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)

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

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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.

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.

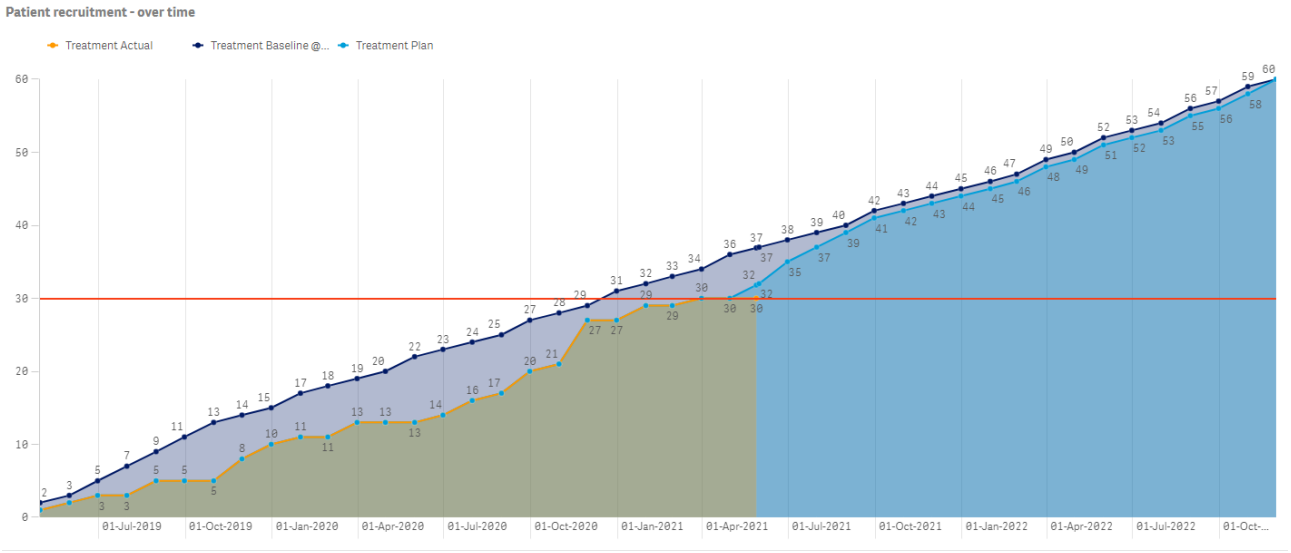
2.3 Study Progress

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

	Planned in Trial	Actual in Trial	Planned Treated	Actual Treated	Planned Completed	Actual 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Out of the 30 patients treated in the study so far, 1 patient has withdrawn from study before completing 4 years in study.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

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.