

## press release

# Sogroya<sup>®</sup> (somapacitan injection) now available in Canada as the first and only once-weekly treatment for both children and adults living with growth hormone deficiency

Sogroya<sup>®</sup> is the first-and-only once-weekly growth hormone treatment for both children and adults living with growth hormone deficiency (GHD)<sup>1</sup>

MISSISSAUGA, ON, October 15, 2025 – Novo Nordisk has announced that Sogroya® (somapacitan injection) is now commercially available in Canada. Sogroya® is indicated for the long-term treatment of pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone (Growth Hormone Deficiency (GHD)) and the replacement of endogenous growth hormone (GH) in adults with growth hormone deficiency (AGHD).¹ Sogroya® is the first and only once-weekly GH treatment for both children and adults.¹

"Growth hormone deficiency, while rare, can significantly affect children by impairing growth and potentially compromising bone density as well as cardiovascular and metabolic health," says Dr. Preetha Krishnamoorthy, pediatric endocrinologist. "It may occur in isolation or in conjunction with other pituitary hormone deficiencies, requiring comprehensive and ongoing follow-up. Fortunately, growth hormone replacement therapy is available and provides effective treatment. Every advancement in growth hormone deficiency treatment and care is an important step in supporting Canadian patients with this rare disease. I am pleased to know that my patients will now have another treatment option to support them in safely and effectively managing their condition, especially in the form of a once-weekly injection."

"At Novo Nordisk, we are committed to making medication delivery simple and convenient. The availability of Sogroya® provides Canada's GHD community with an innovative therapy option, reducing daily treatments to a once-weekly growth hormone therapy, which supports adherence and quality of life, which is especially important for pediatric patients and their families," said John Burrows, Vice President, Rare Disease, Novo Nordisk Canada. "This represents a meaningful difference for many families living with the reality of GHD every day."

### About Sogroya®

Sogroya® (somapacitan injection) is a prescription Human Growth Hormone (GH) analog. Sogroya® is indicated for the long-term treatment of pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone (GHD) and the replacement of endogenous growth hormone (GH) in adults with growth hormone deficiency (AGHD). It was approved by Health Canada on July 26, 2023. For more information on Sogroya® including important safety information please visit NovoNordisk.ca or view the product monograph here.

#### **About REAL 4 and REAL 1 Studies**

Health Canada's approval of Sogroya® for children with GHD is based on data from the phase 3 REAL 4 study. In the study, 200 treatment-naïve patients aged 2.5 – 11 years with GHD were either given once-weekly Sogroya® (N=132) or daily somatropin (N=68) for 52 weeks.<sup>1,2</sup> The results showed that Sogroya® was non-inferior to daily somatropin for the primary endpoint of annualised height velocity (estimated treatment difference: -0.5 cm/year [95% CI: -1.1; 0.2]).<sup>1,2</sup> The most common adverse reactions in the REAL 4 study included headache, hypothyroidism, injection site reactions, peripheral edema, arthralgia, hyperglycemia, fatigue, and adrenocortical insufficiency.<sup>1,2</sup>

In the REAL 1 pivotal phase 3 study of 300 treatment naïve adults with adult growth hormone deficiency, patients either received Sogroya® (N=120), daily growth hormone (n=119), or placebo (N=61). $^{1,3}$  Sogroya® exhibited a significant reduction in truncal fat percentage at 34 weeks, with an estimated difference of -1.53% (-2.68; -0.38; P = 0.0090), demonstrating superiority over placebo. $^{1,3}$  Furthermore, Sogroya® improved other body composition parameters, including visceral fat, lean body mass, and IGF-I SDS. These benefits were sustained at 86 weeks for both Sogroya® and daily GH. Additionally, Sogroya® was well tolerated, with adverse events, including injection site reactions, occurring at rates comparable to those seen with daily GH. $^{1,3}$ 

#### **About GHD**

GHD is a rare disease characterized by the inadequate secretion of GH from the anterior pituitary gland, a small gland located at the base of the brain that is responsible for the production of hormones.<sup>4</sup> GHD can be present from birth (congenital), resulting from genetic mutations or from structural defects in the brain.<sup>2</sup> Not just a disease that impacts children, GHD can be acquired later in life as a result of trauma, infection, radiation therapy, or tumour growth within the brain.<sup>4</sup> GHD may be characterized by variable symptoms including reduced energy levels, altered body composition, osteoporosis, reduced muscle strength, lipid abnormalities such as increased LDL cholesterol, insulin resistance, and impaired cardiac function.<sup>4</sup> The standard

therapy for GHD is recombinant human growth hormone as soon as the disorder is recognized to optimize growth potential.<sup>4</sup>

#### **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 76,300 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.ca, Facebook, Instagram, X, LinkedIn and YouTube.

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<sup>&</sup>lt;sup>1</sup> Novo Nordisk Canada Inc. (2023, September 26). Sogroya® Product Monograph.

<sup>&</sup>lt;sup>2</sup> Miller, B. S., Blair, J. C., Rasmussen, M. H., Maniatis, A., Kildemoes, R. J., Mori, J., Polak, M., Bang, R. B., Böttcher, V., Stagi, S., & Horikawa, R. (2022). Weekly Somapacitan is Effective and Well Tolerated in Children With GH Deficiency: The Randomized Phase 3 REAL4 Trial. The Journal of clinical endocrinology and metabolism, 107(12), 3378–3388. https://doi.org/10.1210/clinem/dgac513

<sup>&</sup>lt;sup>3</sup> Johannsson, G., Gordon, M. B., Højby Rasmussen, M., Håkonsson, I. H., Karges, W., Sværke, C., Tahara, S., Takano, K., & Biller, B. M. K. (2020). Once-weekly Somapacitan is Effective and Well Tolerated in Adults with GH Deficiency: A Randomized Phase 3 Trial. The Journal of clinical endocrinology and metabolism, 105(4), e1358–e1376. https://doi.org/10.1210/clinem/dgaa049

<sup>&</sup>lt;sup>4</sup> National Organization for Rare Disorders. Growth Hormone Deficiency. <a href="https://rarediseases.org/rare-diseases/growth-hormone-deficiency/">https://rarediseases.org/rare-diseases/growth-hormone-deficiency/</a>