PASS Progress Report no. 2

Study ID: NN7088-4029

pathfinder9

A multinational, prospective, open labelled, non-controlled, non-interventional post-authorisation study of turoctocog alfa pegol (N8-GP) during long-term routine prophylaxis and treatment of bleeding episodes in patients with haemophilia A

Non-interventional post authorisation safety study (PASS)

Title page

Study ID	NN7088-4029
ClinicalTrials.gov identifier	NCT04574076
EU PAS register number	EUPAS36536
EU PAS register link	http://www.encepp.eu/encepp/viewResource.htm?id=39327
Study initiated	Actual first patient first visit (FPFV): 23 October 2020
Sponsor	Novo Nordisk A/S Novo Allé DK-2880 Bagsværd Denmark Novo Nordisk
Data cut-off date	21 October 2022

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1 Background

This progress report number 02 relates to the Non-interventional Post Authorisation Safety Study (NIS PASS) NN7088-4029 /pathfinder9 being conducted per commitment to EMA to gain additional knowledge on the safety of Esperoct®/N8-GP in patients with haemophilia A after longer-term treatment and to evaluate possible clinical consequences hereof under observational ('real-world') conditions of local clinical practice.
This study is being conducted in accordance with the marketing authorisation for Esperoct® (EMEA/H/C/4883) granted by the Commission Decision on 20 June-2019.

The cut-off date for the data presented in this report is 21 October 2022.

2 Study progress

2.1 Study Schedule

The pathfinder9 study (NN7088-4029) started on 23rd October 2020 when the first patient was enrolled into the study.

The planned major milestones for the study are listed below:

- Planned last patient first visit (end of study enrolment): 03 June 2022
- Planned data cut date for interim analysis: 23 April 2023
- Planned last patient last visit: 03 June 2027
- Planned end of data collection (Defined as Data base Lock): 19 July 2027
- Planned final study report: 31-Dec-2027

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 participants) participating in the study: Austria, Croatia, Czech Republic, Estonia, Germany, Greece, Hungary, Italy, Lithuania, Portugal, Slovakia, Slovenia, Spain, and Switzerland.

2.3 Study Progress

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

	Planned in study	Actual in study	Planned Treated in study	Actual Treated in study	Planned Completed	Actual Completed
Total	70	71	60	71	50	0

2.4 Status

Study recruitment has recovered and during the last 4 months before the planned end of study enrolment (Last Patient First Visit), recruitment accelerated significantly and the overall global recruitment target of 60 participants was reached 2 weeks ahead of schedule. As per agreement with the participating countries and within the project, study recruitment was kept open until the planned Last Patient First Visit date of 03 June 2022. This enabled countries to honour agreements with recently opened sites. At the end of study enrolment on the 03 June 2022, 71 participants were included in the study. One participant has withdrawn and with the extra included participants, it is expected to fulfil the commitment of having 5 years with 50 participants. Novo Nordisk is of the overall opinion that the study is progressing according to plan.