press release

Once-weekly Sogroya® (somapacitan) receives CHMP positive opinion for expanded use in children and adolescents with growth hormone deficiency

Bagsværd, Denmark, 26 May 2023 – Novo Nordisk today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending once-weekly Sogroya® (somapacitan) for replacement of endogenous growth hormone (GH) in children aged three years and above, and adolescents with growth failure due to growth hormone deficiency.

Symptoms of growth hormone deficiency in children often start early in life, leading to short stature as well as other growth-related health problems.[1] Current treatment for growth hormone deficiency typically requires daily injections of growth hormone.[2] However, frequent injections can be burdensome, disrupting daily life, reducing adherence and thereby affecting clinical outcomes – particularly in children.[3]

"Today's positive CHMP opinion is a step forward to reducing the impact of growth hormone deficiency for children, adolescents and their families in Europe," said Martin Holst Lange, executive vice president for Development at Novo Nordisk. "We are hopeful that Sogroya® will help improve the lives of children as young as three years old by offering a simpler treatment option with fewer injections in an easy-to-use device, whilst helping them to achieve their growth targets."

The positive opinion is based on data from the phase 3 REAL4 study, which showed that once-weekly subcutaneous injection of Sogroya® worked as well as daily injection of Norditropin® (somatropin). This means that at the end of the trial period, prepubertal children who were treated with once-weekly Sogroya® achieved similar growth as children who were treated with once-daily Norditropin®.[4]

The European Commission (EC) will now review the CHMP's positive opinion, and a final decision on the marketing authorisation is expected in the coming months. If approved, Sogroya® will be available in some European countries starting in Q4 2023. It received approval from the US Food & Drug Administration (FDA) in April 2023.

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About the REAL4 study

The REAL4 (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 hormone deficiency.[5] REAL4 is a randomised, multi-national, open label, active-controlled parallel group phase 3 trial, comprised of a 52-week main phase followed by a three-year extension period. Two-hundred growth hormone treatment naïve, prepubertal children with growth hormone deficiency were randomly assigned in a 2:1 ratio to receive weekly subcutaneous injection of 0.16 mg/kg/week Sogroya® (n=132) or daily subcutaneous injection of 0.034 mg/kg/day somatropin (Norditropin®) (n=68).[5] Results from the study showed that annualised height velocity (centimetres grown in a year) in children with growth hormone deficiency treated with once-weekly Sogroya® was 11.2 cm/year, compared to 11.7 cm/year for daily Norditropin® with no statistical difference between the two groups. Sogroya® was well tolerated, with a similar safety and tolerability profile to the well-known profile of Norditropin®.[4]

Growth hormone deficiency

Growth hormone deficiency is a rare disease and a treatable cause of short stature. It is estimated to affect approximately 1 in 3,500 to 10,000 children.[6,7] Growth hormone is essential for growth, muscle and bone strength and it helps to control sugar and fat levels in the body. Growth hormone deficiency in children is characterised by slow growth from an early age and a markedly reduced final adult height compared to that predicted.[8,9] Other symptoms can include reduction of bone mineral density, slow development of facial bones and long bones, and delayed appearance of teeth.[1,10]

About Sogroya® (somapacitan)

Sogroya® is a prescription human growth hormone analogue, similar to current daily growth hormone and can be used to treat adults who do not produce enough growth hormone. Sogroya® was approved in the EU for the replacement of endogenous growth hormone in adults with growth hormone deficiency (AGHD) in 2021.[11]

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 57,100 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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