Press release

Novo's once-weekly Sogroya® (somapacitan) receives positive CHMP opinion in Europe for children with idiopathic short stature (unexplained shortness)

If approved, Sogroya® (somapacitan) would be the first and only growth hormone treatment approved for idiopathic short stature in the EU, providing a much-needed treatment option for children and their families affected by this condition.

- The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended once-weekly Sogroya® (somapacitan) for children in Europe living with idiopathic short stature (ISS) with persistent growth disturbance.
- ISS is a diagnosis given to children who are significantly shorter than their peers when no underlying medical cause can be found, affecting a child's confidence and well-being[1-4]. This affects up to 3% of children worldwide[1,6,8].
- Positive opinion follows the previous recommendation for Sogroya® in the treatment of short stature in children born Small for Gestational Age (SGA) and with Noonan Syndrome (NS) in Europe[5].

Bagsværd, Denmark, 18 September 2026 – Novo Nordisk today welcomed a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA), recommending once-weekly Sogroya® for children with idiopathic short stature (ISS) with persistent growth disturbance.

"Through our research and relationships with the community, we know that 70% of families raising children with ISS and other growth disorders feel unseen, and that the impact on their child's daily life simply isn't recognised," said Ashley Gilmer, chief executive officer of International Coalition of Organizations Supporting Endocrine Patients (ICOSEP). "This recommendation is a meaningful signal that this may be starting to change. What matters now is that recognition turns into real support of timely diagnosis, clear information, and access to care for every family who needs it."

ISS affects up to 3% of children worldwide, yet it remains under-recognised and has limited options for managing its treatment[1,6-8]. As part of the REAL8 clinical trial, Sogroya® has been assessed for the treatment of ISS and acts as a long-acting growth hormone, given as a single injection under the skin once a week[9,10]. If approved, Sogroya® would be the first and only growth hormone treatment approved for ISS in the EU, providing a much-needed treatment option for children and their families living with this condition.

Novo Nordisk A/S
Global Corporate Affairs

Novo Alle 1
2880 Bagsværd
Denmark

Tel: +45 4444 8888
www.novonordisk.com

CVR no: 24 25 67 90

"For too long, treatment options for many children with growth disorders have been limited. Building on our decades of experience in growth hormone medicines, we're committed to changing that. Today's approval recommendation from the CHMP is a very important step forward for children and their families affected by ISS across Europe," said Martin Holst Lange, executive vice president, chief scientific officer and head of Research & Development at Novo.

This opinion follows the CHMP recommendation of Sogroya® for the treatment of short stature in children born small for gestational age (SGA) and Noonan Syndrome (NS) in May 2026[5]. The opinion is now passed to the European Commission, whose decision on marketing authorisation, covering all three indications, is expected later this year.

About once-weekly Sogroya® (somapacitan)

Once-weekly Sogroya® (somapacitan) is a long-acting human growth hormone analogue, given as a single injection under the skin once a week. It uses albumin-binding technology, which allows the growth hormone to attach to a protein naturally present in the blood, allowing it to remain in the body for longer[11].

In the EU, Sogroya® was authorised for the treatment of growth hormone deficiency in adults on 31 March 2021 and in children aged 3 years and older on 24 July 2023[12].

The REAL8 clinical trial data that supported this positive CHMP opinion showed that once-weekly Sogroya® was non-inferior to once-daily growth hormone treatment for mean annualised height velocity at Week 52 in children with idiopathic short stature, born small for gestational age and Noonan Syndrome[9].

What is idiopathic short stature?

Idiopathic short stature is a diagnosis given to children who are significantly shorter than their peers when no underlying medical cause can be found[1]. It affects up to 3% of children worldwide, yet it remains under-recognised and often overlooked – in many countries, it is not a recognised condition[1,6,7]. Children with idiopathic short stature are more likely to face teasing, bullying and social exclusion as a result of their condition – experiences that can affect confidence and wellbeing into adulthood[2,3,13].

Why is idiopathic short stature difficult to diagnose and treat?

The path to a diagnosis is often long and emotionally draining for families, as it can only be identified once other causes of short stature have been ruled out[14]. As many children with idiopathic short stature are not referred for diagnosis until puberty is approaching, the window for effective intervention with growth hormone (GH) therapy is limited[15,16]. Even after diagnosis, treatment with GH therapy is only approved for idiopathic short stature in some regions and used off-label or not at all in others, leaving many children and families without options[14,17,18].

Novo Nordisk A/S
Global Corporate Affairs

Novo Alle 1
2880 Bagsværd
Denmark

Tel: +45 4444 8888
www.novonordisk.com

CVR no: 24 25 67 90

What does it mean to be born small for gestational age?

When a baby is born small for gestational age, it means they are smaller than expected in length, weight, or head circumference[19,20]. There is not always a clear cause, though being born small for gestational age has been associated with genetic factors, problems with the placenta and maternal health, including malnutrition, chronic high blood pressure and chronic infections[21]. Most children born small for gestational age reach their expected height by the age of two, but if catch-up growth has not happened by two or three years of age, a referral to a paediatric endocrinologist may be needed[22,23].

What is Noonan Syndrome?

Noonan Syndrome is a genetic condition affecting both boys and girls, occurring in around 1 in 1,000 to 2,500 births[24,25]. Around half of all cases are caused by a mutation on a gene found on chromosome 12[25]. Noonan Syndrome can have a variety of effects on a child's health and development, including short stature, heart defects present at birth, and certain distinctive facial features[24].

Novo is the global healthcare company that believes lasting health starts now. For over a century, we've combined leading scientific expertise with a deep understanding of people's lives. We develop treatments and support that help millions of people make progress they can see, feel and sustain now and in the future. Every day, over 67,000 employees around the world advance our purpose to drive change for lasting health. Through our partnerships, programmes and investments, we're working to prevent disease, expand access to treatments and reduce our environmental impact to help even more people live healthier lives. For more information, visit novonordisk.com and follow us on Instagram, LinkedIn, TikTok, Facebook, X and YouTube.

Contacts for further information

Novo Media:

Ambre James-Brown
+45 3079 9289
globalmedia@novonordisk.com

Liz Skrbkova (US)
+1 609 917 0632
USMediaRelations@novonordisk.com

Novo Investors:

Michael Novod
+45 3075 6050
nvno@novonordisk.com

Sina Meyer
+45 3079 6656
azey@novonordisk.com

Christoffer Togo Solgaard-Tullin
+45 3079 1471
cftu@novonordisk.com

Ida Schaap Melvold
+45 3077 5649
idmg@novonordisk.com

Mads Berner Bruun
+45 3075 2936
mbbz@novonordisk.com

Frederik Taylor Pitter (US)
+1 609 613 0568
fptr@novonordisk.com

Alex Bruce (US)
+1 640 230 0276
axeu@novonordisk.com

References

1. Wit JM, Clayton PE, Rogol AD, *et al.* Idiopathic short stature: definition, epidemiology, and diagnostic evaluation. *Growth Horm IGF Res*. 2008;18:89-110.
2. A Juul, A Linglart, MH Rasmussen, et al. Impact of Idiopathic Short Stature (ISS) on children's well-being. ESPE Abstracts (2024), 98, P1-68. Paper/Poster presented.
3. Novo Nordisk Data on File. Equips: Evaluating the Quality of Life in People with Short Stature. 2025.
4. The Magic Foundation. Psycological impact of short stature on children and adolescents [online]. Available at: magicfoundation.org/psychologicalimpact. Last accessed: August 2026.
5. Sogroya - opinion on variation to marketing authorisation. European Medicines Agency [online]. Available at: ema.europa.eu/en/medicines/human/variation/sogroya. Last accessed: August 2026.
6. Sharma L, Rani D, Kanchan T, *et al.* Short Stature *StatPearls* Treasure Island (FL); 2026.
7. Novo Nordisk Data on File. Investigating the Association between Idiopathic Short Stature and Health and Well-being: a register study. 2025.
8. Romero CJ and Rapaport R. The challenges of optimising the treatment of children diagnosed with idiopathic short stature. *Ann Hum Biol*. 2026;53:2621718.
9. Once-weekly Sogroya® (somapacitan) is an efficacious and welltolerated 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. Novo Nordisk [online]. Available at: ml-eu.globenewswire.com/Resource/Download/f899ae3b-aa4e-4ef3-9498-9537d9cc424b. Last accessed: August 2026.
10. Sogroya® (somapacitan): SmPC [online]. Available at: ema.europa.eu/en/documents/product-information/sogroya-epar-product-information_en.pdf. Last accessed: August 2026.
11. Johansson E, Nielsen AD, Demuth H, *et al.* Identification of Binding Sites on Human Serum Albumin for Somapacitan, a Long-Acting Growth Hormone Derivative. *Biochemistry*. 2020;59:1410-1419.
12. An overview of Sogroya and why it is authorised in the EU. European Medicines Agency [online]. Available at: ema.europa.eu/en/documents/overview/sogroya-epar-medicine-overview_en.pdf. Last accessed: August 2026.
13. Investigating the Association between Idiopathic Short Stature and Health and Well-being: a register study. 2025.
14. Pedicelli S PE, Violi E, et al. Controversies in the definition and treatment of idiopathic short stature (ISS). *J Clin Res Pediatr Endocrinol*. 2009;1:105-115.

15. Cohen P, Rogol AD, Deal CL, *et al.* Consensus statement on the diagnosis and treatment of children with idiopathic short stature: a summary of the Growth Hormone Research Society, the Lawson Wilkins Pediatric Endocrine Society, and the European Society for Paediatric Endocrinology Workshop. *J Clin Endocrinol Metab*. 2008;93:4210-7.
16. Novo Nordisk Data on File. Adivo – 2023 US GHT Patient Assessment. 2025.
17. Kemp SF and Frindik JP. Emerging options in growth hormone therapy: an update. *Drug Des Devel Ther*. 2011;5:411-9.
18. Murano MC. A Disability Bioethics Reading of the FDA and EMA Evaluations on the Marketing Authorisation of Growth Hormone for Idiopathic Short Stature Children. *Health Care Anal*. 2020;28:266-282.
19. Schlaudecker EP, Munoz FM, Bardaji A, *et al.* Small for gestational age: Case definition & guidelines for data collection, analysis, and presentation of maternal immunisation safety data. *Vaccine*. 2017;35:6518-6528.
20. Lee PA, Chernausek SD, Hokken-Koelega AC, *et al.* International Small for Gestational Age Advisory Board consensus development conference statement: management of short children born small for gestational age, April 24-October 1, 2001. *Pediatrics*. 2003;111:1253-61.
21. Liu Q, Yang H, Sun X, *et al.* Risk factors and complications of small for gestational age. *Pak J Med Sci*. 2019;35:1199-1203.
22. Finken MJJ, van der Steen M, Smeets CCJ, *et al.* Children Born Small for Gestational Age: Differential Diagnosis, Molecular Genetic Evaluation, and Implications. *Endocr Rev*. 2018;39:851-894.
23. Hokken-Koelega ACS, van der Steen M, Boguszewski MCS, *et al.* International Consensus Guideline on Small for Gestational Age: Etiology and Management From Infancy to Early Adulthood. *Endocr Rev*. 2023;44:539-565.
24. Sharma L, Winters R and Corado A. Noonan Syndrome *StatPearls* Treasure Island (FL); 2026.
25. Visser-van Balen H, Sinnema G and Geenen R. Growing up with idiopathic short stature: psychosocial development and hormone treatment; a critical review. *Arch Dis Child*. 2006;91:433-9.