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	Pending - study not yet registered
EU PAS register number	Pending - study not yet registered
EU PAS register link	Pending - study not yet registered
Study initiated	No - study not yet initiated. Planned study start (First Patient First Visit): 15 December 2022
Sponsor	Novo Nordisk A/S Novo Allé DK-2880 Bagsvaerd Denmark
Data cut-off date	31 August 2022

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1 Background

This progress report no 01 of 01 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 31 August 2022.

2 Study progress

2.1 Study Schedule

- Planned study start (FPFV): 15 December 2022
- Planned LPLV: Q4 2032
- Planned final study report: Q2 2033

2.2 Enrolling countries

No countries have enrolled patients into this study yet.

The country allocation for this study will be conducted in a rolling manner, aligned with the commercial 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 and Slovenia.

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	400	0	400	0	400	0

As outlined in the approved study protocol, this study is planned to start (FPFV) on 15Dec2022. Accordingly, no patients have been included in the study as per the cut-off date for this report.

Novo Nordisk acknowledges the 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.

2.4 Status

The study and study start-up is progressing as planned. Novo Nordisk expect to meet the planned study start (FPFV) date by 15 December 2022.