Study ID 202304_AHLO

Name of the Principal Investigator: Anne Helene Olsen
Contact details including institution: Novo Nordisk A/S ahlo@novonordisk.com
Coinvestigators: Faisal Ahmed, Glasgow
Date of Approval: April 2023
Name of study: A non-interventional, observational, register-based study to investigate long-term safety and clinical parameters of somapacitan treatment in children with growth hormone deficiency during routine clinical practice (REAL 10)
Summary Sogroya® (somapacitan) (hereafter only referred to as somapacitan), is a human growth hormone therapy, taken once a week. Following approval by the health authorities, it is required to study the long-term outcomes of somapacitan in a real-world setting. This non-interventional, observational, register-based study is planned to evaluate long-term safety and clinical parameters of somapacitan treatment in children with growth hormone deficiency in the setting of routine clinical practice.
Inclusion criteria – Treated with somapacitan at any time point according to local practice at the discretion of the physician – Primary diagnosis of growth hormone deficiency as per local practice – Male or female below 18 years of age at the time of signing informed consent and inclusion in GloBE-Reg
Exclusion criteria – Patients with active malignancy or in treatment for active pre-existing malignancy
Data to be collected for all participating cases: **Core Data** **Core Data History** **GloBE-Reg rhGH Minimum Dataset** *Diagnosis Case Report Form (CRF)* at the time of original GHD diagnosis and if the diagnosis is revised *Clinician Reported Outcome and Therapy CRFs* - One pre-somapacitan visit (preferably 6-15 months before sompacitan initiation) - One visit at somapacitan initiation - All follow-up visits (somapacitan and any other rhGH formulations or if rhGH stopped) Frequency of data provision to PI – 12 Monthly
Study period **Dec 2024 – Dec 2034**
Data cut time points

Dec 2024, May 2025, Feb 2026, Feb 2027
Expected outputs Novo Nordisk plans to use the data to satisfy regulatory requirements from the EMA. This will involve submission of data via a study report to the EMA. Subsequent publications are planned, primarily as a manuscript.
Publication Plan for authorship in outputs (refer to guidance) Novo Nordisk intends to drive publications in partnership with GloBE-Reg investigators. Authors will be invited to co-author publications based on the ICMJE recommendations. Authors will be invited from the Registry users contributing to the dataset
Other Registration Sites EU PAS Register – EUPAS1000000602