press release

Once-weekly Sogroya® (somapacitan) is an efficacious and well-tolerated long-acting growth hormone in children with growth disorders: results from REAL8 phase 3 basket study presented at the joint Congress of ESPE and ESE 2025

- The REAL8 trial showed that after 52 weeks, once-weekly Sogroya® (somapacitan) had similar clinical outcomes and safety profile to once-daily Norditropin® (somatropin) in children born small for gestational age (SGA)[1], or with Noonan syndrome (NS)[2], or with idiopathic short stature[3].
- Superiority was achieved for once-weekly somapacitan versus daily growth hormone in children with NS[2], as well as compared to lower doses of daily growth hormone in children born SGA[1].
- These conditions are often associated with significant health challenges and a high treatment burden from daily injections[4], which can lead to a lack of adherence and put successful treatment outcomes at risk. Novo Nordisk is committed to bringing our expertise and scientific innovation to help improve the lives of children with conditions that impact their growth.

Bagsværd, Denmark, 12 May 2025 – Novo Nordisk today presented data from the phase 3 REAL8 basket study, which showed that once-weekly Sogroya® (somapacitan) was non-inferior to the once-daily growth hormone Norditropin® (somatropin) in improving yearly growth rate (as measured by height velocity [HV] at Week 52) in pre-pubertal children born small for gestational age (SGA)[1], or with Noonan syndrome (NS)[2], or with idiopathic short stature (ISS)[3]. In addition, superiority was achieved for once-weekly Sogroya® versus daily growth hormone in children with NS[2], as well as compared to lower doses of daily growth hormone in children born SGA[1].

REAL8 data showed that Sogroya® was well-tolerated, with no safety or tolerability issues identified compared to once daily growth hormone[1-3]. Insulin-like growth factor 1 (IGF-1) response in patients treated with once-weekly Sogroya® was similar to those treated with daily growth hormone[1-3]. Results from the Turner syndrome (TS) sub-study of REAL8 will be available later this year. These data were presented as three late-breaking abstracts at the first Joint Congress of the European Society for Paediatric Endocrinology (ESPE) and European Society of Endocrinology (ESE) in Copenhagen, Denmark[1-3].

“Children with growth failure face many health challenges beyond just being shorter than their peers. They often have metabolic disruptions and developmental difficulties that can seriously affect their wellbeing and quality of life, as well as long-term effects such as increased risk of cardiovascular disease or type 2 diabetes,” said Professor Agnès Linglart, Professor of Paediatrics

at the Bicêtre Paris-Saclay University and Hospital, France, and one of the lead investigators on REAL8. “The REAL8 data presented today marks an important step forward in providing these patients with an effective, once-weekly option that can potentially reduce treatment burden and improve adherence and treatment outcomes.”

The REAL8 trial achieved its primary endpoints for the first three sub-studies, demonstrating that once-weekly Sogroya® was non-inferior to once-daily growth hormone treatment at Week 52 across the three indications presented:

- **In children born SGA**, Sogroya® demonstrated superior estimated mean HV when compared with a lower dose (0.035 mg/kg/day) of somatropin (11.0 vs 9.4 cm/year), and non-inferior estimated mean HV when compared with a higher dose (0.067 mg/kg/day) of somatropin (11.0 vs 11.1 cm/year)[1].
- **In children with NS**, Sogroya® demonstrated superior estimated mean HV compared with somatropin (10.4 vs 9.2 cm/year)[2].
- **In children with ISS**, Sogroya® demonstrated non-inferior estimated mean HV compared with daily somatropin (10.5 vs 10.5 cm/year)[3].

Non-adherence to growth hormone treatment is a common problem which puts successful treatment outcomes at risk. Daily injections can be a burden for children and their caregivers, leading to lack of adherence due to discomfort or pain at injection sites, inconvenience and disruption to daily life[5]. One study showed that missed daily injections resulted in a difference of 6.1 cm in height over 3 years when comparing nonadherent with adherent patients[4].

“Treatment adherence is an issue when it comes to improving outcomes in children with growth failure. Imagine if a child misses only one day of treatment each week, amounting to 52 missed days per year. Over a seven-year treatment window, this results in one year of missed treatment and can have a significant knock-on impact on their health,” said Martin Lange, executive vice president for Development at Novo Nordisk. “We are committed to providing a portfolio of growth hormone therapies with flexibility in administration timing and missed doses, which may better suit the needs of children with growth failure. These encouraging results from REAL8 mark a significant step forward in achieving that commitment.”

In April 2025, based on the data from REAL8 and REAL9, the three indications (SGA, NS and ISS) were submitted for regulatory review in both the EU and US.

About REAL8

The REAL8 study is part of the ongoing REAL clinical trial programme, it is a randomised, open-label, active-controlled, parallel-group, phase 3 trial evaluating the efficacy and safety of once-weekly Sogroya® (somapacitan) in children born SGA, or with TS, NS or ISS. The primary treatment period was 52 weeks followed by a two-year safety extension phase[6].

REAL8 has an innovative basket trial design that is investigating once-weekly Sogroya® (somapacitan) in four different but related indications (SGA, TS, NS and ISS) under one trial protocol[6]. This trial design allows for a more efficient clinical development process by speeding up recruitment and consolidating resources[7], potentially bringing treatment to patients with these conditions sooner. This is the first time a trial design of this type has been implemented in the growth disorder space.

In REAL8, pre-pubertal children with NS, TS or ISS were randomised to receive either once-weekly Sogroya® (somapacitan) 0.24 mg/kg/week or once-daily somatropin 0.050 mg/kg/day; children born SGA were randomised to receive either somapacitan 0.24 mg/kg/week, or low dose of somatropin 0.035 mg/kg/day, or high dose of somatropin 0.067 mg/kg/day[6].

About REAL9

The REAL9 study is part of the ongoing REAL clinical trial programme, it is a single-group assignment, phase 3 study evaluating the safety and efficacy of once-weekly Sogroya® (somapacitan) in children 10 years or older born SGA, or with TS, NS or ISS. The study will last for approximately 3 years[8].

About once-weekly Sogroya®

Once-weekly Sogroya® (somapacitan) is a prescription human growth hormone analogue, similar to current daily growth hormone. It is currently approved for once-weekly treatment of children and adults who do not produce enough growth hormone[9,10]. Using albumin-binding prolongation technology, Sogroya® attaches to albumin, a protein in the blood, to help delay its removal from the body. This well-established technology has been used for over 20 years in Novo Nordisk's diabetes treatment. It allows for the growth hormone to work longer[11].

About Novo Nordisk

Novo Nordisk is a leading global healthcare company founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat serious chronic diseases built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 77,400 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, Facebook, Instagram, X, LinkedIn and YouTube.

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