QG] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
31.*	9h. Had the subject been happy? [Had the subject been happy?]	[HEALTH30 : HW_SF36.HW9_QH] ☐ All of the time

		☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
32.*	9i. Did the subject feel tired? [Did the subject feel tired?]	[HEALTH31 : HW_SF36.HW9_QI] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
33.*	10. During the past week, how much of the time had the subject's physical health or emotional problems interfered with the subject's social activities (like visiting with friends, relatives, etc.)? [During the past week, how much of the time had the subject's physical health or emotional problems interfered with the subject's social activities (like visiting with friends, relatives, etc.)?]	[HEALTH32 : HW_SF36.HW10_Q1] ☐ All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time
QUESTIONS 11 [sctHEALTHQ11]		
11.How TRUE or FALSE is each of the following statements for the subject?		
34.*	11a. The subject seems to get sick a little easier than other people [The subject seems to get sick a little easier than other people]	[HEALTH33 : HW_SF36.HW11_QA] ☐ Definitely true ☐ Mostly true ☐ Do not know ☐ Mostly false ☐ Definitely false
35.*	11b. The subject is as healthy as anyone he or she knows [The subject is as healthy as anyone he or she knows]	[HEALTH34 : HW_SF36.HW11_QB] ☐ Definitely true ☐ Mostly true ☐ Do not know ☐ Mostly false ☐ Definitely false
36.*	11c. The subject expect his / her health to get worse [The subject expect his / her health to get worse]	[HEALTH35 : HW_SF36.HW11_QC] ☐ Definitely true ☐ Mostly true ☐ Do not know ☐ Mostly false ☐ Definitely false
37.*	11d. His / her health is excellent [His / her health is excellent]	[HEALTH36 : HW_SF36.HW11_QD] ☐ Definitely true ☐ Mostly true ☐ Do not know ☐ Mostly false ☐ Definitely false
Key: [*] = Item is required Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

ZOSTER-064 (204878): INVESTIGATOR SIGNATURE (Investigator signature) [INVSIGN_CR]		
INVESTIGATOR SIGNATURE [sctINVSIGN]		
1.*	Is this casebook ready to sign? If not, click on the RETURN button below	[INVSIGN : Not submitted - for internal use] ☐
2.	For Data Managers only: Tick or untick this box to require the investigator to re-sign the form. <i>By ticking or unticking this box you are evoking a change to this form back to an unsigned state. This should be done for any change performed by site staff after the original signature. [hidden]</i>	[INVSIG2 : Not submitted - for internal use] ☐
Note: Source verification critical settings made in InForm will override any settings made in Central Designer.		

- 16.1.4. List and description of investigators, including brief (1 page) CVs or equivalent summaries of training and experience relevant to the performance of the clinical study - Study Administrative Table providing information on important participants in the study**

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List and description of investigators

Investigator's name	Sub-investigators	Centre number	Investigational site (institution /hospital)	Location (complete address)	Phone number Fax number
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Caso Covadonga	Bardón Fernández-Pacheco Ignacio Capapé Aguilar Ana O'Connor Pérez Silvia	PPD	Hospital Clinico San Carlos	Dr. Martín Lagos s/n Marid 28040 Spain.	PPD
Díez-Domingo Javier	Perez Breva Lina		FISABIO Fundación para el Fomento Investigación Sanitaria y Biomédica de la Comunitat Valenciana	Av. Cataluña21 Valencia 46020 Spain.	
Farrés Fabrè Xavier	Narejos Pérez Silvia		CAP Balenyà	C/ Major 46 Balenyà (Barcelona) 8550 Spain.	
Martínez Piera Pyrene			ABS Peralada	C/ Toló 3-5 Peralada(Girona) 17491 Spain.	
Narejos Pérez Silvia	Farrés Fabrè Xavier		CAP Centelles	Medicina General, Pla. Del Mestre 7 Centelles (Barcelona) 8540 Spain.	
Núñez López Concepción	González Contreras Fidel Rodrigo García-Pando Consuelo		Hospital La Paz	Servicio de Prevención de Riesgos laborales, Edificio Escuela de Enfermería. 5ª Planta Paseo de la Castellana 261 Madrid 28046 Spain.	
Pérez Vera Mercè	-		CAP La Roca	Plaça de L'era s/nº La Roca del Valles (Barcelona) 8430 Spain.	
Rodríguez Badia Alex	-		ABS Alt Camp Oest(CAP Alcover)	C/ Fonts del Glorieta s/n Alcover(Tarragona) 43460 Spain.	
Rodríguez de la Pinta Mª Luisa	Borda Olivas Jenry Maestre Naranjo María		Hospital Puerta de Hierro	Servicio de Prevención de Riesgos Laborables, 2ª Planta - Peine 1 - Eje Central C/ Manuel de Falla 1 Majadahonda (Madrid) 28222 Spain.	
Terns Riera Manuel	-		CAP Remei	Pasaje Pla Del Remei 10-12 Vic Barcelona, 28500 Spain.	
Sweden					
Bengtsson Niklas	-		Länssjukhuset Ryhov	Infektionskliniken, Länssjukhuset Ryhov, JÖNKÖPING, SE-551 85, Sweden.	
Berndtsson Blom Katarina	-		Ladulaas Kliniska Studier	Skaraborgsvägen 35 E BORÅS SE-506 30 Sweden.	

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204878 (ZOSTER-064)

Report Final

Investigator's name	Sub-investigators	Centre number	Investigational site (institution /hospital)	Location (complete address)	Phone number Fax number
Curiac Dan	-	PPD	SU/Sahlgrenska Universitetssjukhuset	Clinical Trial Center, Gröna Stråket 12, GÖTEBORG, SE-413 45, Sweden	PPD
Koskinen Pekka	-		PharmaSite	PharmaSite, Föreningsgatan 26, MALMÖ, SE-211 52, Sweden	
Liu Bo	-		S3 Clinical Research Center	Vällingby Läkarhus, Indalsbacken 1, plan 2, VÄLLINGBY, SE-162 68, Sweden.	
Lundvall Martin	-		Avdelningen för kliniska prövningar	S-huset Södra Grev Rosengatan ÖREBRO SE-703 62 Sweden.	
Munir Abul Kashem	-		Universitetssjukhuset	Allergicentrum, Brigadgatan 14, LINKÖPING, SE-58758, Sweden.	
Pauksens Karlis	-			Infektionskliniken Akademiska sjukhuset Uppsala SE-751 85 Sweden.	
Rombo Lars	-		Mälarsjukhuset	Infektionskliniken, Kungsvägen, ESKILSTUNA, SE-631 88, Sweden	
Sanmartin Berglund Johan	-		Blekinge Kompetenscentrum	Vårdskolevägen 5 KARLSKRONA SE-371 41 Sweden.	
Taiwan					
Chang Hsiao-Ting	Chen Tzeng-Ji Hwang Shinn-Jang		Taipei Veterans General Hosptital	No. 201, Section 2, Shih-Pai Road, Taipei, 112, Mexico.	
Cheng Huey-Shinn	-		Chang Gung Memorial Hospital - LinKou	No.5 Fuxing St, Guishan Township, Taoyuan County, 333, Taiwan.	
Huang Kuo-Chin	Yu Chong-Jen		National Taiwan University Hospital	Department of Family Medicine, No. 7 Chung Shan South Road, Taipei, 100, Taiwan.	
Liu Chiu-Shong	Lin Chih-Hsueh		China Medical University Hospital	Occupational Medicine and Family Medicine, 2 Yuh-Der Road, Taichung, 40447, Taiwan.	
United Kingdom					
Huong Yieng	Eyre Susannah		Synexus Merseyside	Synexus Merseyside Clinical Research Centre, Burlington House, Crosby Road North, Liverpool, L22 0LG, United Kingdom	
Macari Angela	Cochrane Rose		Springhill Surgery	4A Kileen Avenue Bangor BT19 1NB United Kingdom.	
McNally Damien	Haigney Sean		Ormeau Clinical Trials Limited	120 Ormeau Road Belfast BT7 2EB United Kingdom.	

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Report Final

Investigator's name	Sub-investigators	Centre number	Investigational site (institution /hospital)	Location (complete address)	Phone number Fax number
Nagle Michael	Cusick Peter Hendron Mary	PPD	Abbots Cross Medical Practice	92 Doagh Road Newtonabbey BT37 9QW United Kingdom.	PPD
Patrick Janice	Wyatt Nell		The Health Centre	Station Approach Bradford on Avon Wiltshire BA15 1DQ United Kingdom.	
Purnell-Mullick Samir	-		Atherstone Surgery	1 Ratcliffe Road Atherstone Warwickshire CV9 1EU United Kingdom.	
Redmond Michael	Ferguson Janice		BIBR Limited	76 Main Street Broughshane BT42 4JP United Kingdom.	
United States					
Adams Michael	Christiansen Christy Johnston Mark Law Rachel Vasconez Stefanie Wright Shannon		Synexus	5251 S Green Street Suite 300 Murray Utah 84123 United States.	
Andrews Charles	Holcomb John		Diagnostics Research Group	Suite 360 4410 Medical Drive San Antonio Texas 78229 United States.	
Baron Mira	Kane Pamela Thompson Slyllia		Palm Beach Research Center	2277 Palm Beach Lakes Blvd West Palm Beach Florida 33409 United States.	
Downey Herman Jackson	-		Westside Center for Clinical Research	810 Lane Ave South Jacksonville Florida 32205 United States.	
Earl John	Lail Jennifer Sherrill Kristen Nicole Everhart Ryan Parker Shai Perry		PMG Research of Hickory	Suite 201 221 13th Ave Place NW Hickory North Carolina 28601 United States.	
Ellison William	Billings Michael Blain Diane Goosmann Jean Green Danielle Harrison Katrina Van Patton Sharon Williams Miranda		Synexus	501 Memorial Dr Ext suite A Greer South Carolina 29651 United States.	

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Investigator's name	Sub-investigators	Centre number	Investigational site (institution /hospital)	Location (complete address)	Phone number Fax number
Farrington Cecil	Ledbetter Cortney McNeill Robert Sarah McCarter	PPD	PMG Research of Salisbury LLC	410 Mocksville Avenue Salisbury North Carolina 28144 United States.	PPD
Finneran Matthew	Grable Jessica Raines Joshua Walker Meredith Walker Patricia		Family Practice Center of Wadsworth Inc. dba New Venture Medical Research	251 Leatherman Road Wadsworth Ohio 44281 United States.	
Francyk David	Sheridan Kathryn Wyse Mark Zakikhani Setareh		Family Practice Specialits Ltd	Suite F-150 4350 E Camelback Rd Phoenix Arizona 85018 United States.	
Freeman George Fisher Chester (Former Principal Investigator)	Freeman George		Health Research of Hampton Roads Inc.	Suite 110 720 Thimble Shoals Blvd. Newport News Virginia 23606 United States.	
Hartley Paul	Patnam Sridhar		Preferred Primary Care Physicians Inc	202 Jacob Murphy Lane Suite 102 Uniontown Pennsylvania 15401 United States.	
Houser Patricia	Gilbert Theresa White Jamie		Amherst Family Practice PC	1867 Amherst Street Suite 101 Winchester Virginia 22601 United States.	
Jacqmein Jeff			Jacksonville Center for Clinical Research	Suite 1 4085 University Boulevard South Jacksonville Florida 32216 United States.	
Klaff Leslie	Brazg Ronald		Rainier Clinical Research Center Inc.	Ste 100 723 SW 10th Street Renton Washington 98057 United States.	
Lipetz Robert	-		Encompass Clinical Research	Suite 203 10225 Austin Drive Spring Valley California 91978 United States.	
Malempati Srikanth	Phillips Barbara Wolford Jessica		Tampa Bay Medical Research	3251 McMullen Booth Rd Suite 303 Clearwater Florida 33761 United States.	
Manning Mary Beth	Briskin Toby Gaston Jennifer		Rapid Medical Research INC	3619 Park East Drive Suite 300 Beachwood Ohio 44122 United States.	
Mills Richard	Angotti Olivia Datta Kellen Datta Susan Faurey Frank Walker Kathleen		PMG Research of Charleston	Suite 203 180 Wingo Way Mt. Pleasant South Carolina 29464 United States.	

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Report Final

Investigator's name	Sub-investigators	Centre number	Investigational site (institution /hospital)	Location (complete address)	Phone number Fax number
Poling Terry	Hiebert Jill Klein Thomas Nguyen Johnny Young Gina	PPD	Heartland Research Assoc.	1709 South Rock Rd. Wichita Kansas 67207 United States.	PPD
Powell Stephanie	Belcher Tommy Rhudy Maranda		PMG Research of Bristol	1958 West State Street Bristol Tennessee 37620 United States.	
Raad George	Thompson Nanette		PMG Research of Charlotte LLC	Suite 201 1700 Abbey Pl. Charlotte North Carolina 28209 United States.	
Rankin Bruce	-		Avail Clinical Research LLC	860 Peachwood Dr. DeLand Florida 32720 United States.	
Riffer Ernie	Berry Barbara Blanchard Austin Chouinard Shelby Haught Annamarie Herber Agustin Imber Ryan Lipschitz Barbara Milroy Stephanie Nguyen Gina Trimmer Dorothy Vesely Kelly		Central Phoenix Medical Clinic	7600 N 15th Street Suite 190 & 191 Phoenix Arizona 85020 United States.	
Rosen Robert	Kiker Jennifer		Carolina Medical Trials	2805 Lyndhurst Avenue Winston-Salem North Carolina 27103 United States.	
Rozen Shari	Dobrosky Sarah Gates Michael Labbett Rita Waldo Jill		Preferred Primary Care Physicians Inc.	140 Curry Hollow Road Pittsburgh Pennsylvania 15236 United States.	
Scott John	Dageforde James McKenney James Stephens Tammy		National Clinical Research	Suite 140 2809 Emerywood Parkway Richmond Virginia 23294 United States.	

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Investigator's name	Sub-investigators	Centre number	Investigational site (institution /hospital)	Location (complete address)	Phone number Fax number
Shockey Gerald	Bruce David Devabhaktuni Samyuktha Henry Allen Leon Natalie Metz Danielle Phan Sharine Strasser Rhiannon	PPD	Clinical Research Advantage	Desert Clinical Research, LLC, 2310 E. Brown Road Mesa Arizona 85213 United States.	PPD
Shoffner Sylvia	Davis Evan Devane Wesley Raman Sujatha Schroder Derek Shultz Savannah		PMG Research of Cary	Suite 200A 530 New Waverly Place Cary North Carolina 27518 United States.	
Staub Jonathan	Webster Brian		PMG Research of Wilmington LLC	1202 Medical Ctr Dr Wilmington North Carolina 28401 United States.	
Turner Mark	-		Advanced Clinical Research	Suite 182 2950 E. Magic View Drive Meridian Idaho 83642 United States.	
Vidals Victor	Jokerst Sarah Kelly Goodson Kiesha Marquez Sherri		The Center for Pharmaceutical Research	Suite 426 1010 Carondelet Drive Kansas City Missouri 64114 United States.	
Wilson Jonathan	Frank Jennifer		PMG Research of Winston-Salem	Suite 306 1901 S. Hawthorne Rd Winston-Salem North Carolina 27103 United States.	

**Investigator CVs or equivalent summaries of training and
experience relevant to the performance of the clinical study**

Page(s) removed- Out of Scope of phase 1 of Policy 0070 – Investigator CVs

Study Administrative Table

Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
Monitoring	Central Study Monitor PPD (Central Study co-ordinator)	- co-ordinates operational aspects of running the study from preparation of study supplies and data capture tools, to study tracking - has regular contacts with local monitors in order to review the study progress and any issue raised by the local monitor. In this way compliance with the protocol and GCP/ICH guidelines is ensured during preparation, active and cleaning phases of the study - is responsible for maintaining and archiving a comprehensive study file. If required, transitioning of a study from one monitor to another is documented in the study file - is responsible for reviewing the clinical study report	Syneos Health, Syneos Health, 1 Pinehurst Road, Farnborough, Hampshire, UK, GU14 7BF.
Monitoring	Local Monitor	<u>Prior to study start:</u> - is responsible for the evaluation of the study site and ensures that the staff and facilities are trained and appropriate for running of the study according to protocol and GCP guidelines - is involved in the preparation of study package for submission to Ethics Committee and/or Independent Review Board (EC/IRBs) and appropriate authorities	Brazil: PPD, Rua Leopoldo Couto de Magalhães Júnior, 758 and 7 Itaim Bibi, São Paulo/SP, Brazil. Zip code: 04542-000 Czechia: PPD Czech Republic, s.r.o. Budějovická Alej, Antala Staška 2027/79, 140 00 Praha 4, Česká republika. France : PPD 27-35 Rue Victor Hugo, 94853 IVRY-SUR-SEINE Cedex, France. Italy: Giacomo Tuana Franguel

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Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
			PPD Segreen Business Park Via San Bovio, 3 20090 San Felice Segrate (MI), Italy. Japan: A2 Healthcare Corporation, Sumitomo Fudosan Korakuen Bldg., 1-4-1, Koishikawa, Bunkyo-ku, Tokyo, 112-0002, Japan TEL : +81-3-3830-1122 Sweden: PPD Scandinavia AB, Norra Stationsgatan 67, 113 64 Stockholm Sweden. Taiwan: PPD Pharmaceutical, Product Development, LLC. Taipei 101 Building Unit A, 21st Flr., No. 7, Sec.5, XinYi Rd. Taipei City, Postcode 11049 Taiwan. UK: PPD, Great Abington, Cambridge CB21 6 GQ England UK. US: PPD, 929 North Front Street Wilmington, NC 28401-3331.

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204878 (ZOSTER-064)
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Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
		<u>At study initiation:</u> - conducts study specific training <u>While trial is ongoing:</u> - discusses all aspects of the trial with the study staff - verifies source documents and Case Report Forms (CRFs) - conducts a 100% review of all Informed Consent documentation - checks accountability of investigational product and its storage conditions - checks the collection and storage of biological samples and transport to central laboratory - reviews each SAE report All monitoring visits are documented via a monitoring visit report (MVR), which will be reviewed by the monitor's manager. These reports allow the identification of protocol violation, re-education of site staff and communication of significant issues (SAEs, quality, efficacy and GCP compliance) to the central organisation. In this way the Local Monitors oversee the progress of the clinical trial and ensure that it is conducted, recorded and reported in accordance with the protocol and current GCP/ICH guidelines. The Local Monitor works in close partnership with the Local Medical Advisor and the Central Study Monitor.	
Data Management	Data Manager PPD Oversight Data Manager PPD	- the development of the Case Report Form - the development of checks and listings for data cleaning purposes - the handling/d cleaning of study data (in conjunction with the Clinical Development Manager, Central Study and Local Monitors) in order to provide cleaned database for the statistical analysis	Syneos Health, 1030 Sync Street, Morrisville, NC 27560. GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)

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Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
Statistics	Statistician PPD	- is involved in the study design and is responsible for calculating the sample size, preparation of the randomisation list, identification of appropriate statistical tests to analyse the data, conducting the statistical analysis on the data collected, issuing the statistical report and interpretation of the statistical findings - reviews the final study report to ensure that all aspects of the statistical analysis and findings are accurately represented in the final report	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)
Laboratory assessments	Not Applicable	Not Applicable	Not Applicable
Randomization	Biostatistics & statistical programming	- computer-generated a randomisation list which was used to number the supplies - a randomisation blocking scheme was used to ensure that the balance between vaccine groups was maintained. The randomisation number uniquely identified the vaccine dose to be administered to any subject.	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium) (Using SAS macro)
Clinical lead	Clinical Research Development Lead PPD Sponsor approver: PPD	- provides clinical and scientific input for the study protocol, analysis plan and review of data - reviews the final study report to ensure that clinical and scientific interpretation of the findings are accurately represented in the final report	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium) GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)

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Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
Medical writing	Scientific Writer PPD	- In collaboration with the study team, prepares study protocols, Subject Information Sheet (SIS), Informed Consent Forms (IC), protocol amendments and the Clinical Study Reports. - Co-ordinates the review of the final study report with the study team (including the investigators) to ensure that the report is an accurate account of the study and findings.	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)
Central Safety	Central Safety Department PPD	During the conduct of pre-licensure clinical studies, the Central Safety Department is responsible for: - centralising collection, review and follow-up of all reported SAEs - the issue of Expedited Investigator Safety Reports to inform all investigators in the programme and IRBs of unexpected and related SAEs - the preparation and review of consolidated safety reports related to investigational vaccines - the analysis of safety issues and review of the safety content of the final study report.	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)
Other information			
Location of trial master file	Local Study Monitor Central Study Monitor	The Sponsor's Trial Master file is composed of the following: - The <i>country monitoring study file</i>. This part of the master file is located at the particular GSK office involved in the study. The type of documents retained by the GSK office is given in Annex 1. - The <i>central study file</i>. This part of the master file is located at the GSK offices in Rixensart. The type of documents retained by the GSK central office in Rixensart is given in Annex 2.	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium) Australia: Iron Mountain, 465 Plummer Street (BLDG C), Port Melbourne, VIC 3207, Australia Brazil : Iron Mountain, Estrada dos

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Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
			Bandeirantes, 8464 – Jacarepaguá, Zip code : 22780-083, City: Rio de Janeiro/RJ, Brazil. Canada: Iron Mountain, 195 Summerlea Road, Brampton, Ontario, L6T 4P6. Czechia: PPD Czech Republic, s.r.o. Budějovická Alej Antala Staška 2027/79 140 00 Praha 4, Česká republika Estonia: Kespri Archive OÜ, Tallinn, Katusepapi 20, Estonia. Finland : Iron Mountain Finland Oy Kuussillantie 27, 01230 Vantaa, Finland. France : ARCHIVECO, 15 avenue Marcelin Berthelot, 92390 VILLENEUVE-LA GARENNE, France. Germany : Rhenus Archiv Services GmbH, Elly-Staegmeyr Straße 2, 80999 München

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Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
			Germany. Hong Kong: Crown Worldwide (HK) Limited, Crown Data Centre 2, 1 Leung Yip Street, Yuen Long, Hong Kong / Crown Data Centre 3, 23 Tak Yip Street, Yuen Long, Hong Kong. Italy: GSK, Via Fleming, 2 37135 Verona VR – Italy. Japan: Fuji Xerox Corporation, Nakanosakaue Sun Bright Twin, 2-46-1 Honcho, Nakano-ku, Tokyo 164 0012, Japan. Mexico: Iron Mountain Mexico located Calle 6 Nte. No. 113 Parque Industrial Toluca 2000, 50200 toluca de Lerdo, estado de, Mexico. South Korea: Tong-In Warehouse CO., LTD.: 39, Hwangsae-mal 2- gil, Jorie-up, Paju-se, Gyeonggi-do, 10949, Korea.

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Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
			Spain: GlaxoSmithkline Spain Definitive Archive, C/ Severo Ochoa 2, 28760 Tres Cantos (Madrid), Spain. Sweden: PPD Scandinavia AB, Norra Stationsgatan 67 113 64 Stockholm, Sweden. Taiwan: Iron Mountain Taiwan, Office: 12/F.-1, No.142, Sec 3, Minguang E. Rd., Songshan Dist., Taipei City 105, Taiwan, ROC Warehouse: Iron Mountain, No.110, Ln. 228, Sec. 2, Nankan Rd., Luzhu Dist., Taoyuan City 338, Taiwan. UK: Phlexglobal Ltd, Chesham Records Centre, Deansway, Chesham, Bucks, HP5 2WX. US: GSK, 14200 Shady Grove Road, Rockville, MD 20850.

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Clinical Trial Activity	Performed by	Responsibilities and scope of activities	Site address
Site(s) of manufacture	GSK Biologicals	-	Not Applicable as this study did not have vaccine.
Site of release in Europe	-	-	GlaxoSmithKline Biologicals Rue de l'Institut 89, 1330 Rixensart (Belgium)

16.1.5. Signatures of principal or coordinating investigator(s), and sponsor approver**GlaxoSmithKline Biologicals
Vaccines R&D
Investigator Approval Page**

STUDY TITLE: Observational study to assess frailty of subjects during ZOSTER-006 and ZOSTER-022 and HZ efficacy, immunogenicity and safety of HZ/su by frailty status

Study: 204878 (ZOSTER-064) Development Phase: Not applicable

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Name of Investigator: Dr. McNeil, MD, FRCPC

Affiliation /investigational centre: Izaak Walton Killam Grace Health Sciences Centre, Halifax, Nova Scotia, Canada

Signature of Investigator: _____

Date: _____

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GlaxoSmithKline Biologicals

Vaccines R&D

Investigator Approval Page

STUDY TITLE: Observational study to assess frailty of subjects during ZOSTER-006 and ZOSTER-022 and HZ efficacy, immunogenicity and safety of HZ/su by frailty status

Study: 204878 (ZOSTER-064) Development Phase: Not applicable

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Name of Investigator: Dr. Andrew, MD, MSc(Ph), FRCPC

Affiliation /investigational Izaak Walton Killam Grace Health Sciences
centre: Centre, Halifax, Nova Scotia, Canada

Signature of Investigator: _____

Date: _____

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GlaxoSmithKline Biologicals
Vaccines R&D
Sponsor Signatory Approval Page

Please note that by signing this page, you take responsibility for the content of the Study Report, including appendices

STUDY TITLE: Observational study to assess frailty of subjects during ZOSTER-006 and ZOSTER-022 and HZ efficacy, immunogenicity and safety of HZ/su by frailty status

Study: 204878 (ZOSTER-064) Development Phase: Not applicable

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

Name of Sponsor Signatory: Anne Schuind

Title of Sponsor Signatory: Senior Director, Clinical and Epidemiology
Project Lead for Zoster, Clinical Research and
Development, GlaxoSmithKline Biologicals, SA

Signature: _____

Date: _____

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16.1.8. Audit certificate

Not Applicable

16.1.9. Documentation of statistical methods

 Statistical Analysis Plan	
Detailed Title:	Observational study to assess frailty of subjects during ZOSTER-006 and ZOSTER-022 and HZ efficacy, immunogenicity and safety of HZ/su by frailty status
eTrack study number and Abbreviated Title	204878 (ZOSTER-064)
Scope:	All data pertaining to the above study. All analyses for the primary, secondary and tertiary objectives of the study.
Date of Statistical Analysis Plan	Amendment 1: 18 June 2019

APP 9000058193 Statistical Analysis Plan Template V4 (Effective date: 3 June 2019)

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LIST OF ABBREVIATIONS

AE	Adverse Event
ATP	According-To-Protocol
AUC	Area Under Curve
CI	Confidence Interval
CMI	Cellular-Mediated Immunogenicity
CRF	Case Report Form
CTRS	Clinical Trial Registry
Eli Type	Internal GSK database code for type of elimination code
EQ-5D	Euro-QoL 5 Dimension
GSK	GlaxoSmithKline
LL	Lower Limit of the confidence interval
LSMEANS	Least Squares Means
MAR	Missing at Random
MedDRA	Medical Dictionary for Regulatory Activities
mTVC	Modified Total Vaccinated Cohort
PBMC	Peripheral Blood Mononuclear Cell Processing
pIMD	potential Immune Mediated Diseases
PROC Phreg	SAS Procedure: Proportional Hazards Regression
QOL	Quality of Life
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SBIR	GSK Biological's Internet Randomization System
SD	Standard Deviation
SE	Standard Error

SF-36	Short Form – 36
TTO	Time Trade Off
TVC	Total Vaccinated Cohort
VAS	Visual Analogue Scale
YOA	Years of Age
ZBPI	Zoster Brief Pain Inventory

1. DOCUMENT HISTORY

Date	Description	Protocol Version
27 NOV 2018	Final	Amendment 1: 17 OCT 2018
18 JUN 2019	Amendment 1	Administrative Change 3: 11 FEB 2019

2. STUDY DESIGN

This is a retrospective, observational study, in which pooled data from the ZOSTER-006 and ZOSTER-022 will be analysed. As a consequence no new subjects will be enrolled in this study and no new ICF will be required from study subjects.

In ZOSTER-006 and ZOSTER-022, encoding of Quality of Life (QoL) questionnaires (*SF-36*, *EQ-5D*) was only performed for subjects who developed a suspected Herpes Zoster (HZ) episode during the study. This was done to assess the QoL of subjects who developed suspected cases of HZ between the vaccine group and the placebo group. The remaining study subjects who did not develop suspected cases of HZ completed the questionnaires; however, these questionnaires were never encoded or analysed as part of ZOSTER-006 and ZOSTER-022. The remaining questionnaires will be encoded in ZOSTER-064. These questionnaires will be used, in association with already encoded medical history from each subject, to derive a frailty index and thus assign each subject to a baseline frailty status (non-frail, pre-frail, frail, missing). This will allow efficacy, safety and immunogenicity data to be re-analysed according to frailty status.

The following group names will be used for the statistical analyses:

Group order in tables	Group label in tables	Group definition for footnote
1	HZ/su	Herpes Zoster subunit vaccine
2	Placebo	Placebo

The following sub-groups will be used for the statistical analysis:

Table 1 Details of subgroups

Sub-group category	Sub-group order in tables	Sub-group label in tables	Sub-group definition for footnote
Frailty Status	1	Non-Frail	Subjects with frailty index score ≤ 0.08
	2	Pre-Frail	Subjects with frailty index score > 0.08 and ≤ 0.25
	3	Frail	Subjects with frailty index score > 0.25
	4	Unknown	Subjects who were not assigned a Frailty Status
Gender	1	Male	Male Subjects
	2	Female	Female Subjects

Table 2 Details of age and region subgroups

Analysis by age group

Sub-group order in tables	Sub-group label in tables	Sub-group definition for footnote	Pooled Groups 1 label in tables	Pooled Groups 2 label in tables
1	50-59YOA	50-59 years old subjects	50-59YOA	< 70YOA
2	60-69YOA	60-69 years old subjects	60-69YOA	< 70YOA
3	70-79YOA	70-79 years old subjects	70-79YOA	≥ 70YOA
4	80-89YOA	80-89 years old subjects	≥ 80YOA	≥ 70YOA
5	≥ 90YOA	≥ 90 years old subjects	≥ 80YOA	≥ 70YOA

Analysis by country/region

Sub-group order in tables	Sub-group label in tables	Sub-group definition for footnote	Pooled Groups label in tables
1	CZ	Czechia	Europe
2	EN	Estonia	Europe
3	FI	Finland	Europe
4	FR	France	Europe
5	GE	Germany	Europe
6	IT	Italy	Europe
7	SP	Spain	Europe
8	SW	Sweden	Europe
9	UK	United Kingdom	Europe
10	AS	Australia	Australasia
11	HK	Hong Kong	Australasia
12	JA	Japan	Australasia
13	SK	South Korea	Australasia
14	TW	Taiwan	Australasia
15	BR	Brazil	Latin America
16	MX	Mexico	Latin America
17	US	United States	North America
18	CA	Canada	North America

3. OBJECTIVES

3.1. Primary objective

To assess the baseline frailty of subjects enrolled in ZOSTER-006 and ZOSTER-022.

3.2. Secondary objectives

- To present the distribution of *SF-36* and *EQ-5D* scores in subjects included in ZOSTER-006 and ZOSTER-022 at baseline by country to allow comparison with normative values for those questionnaires in the general population of the countries participating in the study.
- To assess vaccine efficacy (VE) against HZ by frailty status.
- To assess HZ burden of illness (BOI) by frailty status.
- To identify predictive factors for individuals developing HZ.
- To describe safety by frailty status.
- To assess humoral immunogenicity by frailty status.

Tertiary

- To describe CMI by frailty status of subjects enrolled in ZOSTER-006 only.

4. ENDPOINTS

4.1. Primary endpoint

- Baseline Frailty Status.
 - Frailty Status pre-vaccination dose 1 as defined by responses to components of the *SF-36* and *EQ-5D* questionnaire at vaccination day 0 and the subjects coded medical history.

4.2. Secondary endpoints

- *SF-36* and *EQ-5D* scale scores.
 - At months 0, 14, 26 and 38.
- Confirmed HZ cases.
 - Incidence of HZ cases during ZOSTER-006 and ZOSTER-022 for subjects in the modified Total Vaccinated Cohort (mTVC).
- HZ Burden of Illness.
 - HZ Burden of Illness score for subjects in both ZOSTER-006 and ZOSTER-022 as calculated from the Zoster Brief Pain Inventory (ZBPI)

- Solicited local and general symptoms collected in ZOSTER-006 and ZOSTER-022:
 - Occurrence, intensity of each solicited local symptom within 7 days (Days 0-6) after each vaccination, in subjects included in the 7-day diary card subset;
 - Occurrence, intensity and relationship to vaccination of each solicited general symptom within 7 days (Days 0-6) after each vaccination, in subjects included in the 7-day diary card subset.
- Unsolicited adverse events (AEs) collected in ZOSTER-006 and ZOSTER-022:
 - Occurrence, intensity and relationship to vaccination of unsolicited AEs during 30 days (Days 0 - 29) after each vaccination, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification in all subjects.
- Serious Adverse Events (SAEs) collected in ZOSTER-006 and ZOSTER-022.
 - Occurrence and relationship to vaccination of all SAEs from Month 0 to Month 14 in all subjects;
 - Occurrence of SAEs related to study participation or to a concurrent GSK medication/vaccine during the entire study period in all subjects;
 - Occurrence of any fatal SAEs during the entire study period in all subjects.
- Occurrence of pre-defined AEs collected in ZOSTER-006 and ZOSTER-022
 - Occurrence and relationship to vaccination of any potential Immune Mediated Diseases (pIMDs) during the entire study period in all subjects.
- Humoral Immunogenicity of the study vaccine in subset of subjects from ZOSTER-006 and ZOSTER-022.
 - Anti-gE and anti-VZV Ab concentrations as determined by Enzyme-linked Immunosorbent Assay (ELISA), in a subset of subjects at Months 0, 3, 14, 26 and 38.

4.3. Tertiary endpoints

- Cell-mediated immunogenicity (CMI) of the study vaccine in subsets of subjects from ZOSTER-006 only.
 - CMI in terms of frequencies of antigen-specific CD4 T cells at Months 0, 3, 14, 26 and 38
 - Frequencies of CD4 T cells with antigen-specific Interferon gamma (IFN- γ) and/or Interleukin-2 (IL-2) and/or Tumour Necrosis Factor alpha (TNF- α) and/or CD40 Ligand (CD40L) secretion/expression to glycoprotein E (gE) and VZV as determined by intracellular cytokine staining in a subset of subjects at Months 0, 3, 14, 26 and 38.

5. STUDY POPULATION

5.1. Total Vaccinated cohort

The TVC will include all subjects in the TVC in ZOSTER-006 or ZOSTER-022 who were enrolled at centres participating in ZOSTER-064. All subjects in the TVC in ZOSTER-006 or ZOSTER-022 who were enrolled at centres not participating in ZOSTER-064 will be excluded from the TVC.

5.2. Total Vaccinated cohort - diary card subset

The TVC diary card subset for analysis of reactogenicity will include all subjects in the TVC who were also included in the diary card subset in either the ZOSTER-006 or ZOSTER-022 studies.

5.3. Modified Total Vaccinated cohort

The mTVC will include all subjects in the mTVC in ZOSTER-006 or ZOSTER-022 who were enrolled at centres participating in ZOSTER-064.

5.4. According-To-Protocol cohort for analysis of immunogenicity

The ATP cohort for analysis of immunogenicity will consist of all subjects in the ATP cohort for analysis of immunogenicity in ZOSTER-006 or ZOSTER-022 who were enrolled at centres participating in ZOSTER-064.

For the immunogenicity tables where different timepoints are presented, the concept of “Adapted ATP cohort for immunogenicity” will be used to denote that for each timepoint, the corresponding ATP cohort for immunogenicity will be used.

More specifically,

- The analyses at the timepoints Month 0 and Month 3 will be based on the ATP cohort for immunogenicity Month 3;
- The analysis at the timepoint Month 14 will be based on the ATP cohort for immunogenicity Month 14;
- The analysis at the timepoint Month 26 will be based on the ATP cohort for immunogenicity Month 26;
- The analysis at the timepoint Month 38 will be based on the ATP cohort for immunogenicity Month 38;

For the analysis of humoral immunogenicity, ATP cohort is further defined as ATP cohort for immunogenicity – Humoral.

Similarly, for the analysis of cell mediated immunogenicity, ATP cohort is further defined as ATP cohort for immunogenicity – CMI.

6. STATISTICAL METHODS

6.1. Analysis of demographics

Centres that participated in ZOSTER-064 along with their corresponding centre numbers in ZOSTER-006 or ZOSTER-022 will be presented. The distribution of subjects across the study centres will be tabulated by vaccination group and country.

Demographic characteristics (age at first vaccination, gender, race, geographic ancestry and ethnicity) of each study cohort will be tabulated by vaccination group for each of the cohorts defined above. Demographic characteristics will also be tabulated by vaccination group and frailty status.

The mean age (including range and standard deviation) of subjects will be calculated overall, by vaccination group and by frailty status.

The distribution of subjects included in the study across sites will be tabulated overall and per vaccine group.

Frequency tables will be generated for categorical variables such as gender.

Mean, median and standard deviation will be provided for continuous data such as age.

No inferential analyses of demographic data or baseline characteristics are planned.

6.2. Primary Objective

6.2.1. Analysis of Frailty Status

The primary analysis will be based on the TVC.

The number of subjects in each frailty category will be presented by age group, gender and country.

Demographic characteristics will be presented by frailty status.

Details of the assignment of subjects to frailty categories are presented in section [7.1](#).

6.3. Secondary Objectives

6.3.1. SF-36 and EQ-5D

The quality of life questionnaires to be analysed in this study are the SF-36 and EQ-5D. The SF-36 health survey and the EQ-5D questionnaires were to be completed by all subjects at Months 0, 14, 26 and 38 in ZOSTER-006 and ZOSTER-022.

Basic summary statistics (N, Mean, Standard Deviation) of each of the 8 components of the SF-36 Questionnaire (Physical Functioning, Role Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional and Mental Health) and the EQ-5D Utility and visual analogue scale (VAS) scores will be presented at each scheduled timepoint by country and age group.

In addition, a more detailed statistical analysis, including the median, quartiles and minimum and maximum values, of the 10 components will be presented by timepoint, age-category and gender and will be presented in a separate annex.

The EQ-5D utility will be based on country specific Time Trade-off (TTO) values for the analysis by country. The UK TTO will be used for countries for which there is no specific TTO.

Presenting the data by country will allow for comparison with normative values for those questionnaires in the general population of the countries participating in the study

This analysis will be based on the TVC.

6.3.1.1. Analysis of Completion of SF-36 and EQ-5D

Compliance with completion of both SF-36 and EQ-5D questionnaires will be summarised by country at each time point (Months 0, 14, 26 and 38) and overall. This compliance will be presented for the TVC and will include in the calculation both newly encoded and previously encoded questionnaires.

% Completion will be defined for each time point as follows:

$$\% \text{ Completion} = 100 \times N1 / N2$$

Where:

N1 = number of subjects with a completed SF-36/EQ-5D questionnaire.

N2 = number of subjects for whom a questionnaire was expected.

6.3.2. Vaccine efficacy by frailty status

The vaccine efficacy (VE) of the combined ZOSTER-006 and ZOSTER-022 studies will be based on the mTVC and will be classified by frailty status.

The VE will be estimated separately for each frailty category.

Further details of the model used to calculate the VE is contained in the statistical analysis plans (SAPs) for the ZOSTER-006 and ZOSTER-022 studies.

6.3.3. HZ Burden of illness by frailty status

The pooled HZ burden of illness (BOI) scores from the ZOSTER-006 and ZOSTER-022 studies will be presented by frailty category.

The number of subjects with a confirmed HZ episode, the mean BOI scores and the total follow-up time will be presented by Frailty category and vaccination group. The burden of illness vaccine efficacy and 95% confidence intervals (CIs) will be presented by frailty category. This analysis will be carried out for subjects in the mTVC.

6.3.4. Predictive factors for subjects developing HZ

A Cox regression model allowing for time-dependent covariates will be fitted to identify which factors are predictive of developing HZ. The model will include time to HZ as the outcome variable, the demographic variables age and gender and the time dependent *SF-36* variables and *EQ-5D* variables as potential predictors. This analysis will be performed for subjects in the Placebo group in the TVC.

Subjects who did not develop HZ will be censored at the time of their last study visit. The regression model will be used for both minimally adjusted analyses and multivariate analyses. All factors will initially be examined in an age- and gender-adjusted model with further adjustment for the original study (ZOSTER-006 or ZOSTER-022). Factors will be included in the multivariate model if they are associated ($P < 0.05$ using a two-sided Wald test) with HZ in the minimally adjusted model. The multivariate model will also include age, gender and original study. A step-down (backward) variable selection procedure will be used to fit the final multivariate model. This model will be fitted using the PHREG procedure of the *SAS/STAT* package.

The parameter estimates and standard error of each SF-36 and EQ-5D parameter from the minimally adjusted model will be presented. The final multivariate model will also be presented.

The analysis will be performed with the event defined as a HZ confirmed case. Three separate analyses will be performed examining the impact of excluding suspected but not confirmed cases.

The first analysis will exclude subjects who had a suspected case that was later proven not to be a HZ episode.

The second analysis will include all subjects. Those subjects who had a suspected case that was later proven not to be a HZ episode will be censored at their latest available assessment and will be considered not to have had the event.

The third analysis will also include all subjects. The definition of event will be changed to having a suspected case of HZ.

The distribution of confirmed cases of HZ amongst suspected cases will be presented by age group for subjects in the placebo group in the TVC.

Details of the process behind the inclusion of time dependent covariates are included in section 7.4

6.3.5. Analysis of safety by frailty status

The safety analysis will be based on the TVC. The analysis of Reactogenicity will be based on the TVC diary card subset.

All safety analyses will be categorised by frailty status.

The following analyses will be performed for safety endpoints:

- The percentage of subjects with at least one local solicited AE, with at least one general solicited AE and with any solicited AE during the solicited 7-day follow-up period will be tabulated with exact 95% CI after each vaccine dose and overall. The same tabulation will be performed for grade 3; related and grade 3 related AEs;
- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general adverse event (solicited and unsolicited) and with any AE during the solicited 7-day follow-up period will be tabulated with exact 95% CI after each vaccine dose and overall. The same tabulation will be performed for grade 3, related and grade 3 related AEs;
- The percentage of subjects reporting each individual solicited local and general AE during the solicited 7-day-follow-up period will be tabulated with exact 95% CI. For all solicited symptoms, the same tabulation will be performed for grade 3 solicited AEs and for solicited general AEs with relationship to vaccination;
- Summary of temperature value by half degree increment reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall doses and subjects. The same tabulation for fever with relationship to vaccination will be done;
- The number of days with each individual solicited local and general AE during **the solicited** 7-day follow-up period will be tabulated;
- The percentage of subjects with at least one local solicited AE, with at least one general solicited AE and with any solicited AE reported during the solicited 7-day follow-up period and **lasting beyond this period** will be tabulated with exact 95% CI after each vaccine dose and overall. The same tabulation will be performed for grade 3;

- The percentage of subjects with each individual solicited local and general symptoms **ongoing beyond the 7-day follow-up period** will be tabulated. The same tabulation will be performed for grade 3;
- The percentage of subjects with at least one report of unsolicited AE classified by the MedDRA Preferred Terms and reported up to 30 days after each vaccination will be tabulated with exact 95% CI. The same tabulation will be performed for grade 3 unsolicited AEs and for unsolicited AEs with a relationship to vaccination.
- Total number/percentages of doses followed by AEs will be tabulated;
- The percentage of subjects with at least one report of serious adverse event classified by the MedDRA Preferred Terms and reported during the whole post-vaccination follow up period will be tabulated with exact 95% CI;
- The proportion of subjects with at least one report of pIMDs classified by the MedDRA Preferred Terms and reported during the whole post-vaccination period (from dose 1 up to study end) will be tabulated with exact 95% CI.

6.3.6. Analysis of immunogenicity by Frailty status

The analysis of immunogenicity will be categorised by vaccination group and frailty status. The primary analysis will be based on the ATP cohort for analysis of immunogenicity.

6.3.6.1. Humoral immune response

Humoral immune response will be assessed and analysed in the ATP cohort for analysis of immunogenicity – Humoral.

Descriptive statistics

For the humoral immune response, at each timepoint that a blood sample is available (Months 0, 3, 14, 26 and 38), the following parameters (with 95% CIs) will be tabulated by vaccination group and frailty status:

- Geometric mean concentrations (GMCs) of anti-(gE/VZV) Ab with 95% confidence interval (CIs);
- Humoral seropositivity rates with exact 95% CIs;
- Vaccine response rates with 95% CIs;

Inferential Analyses

No inferential analysis will be carried out on the humoral immune response data.

6.3.6.2. Cell-mediated immune response

Cell-mediated immune response will be assessed and analysed in the ATP cohort for analysis of immunogenicity – CMI.

The CMI analyses was performed for ZOSTER-006 only in the Immunogenicity subset in three countries (Czech Republic, Japan and United States) at designated sites that had access to a PBMC processing facility within the acceptable time window from sample collection to PBMC processing. The CMI subset contained approximately 350 subjects. We are expecting some attrition of data, i.e. some centres who took part in the ZOSTER-006 may not take part in the ZOSTER-064. In addition, we are expecting that approximately 5% of subjects will be classified as frail. As a consequence, the analysis of CMI by frailty status will only be carried out if we have a minimum of 20 CMI subjects classified as frail.

Descriptive statistics

For CMI response, the following parameters (for gE and VZV specific CD4[2+] frequency and CD4[+2] T-cell following induction with gE and VZV) will be tabulated by vaccination group, overall and by frailty status at Months 0, 3, 14, 26 and 38:

- descriptive statistics of the frequency of CD4 T-cell secreting at least two different cytokines (IFN- γ , IL-2, TNF- α , CD40L) to both VZV and gE antigens;
- descriptive statistics of the frequency of CD4 T-cell secreting at least IFN- γ and another cytokine (IL-2, TNF- α , CD40L) to both VZV and gE antigens;
- descriptive statistics of the frequency of CD4 T-cell secreting at least IL-2 and another cytokine (IFN- γ , TNF- α , CD40L) to both VZV and gE antigens;
- descriptive statistics of the frequency of CD4 T-cell secreting at least TNF- α and another cytokine (IFN- γ , IL-2, CD40L) to both VZV and gE antigens;
- descriptive statistics of the frequency of CD4 T-cell secreting at least CD40L and another cytokine (IFN- γ , IL-2, TNF- α) to both VZV and gE antigens;
- Vaccine response rate with exact 95% CI at Months 3, 14, 26 and 38 (only in the gE-specific CD4[2+] T-cell frequency at Months 3, 14, 26 and 38)

Inferential Analyses

No inferential analysis will be carried out on the CMI data.

7. STATISTICAL CALCULATIONS

7.1. Derived and transformed data

7.1.1. Demography

Age at vaccination

Age will be calculated as the number of years between the date of birth and the date of first vaccination.

To ensure that the collection of date of birth will not jeopardise the privacy of Personally Identifiable Information (PII), only a partial date of birth (MMYYYY) was collected.

Therefore, the 15th of the month will be used to replace the missing date.

In case the month is missing, the date will be replaced by the June 30th of the year.

Note that due to incomplete date, the derived age may be incorrect by 1 month when month is missing from the birthdate. This may lead to apparent inconsistency between the derived age and the eligibility criteria/the age group used for randomization.

7.1.2. Efficacy data

Details of derived and transformed efficacy data including the methodology behind the VE is contained in the SAPs for the ZOSTER-006 and ZOSTER-022 studies.

7.1.3. Safety

Details of derived and transformed safety data is contained in the SAPs for the ZOSTER-006 and ZOSTER-022 studies.

7.1.4. Immunogenicity

7.1.4.1. Humoral immune response

Full details of the methods used in the humoral immune response analyses are contained in the ZOSTER-006 and ZOSTER-022 SAPs (Demog, Safety, Immuno).

7.1.4.2. Cellular-mediated immune (CMI) response

Full details of the methods used in the CMI analysis including calculation of the frequency of antigen-specific (gE or VZV) CD4[2+] T-cells for each individual subject and the definition of CMI vaccine response to gE and VZV are contained in the ZOSTER-006 SAP (Demog, Safety, Immuno).

7.2. Quality of Life data

7.2.1. SF-36 and EQ-5D

Details of the derivation of the 8 scales generated from the SF-36 and the derivation of the utility score from the EQ-5D are contained in the QoL SAPs for the ZOSTER-006 and ZOSTER-022 studies.

7.2.2. HZ Burden of illness

The HZ BOI scores are based on the ZBPI questionnaire already encoded in the ZOSTER-006 and ZOSTER-022 studies.

Full details of the ZBPI questionnaire and the methodology behind the calculation of the HZ BOI scores are contained in the QoL SAPs for the ZOSTER-006 and ZOSTER-022 studies.

7.3. Frailty Index

Frailty status will be measured in relation to the accumulation of deficits using a frailty index (FI) adapted from the model proposed by Mitnitski et al. [[Mitnitski, 2001](#)]. The different aspects of frailty composing the frailty index will be assessed through the medical history and components of the *SF-36* and *EQ-5D* questionnaires recorded pre-vaccination Dose 1.

The total frailty score will be between 0 and 41. The subject's pre-vaccination questionnaires will contribute a max score of 29 and the medical history will contribute a max score of 12. [Table 3](#) details the components of the SF-36 and EQ-5D questionnaires that contribute to the calculation of the frailty index.

Table 3 Detail of SF-36 and EQ-5D components of frailty Index

Item	Scoring method based on response to question	Max Contribution to Frailty Index
SF-36 Q1	Poor=1, Fair=0.5 Good=0, Very good=0 Excellent=0	1
SF-36 Q11A-11D	Q11A, Q11C Definitely true=1 Mostly true=0.5 Don't know=0 Mostly false=0 Definitely false=0 Q11B, Q11D Definitely true=0 Mostly true=0 Don't know=0 Mostly false=0.5 Definitely false=1	4
SF-36 Q3I - Q3J	Limited a lot=1 Limited a little=0.5 Not limited at all=0	10
SF-36 Q9A - Q9I	Q9A, Q9D, Q9E, Q9H : All of the Time=0 Most of the time=0 Some of the time=0 A little of the time=0.5 None of the time=1 Q9B, Q9C, Q9F, Q9G, Q9I : All of the Time=1 Most of the time=0.5 Some of the time=0 A little of the time=0 None of the time=0	9
SF-36 Q2 Compared to one week before, how did the subject rate his / her health in general?	Much worse=1, Somewhat worse=0.5, Same=0 Somewhat better=0 Better=0	1
EQ-5D Mobility	No Problems=0 Some Problems=0.5 Confined to bed=1	1
EQ-5D Anxiety	No Anxiety=0 Moderate Anxiety=0.5 Extreme Anxiety=1	1
EQ-5D Self care	No Problems=0 Some Problems=0.5 Inability to wash or dress himself /herself=1	1
EQ-5D Usual activities	No Problems=0 Some Problems=0.5 Inability to perform usual activities=1	1
Total		29

The medical history is divided into 12 selected categories; each category contributing a score of 0 or 1. The coded combined ZOSTER-006 and ZOSTER-022 medical history database will be searched and events that fall into any one of the 12 categories will be selected. Table 4 details the MedDRA terms that will be used to search the database. If a subject had any one of the listed events in a category they would be assigned a max score of 1 for that category and a max score of 12 overall.

The frailty index is then calculated by combining the accumulation of deficits into a score from 0 to 1: frailty index = (accumulation of deficits) / (41 – nmissQoL) where nmissQoL is the number of missing components of the 29 items from the SF-36 and EQ-5D questionnaires. If a subject has more than 10 missing QoL components the frailty index will not be calculated.

Each subject will then be assigned to one of three categories, Non-Frail, Pre-Frail and Frail based on the frailty index.

- If the frailty index is **less than or equal to** 0.08 then the subject is classified as Non-Frail. If the score is greater than 0.08 **but less than or equal to** 0.25 then the subject is classified as pre-frail. If the score is **greater than** 0.25 then the subject is classified as Frail. Subjects without a frailty index score will be classified as missing.

Table 4 Detail of Medical history search items

<i>Category</i>	<i>MedDRA version 18 Search Terms</i>
Cancer	Malignancy related conditions (SMQ) Malignant tumours (SMQ)
Diabetes Mellitus	Diabetes mellitus (incl subtypes) (HLT) Diabetic complications (HLGT)
High Blood Pressure, Heart Attack	Hypertension (SMQ) Ischaemic heart disease (SMQ)
CHF	Cardiac failure (SMQ)
Cerebrovascular Disease	Central nervous system vascular disorders (SMQ)
Arthritis	Arthritis (SMQ)
Chronic Lung Disease	Asthma/bronchospasm (SMQ) Interstitial lung disease (SMQ) Pulmonary hypertension (SMQ) Chronic Obstructive Pulmonary Disease (PT) / Infective exacerbation of chronic obstructive airways disease (PT) Bronchiectasis (PT) /Infective exacerbation of bronchiectasis (PT) Cystic fibrosis (PT)/ Cystic fibrosis lung (PT) / Infective pulmonary exacerbation of cystic fibrosis (PT) Chronic respiratory disease (PT) Chronic respiratory failure (PT)
Stomach or Intestinal Ulcers	Gastrointestinal ulceration (SMQ)
Migraine	Migraine headaches (HLT) Migraine prophylaxis (PT)
Cataract	Cataract Conditions (HLT) Cataract operation (PT) Cataract diabetic (PT) Cataract operation complication (PT)
Glaucoma	Glaucoma (SMQ)

- SMQ: Standardised MedDRA queries. HLGT: High Level Group Term. HLT: High Level Term. PT: Preferred Term

7.4. Predictive factors for individuals developing HZ

Only subjects in the placebo group will be included in the analysis of potential predictive factors. A Cox regression model allowing for time-dependent covariates will be fitted to identify which factors are predictive of developing HZ. The model will include time to HZ as the outcome variable, the demographic variables age and gender and the *SF-36* variables and *EQ-5D* variables as potential predictors.

Each EQ-5D and SF-36 assessment at a scheduled time point will be re-classified into time points based on the date of assessment relative to date of vaccination:

Studyday=date of assessment – date of vaccination.

The study day will be time component used in the model.

Since there are a maximum of four SF-36 and EQ-5D assessment times we define the variables T_0, T_1, T_2, T_3 as the study day relative to vaccination (day 0) of the QoL assessment and $QoL_0, QoL_1, QoL_2, QoL_3$ as the values of the QoL assessment at each timepoint. The value of the time-dependent variable QoL_t is equal to QoL_0 if $0 < t \leq T_1$, QoL_1 if $T_1 < t \leq T_2$, QoL_2 if $T_2 < t \leq T_3$, with $QoL_t = QoL_3$ if $t > T_3$.

The above model is implemented in SAS as follows:

```
ODS output ParameterEstimates=PE1;
PROC PHREG DATA=tsurv;
  CLASS study gender;
  MODEL fu_time*hz_conf(0)=age study gender PFT;
  PFT=PFO;
  IF fu_time > time1 and time1 ne . then PFT=PF1;
  IF fu_time > time2 and time2 ne . then PFT=PF2;
  IF fu_time > time3 and time3 ne . then PFT=PF3;
RUN;
```

Spearman correlations coefficients will be presented to display the relationships between pairs of variables. In addition, for the quality of life variables, the variance inflation factor and the condition indices for testing multicollinearity will be estimated.

Example: To illustrate the method the following hypothetical 3 subjects are examined:

Table 5 Data from hypothetical subjects to illustrate time dependent covariates

Subject	QoL0	T0	QoL1	T1	QoL2	T2	QoL3	T3	Censored /day	Event/ day
PPD	80	0	75	425	65	790	24	1050	Yes/1090	No
	90	0	65	420	50	800	45	1050	No	Yes/480
	98	0	43	435	45	790	45	1060	No	Yes/900

Table 6 Resolution of hypothetical subject P_P

Subject	Event	Time Interval	QoL
PPD	0	(0, 425]	80
	0	(425, 790]	75
	0	(790, 1050]	65
	0	(1050, 1090]	24

Subject P_P will be censored at day 1090.

Table 7 Resolution of hypothetical subject P_P

Subject	Event	Time Interval	QoL
PPD	0	(0, 420]	90
	1	(420, 480]	65

Subject P_P had the HZ episode on day 480. The QoL assessment on day 420 is considered as leading to the HZ episode. The subsequent QoL assessments will not be included in the analysis.

Table 8 Resolution of hypothetical subject P_P

Subject	Event	Time Interval	QoL
PPD	0	(0, 435]	98
	0	(435, 790]	43
	1	(790, 900]	45

Subject P_P had the HZ episode on day 900. The QoL assessment on day 790 is considered as leading to the HZ episode. The subsequent QoL assessment at day 1060 will not be included in the analysis.

7.5. Handling of missing data

7.5.1. Demography

For a given subject and a given demographic variable, the missing measurement will not be replaced except for age.

7.5.2. Quality of Life data

If any item of the SF-36 or EQ-5D is missing it will not be imputed.

7.6. Number of Decimals

The following decimal description from the decision rules will be used for the demography, QoL and safety/reactogenicity analysis.

Display Table	Parameters	Number of decimal digits
Demographic characteristics	Mean, median age	1
Demographic characteristics	SD (age)	2
QoL	SF-36 Components, including LL & UL of CI	2
	EQ-5D Utility Scores, including LL & UL of CI	3
	EQ-5D VAS Scores, including LL & UL of CI	1
Reactogenicity	Mean, Min, Q1, Median, Q3, Max for duration	1
All summaries	% of count, including LL & UL of CI	1
All summaries	% of difference, including LL & UL of CI	2
Efficacy	VE, including LL & UL of CI	2
	IR	2
	T, T/N	1
	p-value	4

8. CONDUCT OF ANALYSES**8.1. Sequence of analyses**

Description	Analysis ID	Disclosure Purpose	Reference for TFL
End of study analysis	E1_01	CTRS, Study report	All tables identified as TFL

8.2. Statistical considerations for interim analyses

No interim analysis is planned.

9. CHANGES FROM PLANNED ANALYSES

- In the protocol the following secondary objective was intended for baseline only:
 - To present the distribution of *SF-36* and *EQ-5D* scores in subjects included in ZOSTER-006 and ZOSTER-022 at baseline by country to allow comparison with normative values for those questionnaires in the general population of the countries participating in the study.
 - In order to align with the corresponding endpoint, the analysis will be performed at baseline, Months 14, 26 and 38 by country and gender
- The definition of the TVC, mTVC and ATP cohorts have been clarified. In order to minimize bias it was decided that only subjects belonging to centres that participate in ZOSTER-064 will be included. Subjects with data already encoded as part of the ZOSTER-006 or ZOSTER-022 studies will be excluded if the centre to which they belong did not take part in the ZOSTER-064.
- SAEs and pIMDs will not be described in detail as no new safety data was collected in ZOSTER-064 and all SAEs and pIMDs were described in detail in the ZOSTER-006 and ZOSTER-022 CSRs
- Due to the large number of QoL tables generated as a result of the planned analysis by various categories, the key summary tables will be presented as post-text tables in the CSR and more detailed tables will be presented separately in an Annex

10. REFERENCES

Mitnitski AB, Mogilner AJ, Rockwood K. Accumulation of deficits as a proxy measure of aging. Sci World J. 2001; 1: 323-36.

Statistical Analysis Plan



Study alias & e-track number(s): ZOSTER-064 (204878)

Detailed Title:	Observational study to assess frailty of subjects during ZOSTER-006 and ZOSTER-022 and HZ efficacy, immunogenicity and safety of HZ/su by frailty status
SAP version:	Final
SAP date:	27-NOV-2018
Scope:	All data pertaining to the above study.
Co-ordinating author:	PPD [REDACTED] (Value Evidence)
Other author(s):	PPD [REDACTED] (Clinical STAT)
Reviewers:	PPD [REDACTED] (Lead stat analyst) PPD [REDACTED] (CRDL) PPD [REDACTED] (CEPL)
Approved by:	PPD [REDACTED] (Director, Value Evidence) PPD [REDACTED] (Lead Statistician), PPD [REDACTED] (Lead Sc writer), PPD [REDACTED] (CRDL)

Statistical Analysis Plan	
Study alias & e-track number(s): ZOSTER-064 (204878)	

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Statistical Analysis Plan



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The complete statistical analysis plan and results presentation is divided into 2 parts: the first part detailing the analyses to be performed (known as SAP, current document) and a second part, annex (-es) (called TFL) describing the flow and format of tables, figures and listings to be annexed to the CSR.

LIST OF ABBREVIATIONS

AE	Adverse Event
ATP	According-To-Protocol
AUC	Area Under Curve
CI	Confidence Interval
CMI	Cellular-Mediated Immunogenicity
CRF	Case Report Form
CTRS	Clinical Trial Registry
Eli Type	Internal GSK database code for type of elimination code
EQ-5D	Euro-QoL 5 Dimension
GSK	GlaxoSmithKline
LL	Lower Limit of the confidence interval
LSMEANS	Least Squares Means
MAR	Missing at Random
MedDRA	Medical Dictionary for Regulatory Activities
mTVC	Modified Total Vaccinated Cohort
SAE	Serious Adverse Event
PBMC	Peripheral Blood Mononuclear Cell Processing
pIMD	potential Immune Mediated Diseases
PROC Phreg	SAS Procedure: Proportional Hazards Regression
QOL	Quality of Life
SAP	Statistical Analysis Plan
SBIR	GSK Biological's Internet Randomization System
SD	Standard Deviation
SE	Standard Error

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SF-36	Short Form – 36
TTO	Time Trade Off
TVC	Total Vaccinated Cohort
VAS	Visual Analogue Scale
YOA	Years of Age
ZBPI	Zoster Brief Pain Inventory

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Study alias & e-track number(s): ZOSTER-064 (204878)

1. DOCUMENT HISTORY

Date	Description	Protocol Version
27-NOV-2018	Final	Amendment 1 17-OCT-2018

2. STUDY DESIGN

This is a retrospective, observational study, in which pooled data from the ZOSTER-006 and ZOSTER-022 will be analysed. As a consequence no new subjects will be enrolled in this study and no new ICF will be required from study subjects. In ZOSTER-006 and ZOSTER-022, encoding of QoL questionnaires (*SF-36*, *EQ-5D*) was only performed for subjects who developed a suspected HZ episode during the study. This was done to assess the QoL of subjects who developed suspected cases of HZ between the vaccine group and the placebo group. The remaining study subjects who did not develop suspected cases of HZ completed the questionnaires; however, these questionnaires were never encoded or analysed as part of ZOSTER-006 and ZOSTER-022. The remaining questionnaires will be encoded in ZOSTER 064. These questionnaires will be used, in association with already encoded medical history from each subject, to derive a frailty index and thus assign each subject to a baseline frailty status (non-frail, pre-frail, frail, missing). This will allow efficacy, safety and immunogenicity data to be re-analysed according to frailty status.

The following group names will be used for the statistical analyses:

Group order in tables	Group label in tables	Group definition for footnote
1	HZ/su	Herpes Zoster subunit vaccine
2	Placebo	Placebo

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The following sub-groups will be used for the statistical analysis:

Table 1 Details of subgroups

Sub-group category	Sub-group order in tables	Sub-group label in tables	Sub-group definition for footnote
Frailty Status	1	Non-Frail	Subjects with frailty index ≤ 0.08 are considered as Non frail
	2	Pre-Frail	Subjects with frailty index > 0.08 and ≤ 0.25 are considered as pre fail
	3	Frail	Subjects with frailty index > 0.25 are considered as frail
	4	Missing	Subjects who were not assigned a Frailty category
Gender	1	Male	Male Subjects
	2	Female	Female Subjects

Table 2 Details of age and region subgroups

Analysis by age group

Sub-group order in tables	Sub-group label in tables	Sub-group definition for footnote	Pooled Groups 1 label in tables	Pooled Groups 2 label in tables
1	50-59YOA	50-59 years old subjects	50-59YOA	< 70 YOA
2	60-69YOA	60-69 years old subjects	60-69YOA	< 70 YOA
3	70-79YOA	70-79 years old subjects	70-79YOA	≥ 70 YOA
4	80-89YOA	80-89 years old subjects	≥ 80 YOA	≥ 70 YOA
5	≥ 90 YOA	≥ 90 years old subjects	≥ 80 YOA	≥ 70 YOA

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Analysis by country/region

Sub-group order in tables	Sub-group label in tables	Sub-group definition for footnote	Pooled Groups label in tables
1	CZ	Czechia	Europe
2	EN	Estonia	Europe
3	FI	Finland	Europe
4	FR	France	Europe
5	GE	Germany	Europe
6	IT	Italy	Europe
7	SP	Spain	Europe
8	SW	Sweden	Europe
9	UK	United Kingdom	Europe
10	AS	Australia	Australasia
11	HK	Hong Kong	Australasia
12	JA	Japan	Australasia
13	SK	South Korea	Australasia
14	TW	Taiwan	Australasia
15	BR	Brazil	Latin America
16	MX	Mexico	Latin America
17	US	United States	North America
18	CA	Canada	North America

3. OBJECTIVES

3.1. Primary objective

To assess the baseline frailty of subjects enrolled in ZOSTER-006 and ZOSTER-022.

3.2. Secondary objectives

- To present the distribution of *SF-36* and *EQ-5D* scores in subjects included in ZOSTER-006 and ZOSTER-022 at baseline by country to allow comparison with normative values for those questionnaires in the general population of the countries participating in the study.
- To assess vaccine efficacy against HZ by frailty status.
- To assess HZ burden of illness (BOI) by frailty status.
- To identify predictive factors for individuals developing HZ.
- To describe safety per frailty status.
- To assess humoral immunogenicity by frailty status.

Tertiary

- To describe CMI by frailty status of subjects enrolled in ZOSTER-006 only.

4. ENDPOINTS

4.1. Primary endpoint

- Baseline Frailty Status.
 - Frailty Status pre-vaccination dose 1 as defined by responses to components of the *SF-36* and *EQ-5D* questionnaire at vaccination day 0 and the subjects coded medical history.

4.2. Secondary endpoints

- *SF-36* and *EQ-5D* scale scores.
 - At months 0, 14, 26 and 38.
- Confirmed HZ cases.
 - Incidence of HZ cases during ZOSTER-006 and ZOSTER-022 for subjects in the modified Total Vaccinated Cohort (mTVC).

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- HZ Burden of Illness.
 - HZ Burden of Illness score for subjects in both ZOSTER-006 and ZOSTER-022 as calculated from the Zoster Brief Pain Inventory (ZBPI)
- Solicited local and general symptoms from ZOSTER-006 and ZOSTER-022:
 - Occurrence, intensity of each solicited local symptom within 7 days (Days 0-6) after each vaccination, in subjects included in the 7-day diary card subset;
 - Occurrence, intensity and relationship to vaccination of each solicited general symptom within 7 days (Days 0-6) after each vaccination, in subjects included in the 7-day diary card subset.
- Unsolicited adverse events (AEs) from ZOSTER-006 and ZOSTER-022:
 - Occurrence, intensity and relationship to vaccination of unsolicited AEs during 30 days (Days 0 - 29) after each vaccination, according to the Medical Dictionary for Regulatory Activities (MedDRA) classification in all subjects.
- Serious Adverse Events (SAEs) from ZOSTER-006 and ZOSTER-022.
 - Occurrence and relationship to vaccination of all SAEs from Month 0 to Month 14 in all subjects;
 - Occurrence of SAEs related to study participation or to a concurrent GSK medication/vaccine during the entire study period in all subjects;
 - Occurrence of any fatal SAEs during the entire study period in all subjects.
- Occurrence of pre-defined AEs
 - Occurrence and relationship to vaccination of any pIMDs during the entire study period in all subjects.
- Humoral Immunogenicity of the study vaccine in subset of subjects from ZOSTER-006 and ZOSTER-022.
 - Anti-gE and anti-VZV Ab concentrations as determined by Enzyme-linked Immunosorbent Assay (ELISA), in a subset of subjects at Months 0, 3, 14, 26 and 38.

4.3. Tertiary endpoints

- Cell-mediated immunogenicity (CMI) of the study vaccine in subsets of subjects from ZOSTER-006 only.
 - CMI in terms of frequencies of antigen-specific CD4 T cells at Months 0, 3, 14, 26 and 38
 - Frequencies of CD4 T cells with antigen-specific Interferon gamma (IFN- γ) and/or Interleukin-2 (IL-2) and/or Tumour Necrosis Factor alpha (TNF- α) and/or CD40 Ligand (CD40L) secretion/expression to glycoprotein E (gE) and VZV as determined by intracellular cytokine staining in a subset of subjects at Months 0, 3, 14, 26 and 38.

5. STUDY POPULATION

5.1. Total Vaccinated cohort - ZOSTER-006 and ZOSTER-022

This cohort corresponds to the 29305 subjects of the total vaccinated cohort (TVC) in either the ZOSTER-006 or ZOSTER-022 studies.

5.2. Total Vaccinated cohort - ZOSTER-064

The TVC for ZOSTER-064 will include subjects in the TVC - ZOSTER-006 and ZOSTER-022 but excludes those subjects from centres that did not participate in the ZOSTER-064. All subjects who had a HZ suspected case in either the ZOSTER-006 or ZOSTER-022 studies are included in this cohort as their QoL data has already been entered in the database as part of these studies.

5.3. Total Vaccinated cohort - diary card subset

The TVC diary card subset for analysis of reactogenicity will include all subjects in the TVC ZOSTER-064 who were also included in the diary card subset in either the ZOSTER-006 or ZOSTER-022 studies.

5.4. Modified Total Vaccinated cohort - ZOSTER-006 and ZOSTER-022

This cohort corresponds to the mTVC of the ZOSTER-006 and ZOSTER-022 studies. The difference from the TVC ZOSTER-006 and ZOSTER-022 is that subjects who were not administered the second vaccination or who developed a confirmed case of HZ prior to 1 month after the second vaccination are excluded.

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5.5. Modified Total Vaccinated cohort - ZOSTER-064

The mTVC for ZOSTER-064 will include subjects in the mTVC in the ZOSTER-006 and ZOSTER-022 studies but excludes all subjects from centres that did not participate in the ZOSTER-064. In contrast to the definition of total vaccinated cohort ZOSTER-064 subjects who had a suspected case of HZ in either the ZOSTER-006 or ZOSTER-022 studies, will be removed from the cohort if they belong to a centre not participating in ZOSTER-064.

5.6. According-To-Protocol cohort for analysis of immunogenicity

The ATP cohort for analysis of immunogenicity will consist of all subjects in the ATP cohort for analysis of immunogenicity in either the ZOSTER-006 or ZOSTER-022 studies who are also part of the TVC-ZOSTER-064 as described above.

The adapted ATP cohort for immunogenicity will similarly consist of all subjects in this cohort in either the ZOSTER 006 or ZOSTER 022 studies who are also part of the TVC-ZOSTER-064.

For the analysis of humoral immunogenicity, ATP cohort is further defined as ATP cohort for immunogenicity – Humoral.

Similarly, for the analysis of cell mediated immunogenicity, ATP cohort is further defined as ATP cohort for immunogenicity – CMI.

6. STATISTICAL METHODS

6.1. Analysis of demographics/baseline characteristics

The distribution of subjects across the study sites and country will be tabulated. The number of subjects with data encoded and the number of subjects who were expected to have data encoded will be tabulated by center. The resulting percentage will provide an encoding compliance rate. This analysis will be performed on the TVC ZOSTER-006 and ZOSTER-022.

Demographic characteristics (age at first vaccination, gender, race, geographic ancestry and ethnicity) of each study cohort will be tabulated overall.

The mean age (including range and standard deviation) of subjects will be calculated overall, by vaccination group and by frailty status.

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The distribution of subjects included in the study across sites will be tabulated overall and per vaccine group.

Frequency tables will be generated for categorical variables such as gender.

Mean, median and standard deviation will be provided for continuous data such as age.

No inferential analyses of demographic data or baseline characteristics are planned.

6.2. Primary Objective

6.2.1. Analysis of Frailty Status

The primary analysis will be based on the TVC – ZOSTER-064.

The number of subjects in each frailty category will be presented by pooled age categories 1 and 2 as detailed in [Table 2](#). The number of subjects in each frailty category will also be presented by country.

Demographic characteristics will be presented by frailty status.

Details of the assignment of subjects to frailty categories are presented in section [7.1](#).

6.3. Secondary Objectives

6.3.1. SF-36 and EQ-5D

The quality of life questionnaires to be analysed in this study are the SF-36 and EQ-5D. The SF-36 health survey and the EQ-5D questionnaires were to be completed by all subjects at Months 0, 14, 26 and 38.

Summary statistics of each of the 8 components of the SF-36 Questionnaire (Physical Functioning, Role Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional and Mental Health) and the EQ-5D Utility and VAS scores will be presented at each scheduled visit by country, gender, age group and overall. The EQ-5D utility will be based on country specific Time Trade-off (TTO) values for the analysis by country. The UK TTO will be used for countries for which there is no specific TTO.

Presenting the data by country will allow for comparison with normative values for those questionnaires in the general population of the countries participating in the study

This analysis will be based on the TVC ZOSTER-064.

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6.3.1.1. Analysis of Completion of SF-36 and EQ-5D

The number of questionnaires encoded and evaluable will be tabulated by center and country and overall. A questionnaire will be considered evaluable if it has a full completion date.

% Completion will be defined for each time point as follows:

$$\% \text{ Completion} = 100 \times N1 / N2$$

Where:

N1 = number of subjects with a completed and newly encoded SF-36/EQ-5D questionnaire.

N2 = number of subjects for whom a questionnaire was expected, i.e. every subject in the TVC ZOSTER-006 and ZOSTER-022 with the exception the subjects who had a suspected HZ episode in either the ZOSTER-006 or ZOSTER-022

Compliance with completion of QoL questionnaires will also be summarized by country at each time point (Months 0, 14, 26 and 38). This compliance will be presented for the TVC ZOSTER-064 and will include in the calculation both newly encoded and previously encoded questionnaires.

6.3.2. Vaccine efficacy by frailty status

The vaccine efficacy (VE) of the combined ZOSTER-006 and ZOSTER-022 studies will be based on the mTVC ZOSTER-064 and will be stratified by frailty status.

The overall VE estimate will be obtained from the model that is stratified by the 3 frailty strata. The VE will also be estimated separately for each individual frailty strata, with the same model being run using only the data pertaining to the strata under consideration.

Further details of the model used to calculate the VE is contained in the statistical analysis plans (SAPs) for the ZOSTER-006 and ZOSTER-022 studies.

6.3.3. HZ Burden of illness by frailty status

The pooled HZ burden of illness scores from the ZOSTER-006 and ZOSTER-022 studies will be presented by frailty category.

The number of subjects with a confirmed zoster episode, the mean burden of illness scores and the total follow-up time will be presented by Frailty category and vaccination group. The burden of illness vaccine efficacy and 95% confidence intervals will be presented by frailty category. This analysis will be carried out for subjects in the mTVC – ZOSTER 064.

6.3.4. Predictive factors for subjects developing HZ

A Cox regression model allowing for time-dependent covariates will be fitted to identify which factors are predictive of developing HZ. The model will include time to HZ as the outcome variable, the demographic variables age and gender and the time dependent *SF-36* variables and *EQ-5D* variables as potential predictors. This analysis will be performed for subjects in the Placebo group in the mTVC- ZOSTER 064.

In addition, all subjects from centres who had a poor compliance in encoding data from the ZOSTER-006 and ZOSTER-022 studies will not be included. If a centre encoded less than 50 % of the available data then all subjects, including those who had a HZ suspected case in either the ZOSTER-006 or ZOSTER-022, belonging to that centre will be removed from the mTVC for the purposes of this analysis.

Subjects who did not develop HZ will be censored at the time of their last study visit. The regression model will be used for both minimally adjusted analyses and multivariate analyses. All factors will initially be examined in an age- and gender-adjusted model with stratification for the clinical trial. Factors will be included in the multivariate model if they are associated ($P < 0.05$ using a two-sided Wald test) with HZ in the minimally adjusted model. The multivariate model will also include age and gender with stratification for the clinical trial (i.e. ZOSTER-006 and ZOSTER-022). A step-down (backward) variable selection procedure will be used to fit the final multivariate model. This model will be fitted using the PHREG procedure of the *SAS/STAT* package.

The parameter estimates and standard error of each SF-36 and EQ-5D parameter from the minimally adjusted model will be presented. The final multivariate model will also be presented.

The analysis will be performed with the event defined as a HZ confirmed case. Three separate analyses will be performed examining the impact of excluding suspected but not confirmed cases.

The first analysis will exclude subjects who had a suspected case that was later proven not to be a HZ episode.

The second analysis will include all subjects. Those subjects who had a suspected case that was later proven not to be a HZ episode will be censored at their latest available assessment and will be considered not to have had the event.

The third analysis will also include all subjects. The definition of event will be changed to having a suspected case of HZ.

Details of the process behind the inclusion of time dependent covariates are included in section [7.4](#)

6.3.5. Analysis of safety by frailty status

The safety analysis will be based on the TVC – ZOSTER-064. The analysis of Reactogenicity will be based on the TVC – ZOSTER 064 diary card subset.

All safety analyses will be categorised by frailty status.

The following analyses will be performed for safety endpoints:

- The percentage of subjects with at least one local solicited AE, with at least one general solicited AE and with any solicited AE during the solicited 7-day follow-up period will be tabulated with exact 95% CI after each vaccine dose and overall. The same tabulation will be performed for grade 3; related and grade 3 related AEs;
- The percentage of subjects with at least one local AE (solicited and unsolicited), with at least one general adverse event (solicited and unsolicited) and with any AE during the solicited 7-day follow-up period will be tabulated with exact 95% CI after each vaccine dose and overall. The same tabulation will be performed for grade 3, related and grade 3 related AEs;
- The percentage of subjects reporting each individual solicited local and general AE during the solicited 7-day-follow-up period will be tabulated with exact 95% CI. For all solicited symptoms, the same tabulation will be performed for grade 3 solicited AEs and for solicited general AEs with relationship to vaccination;
- Summary of temperature value by half degree increment reported during the 7-day (Days 0-6) post-vaccination period following each dose and overall doses and subjects. The same tabulation for fever with relationship to vaccination will be done;
- The number of days with each individual solicited local and general AE during **the solicited** 7-day follow-up period will be tabulated;

- The percentage of subjects with at least one local solicited AE, with at least one general solicited AE and with any solicited AE reported during the solicited 7-day follow-up period and **lasting beyond this period** will be tabulated with exact 95% CI after each vaccine dose and overall. The same tabulation will be performed for grade 3;
- The percentage of subjects with each individual solicited local and general symptoms **ongoing beyond the 7-day follow-up period** will be tabulated. The same tabulation will be performed for grade 3;
- The percentage of subjects with at least one report of unsolicited AE classified by the MedDRA Preferred Terms and reported up to 30 days after each vaccination will be tabulated with exact 95% CI. The same tabulation will be performed for grade 3 unsolicited AEs and for unsolicited AEs with a relationship to vaccination.
- Total number/percentages of doses followed by AEs will be tabulated;
- SAEs will be described in detail;
- The percentage of subjects with at least one report of serious adverse event classified by the MedDRA Preferred Terms and reported during the whole post-vaccination follow up period will be tabulated with exact 95% CI;
- pIMDs will be described in detail.
- The proportion of subjects with at least one report of pIMDs classified by the MedDRA Preferred Terms and reported during the whole post-vaccination period (from dose 1 up to study end) will be tabulated with exact 95% CI.

6.3.6. Analysis of immunogenicity by Frailty status

The analysis of immunogenicity will be categorised by vaccination group and frailty status. The primary analysis will be based on the ATP cohort for analysis of immunogenicity – ZOSTER064.

6.3.6.1. Cell-mediated immune response

Cell-mediated immune response will be assessed and analysed in the ATP cohort for analysis of immunogenicity – CMI.

The CMI analyses was performed for ZOSTER-006 only in the Immunogenicity subset in three countries (Czech Republic, Japan and United States) at designated sites that had access to a PBMC processing facility within the acceptable time window from sample collection to PBMC processing. The CMI subset contained approximately 350 subjects. We are expecting some attrition of data, i.e. some centres who took part in the ZOSTER-006 may not take part in the ZOSTER-064. In addition, we are expecting that approximately 5% of subjects will be classified as frail. As a consequence, the analysis of CMI by frailty status will only be carried out if we have a minimum of 20 CMI subjects classified as frail.

6.3.6.2. Descriptive statistics

For CMI response, the following parameters (for gE and VZV specific CD4[2+] frequency and CD4[+2] T-cell following induction with gE and VZV) will be tabulated by vaccination group, overall and by frailty status at Months 0, 3, 14, 26 and 38:

- descriptive statistics of the frequency of CD4 T-cell secreting at least two different cytokines (IFN- γ , IL-2, TNF- α , CD40L) to both VZV and gE antigens;
- descriptive statistics of the frequency of CD4 T-cell secreting at least IFN- γ and another cytokine (IL-2, TNF- α , CD40L) to both VZV and gE antigens;
- descriptive statistics of the frequency of CD4 T-cell secreting at least IL-2 and another cytokine (IFN- γ , TNF- α , CD40L) to both VZV and gE antigens;
- descriptive statistics of the frequency of CD4 T-cell secreting at least TNF- α and another cytokine (IFN- γ , IL-2, CD40L) to both VZV and gE antigens;
- descriptive statistics of the frequency of CD4 T-cell secreting at least CD40L and another cytokine (IFN- γ , IL-2, TNF- α) to both VZV and gE antigens;
- Vaccine response rate with exact 95% CI at Months 3, 14, 26 and 38 (only in the gE-specific CD4[2+] T-cell frequency at Months 3, 14, 26 and 38)

6.3.6.3. Inferential Analyses

No inferential analysis will be carried out on the CMI data.

6.3.6.4. Humoral immune response

Humoral immune response will be assessed and analysed in the ATP cohort for analysis of immunogenicity – Humoral.

6.3.6.5. Descriptive statistics

For the humoral immune response, at each timepoint that a blood sample is available (Months 0, 3, 14, 26 and 38), the following parameters (with 95% CIs) will be tabulated by vaccination group and frailty status:

- Geometric mean concentrations (GMCs) of anti-gE Ab with 95% confidence interval (CIs);
- Humoral seropositivity rates with exact 95% confidence interval (CIs);
- Vaccine response rates with 95% confidence interval (CIs);

6.3.6.6. Inferential Analyses

No inferential analysis will be carried out on the humoral immune response data.

7. STATISTICAL CALCULATIONS

7.1. Derived and transformed data

7.1.1. Demography

Age at vaccination

Age will be calculated as the number of years between the date of birth and the date of first vaccination.

To ensure that the collection of date of birth will not jeopardise the privacy of Personally Identifiable Information (PII), only a partial date of birth (MMYYYY) was collected.

Therefore, the 15th of the month will be used to replace the missing date.

In case the month is missing, the date will be replaced by the June 30th of the year.

Note that due to incomplete date, the derived age may be incorrect by 1 month when month is missing from the birthdate. This may lead to apparent inconsistency between the derived age and the eligibility criteria/the age category used for randomization.

7.1.2. Efficacy data

Details of derived and transformed efficacy data including the methodology behind the VE is contained in the SAPs for the ZOSTER-006 and ZOSTER-022 studies.

7.1.3. Safety

Details of derived and transformed safety data is contained in the SAPs for the ZOSTER-006 and ZOSTER-022 studies.

7.1.4. Immunogenicity**7.1.4.1. Humoral immune response**

Full details of the methods used in the humoral immune response analyses are contained in the ZOSTER-006 and ZOSTER-022 SAPs (Demog, Safety, Immuno)

7.1.4.2. Cellular-mediated immune (CMI) response

Full details of the methods used in the CMI analysis including calculation of the frequency of antigen-specific (gE or VZV) CD4[2+] T cells for each individual subject and the definition of CMI vaccine response to gE and VZV are contained in the ZOSTER-006 SAP (Demog, Safety, Immuno)

7.2. Quality of Life data**7.2.1. SF-36 and EQ-5D**

Details of the derivation of the 8 scales generated from the SF-36 and the derivation of the utility score from the EQ-5D are contained in the quality of life (QoL) SAPs for the ZOSTER-006 and ZOSTER-022 studies.

7.2.2. HZ Burden of illness

The HZ burden of illness scores are based on the ZBPI questionnaire already encoded in the ZOSTER-006 and ZOSTER-022 studies.

Full details of the ZBPI questionnaire and the methodology behind the calculation of the HZ burden of illness scores are contained in the statistical analysis plans (QoL) for the ZOSTER-006 and ZOSTER-022 studies.

7.3. Frailty Index

Frailty status will be measured in relation to the accumulation of deficits using a frailty index (FI) adapted from the model proposed by Mitnitski et al. [[Mitnitski](#), 2001]. The different aspects of frailty composing the frailty index will be assessed through the medical history and components of the *SF-36* and *EQ-5D* questionnaires recorded pre-vaccination Dose 1.

The total frailty score will be between 0 and 41. The subject's pre-vaccination questionnaires will contribute a max score of 29 and the medical history will contribute a max score of 12. [Table 3](#) details the components of the SF-36 and EQ-5D questionnaires that contribute to the calculation of the frailty index.

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Table 3 Detail of SF-36 and EQ-5D components of frailty Index

Item	Scoring method based on response to question	Max Contribution to Frailty Index
SF-36 Q1	Poor=1, Fair=0.5 Good=0, Very good=0 Excellent=0	1
SF-36 Q11A-11D	Q11A, Q11C Definitely true=1 Mostly true=0.5 Don't know=0 Mostly false=0 Definitely false=0 Q11B, Q11D Definitely true=0 Mostly true=0 Don't know=0 Mostly false=0.5 Definitely false=1	4
SF-36 Q3I - Q3J	Limited a lot=1 Limited a little=0.5 Not limited at all=0	10
SF-36 Q9A - Q9I	Q9A, Q9D, Q9E, Q9H : All of the Time=0 Most of the time=0 Some of the time=0 A little of the time=0.5 None of the time=1 Q9B, Q9C, Q9F, Q9G, Q9I : All of the Time=1 Most of the time=0.5 Some of the time=0 A little of the time=0 None of the time=0	9
SF-36 Q2 Compared to one week before, how did the subject rate his / her health in general?	Much worse=1, Somewhat worse=0.5, Same=0 Somewhat better=0 Better=0	1
EQ-5D Mobility	No Problems=0 Some Problems=0.5 Confined to bed=1	1
EQ-5D Anxiety	No Anxiety=0 Moderate Anxiety=0.5 Extreme Anxiety=1	1
EQ-5D Self care	No Problems=0 Some Problems=0.5 Inability to wash or dress himself /herself=1	1

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Item	Scoring method based on response to question	Max Contribution to Frailty Index
EQ-5D Usual activities	No Problems=0 Some Problems=0.5 Inability to perform usual activities=1	1
Total		29

The medical history is divided into 12 categories; each category contributing a score of 0 or 1. The coded combined ZOSTER-006 and ZOSTER-022 medical history database will be searched and events that fall into any one of the 12 categories will be selected [Table 4](#) details the MedDRA terms that will be used to search the database. If a subject had any one of the listed events in a category they would be assigned a max score of 1 for that category and a max score of 12 overall.

The frailty index is then calculated by combining the accumulation of deficits into a score from 0 to 1: frailty index = (accumulation of deficits) / (41 – nmissQoL) where nmissQoL is the number of missing components of the 29 items from the SF-36 and EQ-5D questionnaires. If a subject has more than 10 missing QoL components the frailty index will not be calculated.

Each subject will then be assigned to one of three categories, Non-Frail, Pre-Frail and Frail based on the frailty index.

- If the frailty index is **less than or equal to** 0.08 then the subject is classified as Non-Frail. If the score is greater than 0.08 **but less than or equal to** 0.25 then the subject is classified as pre-frail. If the score is **greater than** 0.25 then the subject is classified as Frail. Subjects without a frailty index score will be classified as missing.

Table 4 Detail of Medical history search items

Category	MedDRA version 18 Search Terms
Cancer	Malignancy related conditions (SMQ) Malignant tumours (SMQ)
Diabetes Mellitus	Diabetes mellitus (incl subtypes) (HLT) Diabetic complications (HLGT)
High Blood Pressure,	Hypertension (SMQ)
Heart Attack	Ischaemic heart disease (SMQ)
CHF	Cardiac failure (SMQ)
Cerebrovascular Disease	Central nervous system vascular disorders (SMQ)
Arthritis	Arthritis (SMQ)
Chronic Lung Disease	Asthma/bronchospasm (SMQ) Interstitial lung disease (SMQ) Pulmonary hypertension (SMQ) Chronic Obstructive Pulmonary Disease (PT) / Infective exacerbation of chronic obstructive airways disease (PT) Bronchiectasis (PT) /Infective exacerbation of bronchiectasis (PT) Cystic fibrosis (PT)/ Cystic fibrosis lung (PT) / Infective pulmonary exacerbation of cystic fibrosis (PT) Chronic respiratory disease (PT) Chronic respiratory failure (PT)
Stomach or Intestinal Ulcers	Gastrointestinal ulceration (SMQ)
Migraine	Migraine headaches (HLT) Migraine prophylaxis (PT)
Cataract	Cataract Conditions (HLT) Cataract operation (PT) Cataract diabetic (PT) Cataract operation complication (PT)
Glaucoma	Glaucoma (SMQ)

- SMQ: Standardised MedDRA queries. HLGT: High Level Group Term. HLT: High Level Term. PT: Preferred Term

7.4. Predictive factors for individuals developing HZ

Only subjects in the placebo group will be included in the analysis of potential predictive factors. A Cox regression model allowing for time-dependent covariates will be fitted to identify which factors are predictive of developing HZ. The model will include time to HZ as the outcome variable, the demographic variables age and gender and the *SF-36* variables and *EQ-5D* variables as potential predictors.

Each EQ-5D and SF-36 assessment at a scheduled time point will be re-classified into time points based on the date of assessment relative to date of vaccination:

Studyday=date of assessment – date of vaccination.

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The study day will be time component used in the model.

Since there are a maximum of four SF-36 and EQ-5D assessment times we define the variables T_0, T_1, T_2, T_3 as the study day relative to vaccination (day 0) of the QoL assessment and $QoL_0, QoL_1, QoL_2, QoL_3$ as the values of the QoL assessment at each timepoint. The value of the time-dependent variable QoL_t is equal to QoL_0 if $0 < t \leq T_1$, QoL_1 if $T_1 < t \leq T_2$, QoL_2 if $T_2 < t \leq T_3$, with $QoL_t = QoL_3$ if $t > T_3$.

The above model is implemented in SAS as follows:

```
ODS output ParameterEstimates=PE1;
PROC PHREG DATA=tsurv;
  CLASS study gender;
  MODEL fu_time*hz_conf(0)=age study gender PFT;
  PFT=PFO;
  IF fu_time > time1 and time1 ne . then PFT=PF1;
  IF fu_time > time2 and time2 ne . then PFT=PF2;
  IF fu_time > time3 and time3 ne . then PFT=PF3;
RUN;
```

Spearman correlations coefficients will be presented to display the relationships between pairs of variables. In addition for the quality of life variables, the variance inflation factor and the condition indices for testing multicollinearity will be estimated.

Example: To illustrate the method the following hypothetical 3 subjects are examined:

Table 5 Data from hypothetical subjects to illustrate time dependent covariates

Subject	QoL0	T0	QoL1	T1	QoL2	T2	QoL3	T3	Censored /day	Event/ day
P	80	0	75	425	65	790	24	1050	Yes/1090	No
P	90	0	65	420	50	800	45	1050	No	Yes/480
D	98	0	43	435	45	790	45	1060	No	Yes/900

Table 6 Resolution of hypothetical subject 1

Subject	Event	Time Interval	QoL
P	0	(0, 425]	80
P	0	(425, 790]	75
D	0	(790, 1050]	65
	0	(1050, 1090]	24

- Subject P will be censored at day 1090.

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Table 7 Resolution of hypothetical subject 1

Subject	Event	Time Interval	QoL
P	0	(0, 420]	90
P	1	(420, 480]	65

Subject **P** had the HZ episode on day 480. The QoL assessment on day 420 is considered as leading to the HZ episode. The subsequent QoL assessments will not be included in the analysis.

Table 8 Resolution of hypothetical subject 3

Subject	Event	Time Interval	QoL
PP	0	(0, 435]	98
D	0	(435, 790]	43
	1	(790, 900]	45

Subject **P** had the HZ episode on day 900. The QoL assessment on day 790 is considered as leading to the HZ episode. The subsequent QoL assessment at day 1060 will not be included in the analysis.

7.5. Handling of missing data

7.5.1. Demography

For a given subject and a given demographic variable, the missing measurement will not be replaced except for age.

7.5.2. Quality of Life data

If any item of the SF-36 or EQ-5D is missing it will not be imputed.

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7.6. Number of Decimals

The following decimal description from the decision rules will be used for the demography, QoL and safety/reactogenicity analysis.

Display Table	Parameters	Number of decimal digits
Demographic characteristics	Mean, median age	1
Demographic characteristics	SD (age)	2
QoL	SF-36 Components, including LL & UL of CI	2
	EQ-5D Utility Scores, including LL & UL of CI	3
	EQ-5D VAS Scores, including LL & UL of CI	1
Reactogenicity	Mean, Min, Q1, Median, Q3, Max for duration	1
All summaries	% of count, including LL & UL of CI	1
All summaries	% of difference, including LL & UL of CI	2
Efficacy	VE, including LL & UL of CI	2
	IR	2
	T, T/N	1
	p-value	4

8. CONDUCT OF ANALYSES

8.1. Sequence of analyses

Description	Analysis ID	Disclosure Purpose	Reference for TFL
End of study analysis	E1_01	CTRS, Study report	All tables identified as TFL

8.2. Statistical considerations for interim analyses

No interim analysis is planned.

9. CHANGES FROM PLANNED ANALYSES

In the protocol the following secondary objective was intended for baseline only:

- To present the distribution of *SF-36* and *EQ-5D* scores in subjects included in ZOSTER-006 and ZOSTER-022 at baseline by country to allow comparison with normative values for those questionnaires in the general population of the countries participating in the study.
- In order to align with the corresponding endpoint, the analysis will be performed at baseline, months 14, 26 and 38 by country

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10. REFERENCES

Mitnitski AB, Mogilner AJ, Rockwood K. Accumulation of deficits as a proxy measure of aging. Sci World J. 2001; 1: 323-36.