paradigm8 Study/Trial ID: NN7999-4031 UTN No: U1111-1165-8657 PASS Progress report no 03

Date: Version: Status:

Final 1 of 8

01 June 2021 Novo Nordisk 1.0

PASS Progress Report no. 03

Study ID: NN7999-4031



A Non-Interventional Post-Authorisation Safety Study (PASS) in male haemophilia B patients receiving Nonacog Beta Pegol (N9-GP) prophylaxis treatment

Non-interventional post authorisation safety study (PASS)

 paradigm8
 Date:
 01 June 2021
 Novo Nordisk

 Study/Trial ID: NN7999-4031
 Version:
 1.0
 1.0

 UTN No: U1111-1165-8657
 Status:
 Final

 PASS Progress report no 03
 Page:
 2 of 8

Title page

Study ID	NN7999-4031
ClinicalTrials.gov identifier	NCT03745924
EU PAS register number	EUPAS26592
EU PAS register link	http://www.encepp.eu/encepp/viewResource.htm?id=29248
Study initiated	Actual FPFV: 01-Apr-2019
Sponsor	Novo Nordisk A/S Novo Allé 1 2880 Bagsværd Denmark
Data cut-off date	31 May 2021

61210.0

 paradigm8
 Date:
 01 June 2021
 Novo Nordisk

 Study/Trial ID: NN7999-4031
 Version:
 1.0

 UTN No: U1111-1165-8657
 Status:
 Final

 PASS Progress report no 03
 Page:
 3 of 8

Table of contents

			Page
Ti	itle pa	ge	2
		f contents	
Тa	able of	f tables	4
Та	able of	f figures	5
		sground	
2	Study	y progress	7
	2.1	Study Schedule	7
	2.2	Enrolling countries.	7
	2.3	Enrolling countries Study Progress	7
		Status	8

PulkliguRatgistrAtriogresis Respublis (RleJunla 2012)1 prasss progressis respontine da 23 de NN 7999 - 4031

paradigm8		Date:	01 June 2021	Novo Nordisk
Study/Trial ID: NN7999-4031	CONFIDENTIAL	Version:	1.0	
UTN No: U1111-1165-8657	CONFIDENTIAL	Status:	Final	
PASS Progress report no 03		Page:	4 of 8	

Table of tables

		Page	
able 2–1	Number of patients screened, treated and completed (planned and actual)	7	

PulkliguRatgiiştrAtriogræsis Ræspolut (Rle.Ljunla2012)1 ppasss pprogræsss næpponttræda03eld NN7999 -4031

paradigm8		Date:	01 June 2021	Novo Nordisk
Study/Trial ID: NN7999-4031	CONFIDENTIAL	Version:	1.0	
UTN No: U1111-1165-8657	CONFIDENTIAL	Status:	Final	
PASS Progress report no 03		Page:	5 of 8	

Table of figures

	P	age
Figure 2-1	Actual versus planned enrolment during the review period	8

PulkliguRatgistrAtiogreefs Respublis (Relanda 2024 prasss progresss reprontined a 23 d	61210.0
--	---------

paradigm8		Date:	01 June 2021 Novo Nordi	isk
Study/Trial ID: NN7999-4031	CONFIDENTIAL	Version:	1.0	
UTN No: U1111-1165-8657	CONFIDENTIAL	Status:	Final	
PASS Progress report no 03		Page:	6 of 8	

1 Background

This progress report number 03 is related to the non-interventional Post Authorisation Safety Study (NIS PASS) (NN7999-4031), which is conducted in accordance with the marketing authorisation for Refixia® (EMEA/H/C/004178) granted by the Commission Decision in June 2017.

This progress report number 03 has been prepared in agreement with the commitment as requested by PRAC assessor in the 3rd PSUR. (29th May 2019).

The cut-off for the data presented in this report is 31-May-2021.

paradigm8		Date:	01 June 2021	Novo Nordisk
Study/Trial ID: NN7999-4031 UTN No: U1111-1165-8657	CONFIDENTIAL	Version: Status:	Final	
PASS Progress report no 03		Page:	7 of 8	

2 Study progress

2.1 Study Schedule

• Planned LPLV: Q4 2027

• Planned final study report: Q2 2028

The planned timelines may be subject for adjustment during the course of the study.

2.2 Enrolling countries

The following countries are actively (have enrolled patients) participating in the study: Austria, Canada, Denmark, Germany, Norway, Portugal & United Kingdom

The following countries are participating but have not started enrolment yet: Belgium, Bulgaria, Croatia, Estonia, Latvia, Greece & Switzerland.

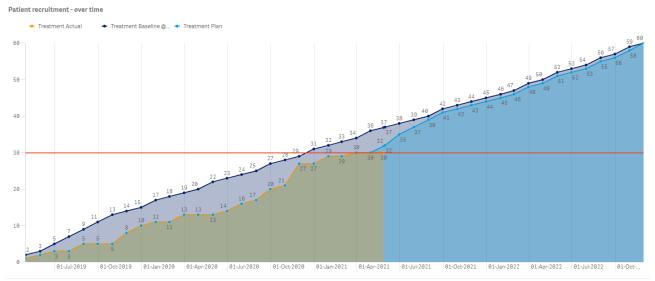
2.3 Study Progress

Table 2–1 Number of patients screened, treated and completed (planned and actual)

	Planned in	Actual in	Planned	Actual	Planned	Actual
	Trial	Trial	Treated	Treated	Completed	Completed
Total	70	30	60	30	50	0

Out of the 30 patients treated in the study so far, 1 patient has withdrawn from study before completing 4 years in study. The reason for withdrawal for this patient was "withdrawal of consent by patient" – no further reason was provided.

Figure 2-1 Actual versus planned enrolment during the review period



2.4 Status

paradigm8

Study/Trial ID: NN7999-4031

UTN No: U1111-1165-8657

PASS Progress report no 03

Within the last 6 months the study enrolment has been slightly lower than planned. Study enrolment is expected to recover again within the coming year and end of study enrolment (LPFV) is still planned for November 2022. Therefore, Novo Nordisk is of the opinion that the study is progressing according to plan.