14 December 2020 | Novo Nordisk 1.0

Final

1 of 8

PASS Progress Report

Study ID: NN7999-4031

paradigm8

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:	14 December 2020	Novo Nordisk
Study/Trial ID: NN7999-4031	Version:	1.0	
UTN No: U1111-1165-8657	Status:	Final	
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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	01 December 2020

paradigm8	Date:	14 December 2020	Novo Nordisk
Study/Trial ID: NN7999-4031	Version:	1.0	
UTN No: U1111-1165-8657	Status:	Final	
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paradigm8	Date: 14 December 2	2020 Novo Nordisk
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1 Background

This progress report number 2 of 2 is related to the Post Authorisation Safety Study (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 2 of 2 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 the report is 01-Dec-2020.

paradigm8	Date:	14 December 2020	Novo Nordisk
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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 participating in the study: Austria, Canada, Denmark, Germany, Portugal & United Kingdom

The following countries are participating but have not started enrolment yet: Belgium, Greece, The Netherlands, Norway, Spain, Sweden & Switzerland.

2.3 Study Progress

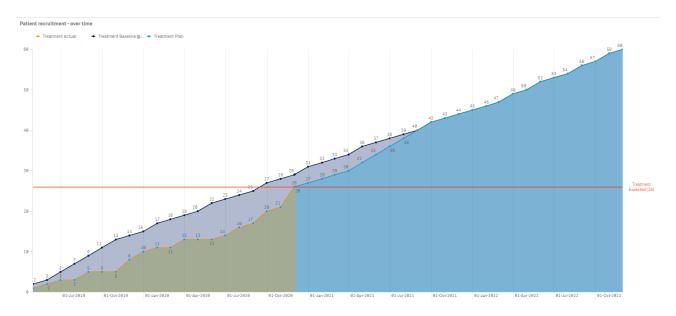
Table 2-1 Number of patients screened, treated and completed (planned and actual)

	Planned in	Actual in	Planned	Actual	Planned	Actual
	Trial	Trial	Treated	Treated	Completed	Completed
Total	70	26	60	26	50	0

Out of the 26 patients actually treated in the study, 1 patient has withdrawn from study before completing 4 years in study.

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



2.4 Status

The study is progressing according to the plan.