Sogroya® (somapacitan-beco) – Expanded indication, new dosage strength

- On April 28, 2023, the FDA approved NovoNordisk's Sogroya (somapacitan-beco), for the treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH).
    - Sogroya was previously approved for the replacement of endogenous GH in adults with GH deficiency.
- In addition to the expanded indication, the FDA also approved a new dosage strength, 15 mg/1.5 mL (10 mg/mL) in a single-patient-use prefilled pen, of Sogroya.
- The approval of Sogroya for the expanded pediatric indication was based on a randomized, open-label, active-controlled, parallel-group study conducted in 200 treatment-naïve, pediatric patients with GH deficiency. Patients received weekly Sogroya or daily somatropin. The primary efficacy endpoint was annualized height velocity at week 52.
    - Annualized height velocity was 11.2 cm/year in the Sogroya group vs. 11.7 cm/year in the somatropin group (treatment difference: -0.5; 95% CI: -1.1; 0.2).
- The most common adverse reactions (≥ 5%) with Sogroya use in pediatric patients were nasopharyngitis, headache, pyrexia, pain in extremity, and injection site reaction.
- The recommended dose of Sogroya for the treatment of pediatric patients is 0.16 mg/kg based on actual body weight subcutaneously (SC) once weekly for treatment-naïve patients and patients switching from daily GH (somatropin).
    - Sogroya treatment should be supervised by a healthcare provider who is experienced in the diagnosis and management of pediatric patients with growth failure due to GH deficiency.
    - Dosage should be individualized for each patient based on the growth response.
    - Refer to the Sogroya drug label for further dosing recommendations and for dosing in adults.