PASS Progress Report no. 1

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	ANCT04574076
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 DenmarkNovo Nordisk
Data cut-off date	23 October 2021

Table of contents

Page

Table of figures

Page

Table of tables

Page

1 Background

This progress report number 01 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 23 October 2021.

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 future 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 patients) participating in the study: Austria, Germany, Hungary, Italy, Lithuania, Slovenia and Switzerland.

The following countries are planned to participate in the study but have not started enrolment yet: Croatia, Czech Republic, Greece, Portugal, Slovakia and Spain.

The countries planned to participate may be subject for adjustment during the course of the study.

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	25	60	25	50	0

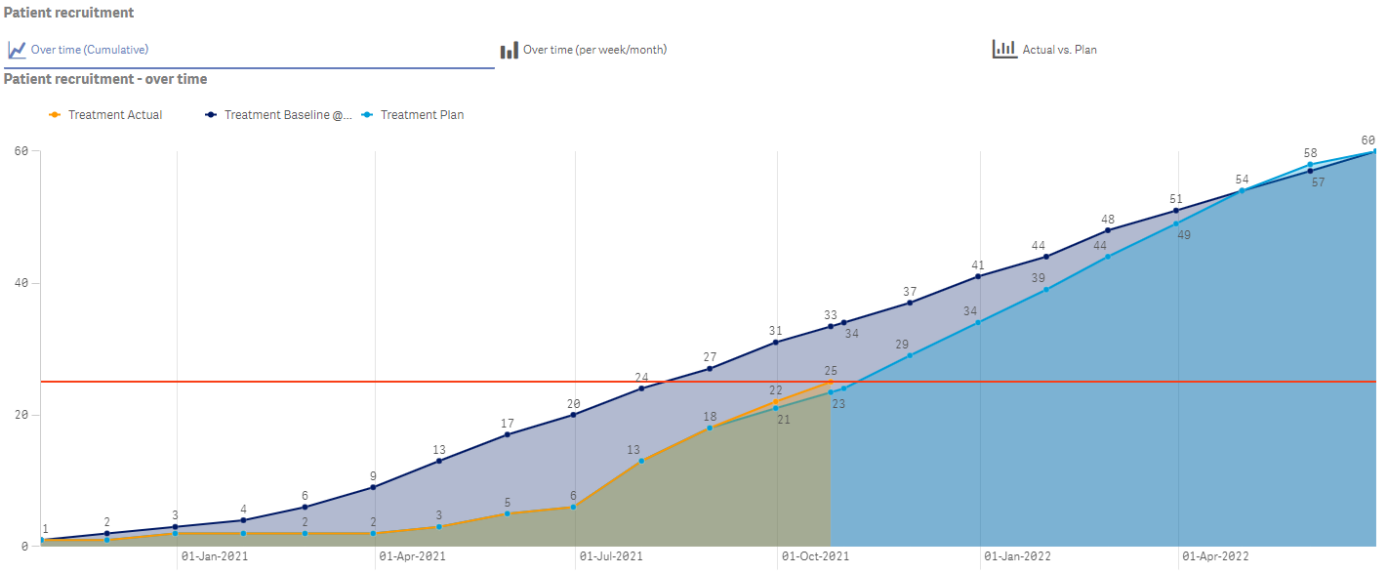

Figure 2-1 Actual versus planned enrolment during the review period

2.4 Status

During the first 8 months following study start, the enrolment of patients into the study was significantly below the planned enrolment rate. The primary reasons for the initial low enrolment rate, were the numerous negative impacts of the COVID-19 pandemic and also the fact, that the study protocol had to be amended in order for the study to be accepted as non-interventional.

Study enrolment has however recovered promisingly within the past 4 months, and end of study enrolment (last patient first visit) is still planned for June 2022. Therefore, Novo Nordisk is of the overall opinion that the study is currently progressing according to plan.