Sogroya® (somapacitan-beco) – New drug approval

- On August 28, 2020, Novo Nordisk announced the FDA approval of Sogroya (somapacitan-beco), for replacement of endogenous growth hormone in adults with growth hormone deficiency (GHD).

- Adults diagnosed with GHD do not produce sufficient growth hormone. GHD can affect their bodies in many ways including changes in body composition, lipids, carbohydrate metabolism, bones, and muscle mass.

    — More than 50,000 adults in the U. S. have GHD, with about 6,000 new patients diagnosed each year.

- Sogroya is a human growth hormone analog.

- The efficacy of Sogroya was established in a 35-week, double-blind, placebo-controlled study in 299 treatment-naïve adult patients with GHD. Patients were randomized to once-weekly Sogroya, placebo, or a daily somatropin product.

    — Treatment with Sogroya demonstrated superiority vs. placebo in reduction in truncal fat percentage with a change of -1.06% for Sogroya and +0.47% for placebo (Absolute treatment difference: -1.53; 95% CI: -2.68, -0.38; p = 0.0090). Patients treated with daily somatropin achieved a change in truncal fat % of -2.23%.
    — Sogroya normalized the mean insulin-like growth factor 1 (IGF-I) standard deviation score (SDS) level with a IGF-1 SDS of -0.17 in Sogroya-treated patients vs. -2.62 in placebo-treated patients. The mean IGF-I SDS levels in daily somatropin-treated patients was -0.23.

- Sogroya is contraindicated in patients with:

    — Acute critical illness after open-heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure because of the risk of increased mortality with use of pharmacologic doses of Sogroya;
    — Active malignancy;
    — Hypersensitivity to Sogroya or any of its excipients. Systemic hypersensitivity reactions have been reported post-marketing with other growth hormone products; and
    — Active proliferative or severe non-proliferative diabetic retinopathy.

- Warnings and precautions for Sogroya include increased mortality in patients with acute critical illness, increased risk of neoplasms, glucose intolerance and diabetes mellitus, intracranial hypertension, severe hypersensitivity, fluid retention, hypoadrenalism, hypothyroidism, pancreatitis, lipohypertrophy/lipoatrophy, and laboratory tests (serum levels of inorganic phosphorus, alkaline phosphatase, and parathyroid hormone may increase after somatropin therapy).

- The most common adverse reactions (≥ 2%) with Sogroya use were back pain, arthralgia, dyspepsia, sleep disorder, dizziness, tonsillitis, peripheral edema, vomiting, adrenal insufficiency, hypertension, increased blood creatine phosphokinase, increased weight, and anemia.

- The recommended initial dose of Sogroya is 1.5 mg subcutaneously once weekly for treatment naïve patients and patients switching from daily growth hormone (somatropin). Increase the weekly dosage every 2 to 4 weeks by approximately 0.5 mg to 1.5 mg until the desired response is achieved.

Continued . . .

- The dosage should be titrated based on clinical response and serum IGF-1 concentrations. IGF-1 samples should be drawn 3 to 4 days after the prior dose.
- The maximum recommended dosage is 8 mg once weekly.
- Therapy with Sogroya should be supervised by a physician who is experienced in the diagnosis and management of patients with the conditions for which Sogroya is indicated.
- Consult the Sogroya drug label for further dosing instructions.

- Novo Nordisk's launch plans for Sogroya are pending. Sogroya will be available as a 10 mg/1.5 mL solution in a single-patient-use prefilled pen.