PASS Progress Report

Study ID: NN8640-4515

A multi-national, multi-centre, prospective, single-arm, observational, non-interventional post-authorisation safety study to investigate long-term safety of Sogroya® (somapacitan) in adults with growth hormone deficiency (AGHD) under routine clinical practice

Title page

Study ID	NN8640-4515
ClinicalTrials.gov identifier	NCT05718570
EU PAS register number	EUPAS104526
EU PAS register link	https://www.encepp.eu/encepp/viewResource.htm?id=104527
Study initiated	Actual FPFV: 03 February 2023
Sponsor	Novo Nordisk A/S Novo Allé DK-2880 Bagsvaerd Denmark
Data cut-off date	28 February 2023

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1 Background

This progress report no 02 of 02 is related to the Post Authorisation Safety Study (PASS) NN8640-4515 which is to be conducted in accordance with the marketing authorisation for Sogroya® (MA number: EU/1/20/1501 & Agency product number: EMEA/H/C/005030) granted by the Commission Decision on 31 March 2021.

This present progress report has been prepared in agreement with the commitment outlined by the PRAC Rapporteur in the PRAC PASS protocol assessment report adopted by the CHMP on 22 April 2022.

The cut-off for the data presented in the report is 28 February 2023.

2 Study progress

2.1 Study Schedule

The planned and actual dates are:

- Actual FPFV: 03 February 2023
- Planned LPLV: Q4 2032
- Planned final study report: Q2 2033

2.2 Enrolling countries

The following country has enrolled patients: Slovenia.

The country allocation for this study will be conducted in a rolling manner, aligned with the launch of Sogroya® for the indication of Adult Growth Hormone Deficiency in the individual countries.

As per the cut-off date for this present report, the following countries have been allocated to participate in the study: Australia, Saudi-Arabian, Brazil, Germany, Slovenia and United Kingdom.

2.3 Study Progress

Study progress is depicted in below table Table 2–1.

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

	Planned in Trial	Actual in Trial	Planned Treated	Actual exposed	Planned Completed	Actual Completed
Total	400	3	400	3	400	0

Novo Nordisk acknowledges PRAC's comment as laid forward in the PASS protocol assessment report that global recruitment is agreed and while recruitment of patients from the United States, Israel and Australia as well as other non-EU study countries is supported, an attempt should be made to recruit as many EU patients as possible for the study.

Additionally, Novo Nordisk commits to add information on patient enrolment distribution between countries participating in the PASS in each progress and interim report going forward. This information will include detailed information on the absolute number and percentage of the EU patient population.

Currently, this early in the study, an absolute number of 3 participants have been recruited in Europe (Slovenia), which is 100 percent of all recruited participants in the study.

2.4 Status

The study is progressing according to the plan.