NN8640-4515 A multi-national, multicentre, prospective, single-arm, observational, non-interventional postauthorisation safety study to investigate long-term safety of Sogroya® (somapacitan) in adults with growth hormone deficiency (AGHD) under routine clinical practice

First published: 20/04/2023 Last updated: 23/04/2024



Ongoing

### Administrative details

**EU PAS number** 

EUPAS104526

Study ID

105300

**DARWIN EU® study** 

Study countries  Australia
☐ Brazil
Germany
Saudi Arabia
Slovenia
United Kingdom
United States

#### Study description

In this study, the general long-term safety and effectiveness of Sogroya (somapacitan) in adults with growth hormone deficiency (AGHD) being treated per normal clinical practice is looked into. In the study, information on side effects and how well Sogroya (somapacitan) works during long term treatment in people with Adult Growth Hormone Deficiency (AGHD) will be collected and analysed. Participants will be treated with Sogroya (somapacitan) as prescribed by the study doctor, in accordance with normal clinical practice. The study will last for 5-10 years, depending on when the participant join the study. The participant will be asked to complete two short questionnaires during every visit to the clinic. The questionnaires will collect information on the participant's well-being, work ability and ability to perform daily activities.

#### Study status

Ongoing

Research institutions and networks

Institutions

### **Novo Nordisk**

First published: 01/02/2024

Last updated: 01/02/2024

Institution

### Contact details

#### **Study institution contact**

Clinical Transparency (dept. 2834) Novo Nordisk A/S pactadmin@novonordisk.com

**Study contact** 

pactadmin@novonordisk.com

### **Primary lead investigator**

Clinical Transparency (dept. 2834) Novo Nordisk A/S

**Primary lead investigator** 

### Study timelines

Date when funding contract was signed

Actual: 15/02/2022

### Study start date

Actual: 03/02/2023

### Date of final study report

Planned: 15/12/2033

### Sources of funding

• Pharmaceutical company and other private sector

### More details on funding

Novo Nordisk A/S

### Study protocol

4515 16-1-01 protocol eu-pas-reg-redacted.pdf (1.08 MB)

### Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

# Other study registration identification numbers and links

U1111-1264-8642 NCT05718570

### Methodological aspects

Study type

Study type list

#### Study type:

Non-interventional study

#### Scope of the study:

Safety study (incl. comparative)

#### Main study objective:

To investigate long-term safety of Sogroya® (somapacitan) therapy in patients with AGHD in the setting of routine clinical practice with special focus on neoplasms and diabetes mellitus type 2.

### Study Design

#### Non-interventional study design

Cohort

### Study drug and medical condition

## Study drug International non-proprietary name (INN) or common name SOMAPACITAN

#### Medical condition to be studied

Growth hormone deficiency

#### Additional medical condition(s)

Adults with growth hormone deficiency

### Population studied

#### Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

#### **Estimated number of subjects**

400

### Study design details

#### **Outcomes**

Number of Adverse drug reaction (ADRs) Incident Neoplasm Incident Diabetes
Mellitus type 2, Number of Adverse Events (AEs) Number of Serious Adverse
Events (SAEs) Number of Medication Errors (incorrect dose administration rate)

#### **Data analysis plan**

Frequencies of ADRs during the study period will be summarised by MedDRA SOC and PT. This summary is displayed with number and proportion of patients with at least one event, number of event and event rate (events per 100 patient-years of exposure). In addition, incidence rates will be calculated for the endpoints Neoplasm and Diabetes Mellitus type 2.

### **Documents**

#### **Study report**

4515 regulatory pass progress report no. 1 eu-pas-reg redacted.pdf (387.35 KB) 4515 regulatory pass progress report no. 2 eu-pas-reg redacted.pdf (436.97 KB)

#### Study, other information

4515 regulatory pass progress report no. 2 eu-pas-reg redacted.pdf (436.97 KB)

### Data management

### **ENCePP Seal**

The use of the ENCePP Seal has been discontinued since February 2025.

The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

### Data sources

#### **Data sources (types)**

Other

### Data sources (types), other

Prospective patient-based data collection

### Use of a Common Data Model (CDM)

### **CDM** mapping

No

### Data quality specifications

### **Check stability**

**Check conformance** 

Unknown

### **Check logical consistency**

Unknown

### Data characterisation

#### **Data characterisation conducted**

No