

press release

Sogroya® data show potential as once-weekly treatment in children living with growth hormone deficiency

Investigational phase 3 data for Sogroya® (somapacitan) injection in children with growth hormone deficiency presented today at the ENDO 2022 Congress¹

Atlanta, Georgia (US), 12 June 2022 – Today, Novo Nordisk announced results of once-weekly Sogroya® (somapacitan) injection in helping children achieve growth targets of annualised height velocity (AHV).¹ These phase 3 results from the REAL 4 study, in prepubertal children with growth hormone deficiency (GHD), were presented today at the Endocrine Society's Annual Meeting (ENDO 2022) in Atlanta, Georgia (US).

"The existing treatment options available for children with growth hormone deficiency require daily injections for many years," said Dr. Bradley Miller, MD, PhD, Division of Pediatric Endocrinology, University of Minnesota Masonic Children's Hospital. "Based on the results of the REAL 4 study, there is potential for a once-weekly option for children with growth hormone deficiency."

GHD is a rare disease, estimated to affect approximately 1 in 3,500 to 10,000 children.^{2,3} Symptoms often start early in life, leading to short stature as well as other growth-related health complications.⁵

"We are excited about the REAL 4 phase 3 study results showing that the weekly use of Sogroya® worked as well as daily treatment with Norditropin® (somatropin) injection," said Martin Lange, executive vice president and head of Development at Novo Nordisk. "Sogroya® shows Novo Nordisk's commitment to the rare endocrine community and our continued vision to deliver innovative therapeutic solutions for all patient needs."

About the REAL4 trial

The REAL 4 (REversible ALbumin) study (NCT03811535) is part of the ongoing REAL clinical study programme and was designed to evaluate the efficacy and safety of Sogroya® (somapacitan) injection in children with growth disorders.⁷

REAL 4 is a randomised, multi-national, open label, active-controlled parallel group phase 3 trial, comprising a 52-week main phase followed by a three-year extension period.¹ Two-hundred growth hormone (GH) treatment naïve, prepubertal children with GHD (74.5% male) were

randomly assigned in a 2:1 ratio to receive weekly subcutaneous 0.16 mg/kg/week Sogroya® (n=132) or daily subcutaneous 0.034 mg/kg/day somatropin (Norditropin®) (n=68).¹ In the phase 3 study, REAL 4, Sogroya® showed a not significantly different AHV of 11.2 cm/year, compared to 11.7 cm/year for Norditropin®. Based on the main phase results of REAL 4, once-weekly Sogroya® was shown to work as well as daily Norditropin® for children with GHD, meeting its primary endpoint of non-inferiority. The most common AEs observed in ≥5% were events commonly observed in children, including headache, nasopharyngitis, pyrexia, pain in extremity, bronchitis and vomiting.¹

About paediatric growth hormone deficiency (GHD)

GHD is a rare condition characterised by the insufficient amount of GH circulating in the body.⁵ GH is essential for growth, muscle and bone strength and it helps to control sugar and fat levels in the body.⁴ GHD can result in slow growth, short stature and other health problems.⁵

About Sogroya® (somapacitan)

Sogroya® (somapacitan) injection is a prescription human growth hormone analogue medicine, similar to the growth hormone made by the body, and is used to treat adults who do not make enough growth hormone. Sogroya® is approved for the replacement of endogenous growth hormone in adults with growth hormone deficiency (AGHD) in the US, Europe, Japan, Australia, and Saudi Arabia. The use of Sogroya® in children with GHD is investigational and not approved.^{8,9}

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 diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 49,300 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, [Facebook](#), [Twitter](#), [LinkedIn](#) and [YouTube](#).

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- ⁸ Summary of Product Characteristics https://www.ema.europa.eu/en/documents/product-information/sogroya-epar-product-information_en.pdf Accessed: April 2022.
- ⁹ Sogroya® (somapacitan) US Prescribing Information. Available at: <https://www.novo-pi.com/sogroya.pdf>. Last accessed: June 2022.