Zomacton® (somatropin) – Expanded indication

- On January 31, 2018, Ferring Pharmaceuticals announced the FDA approval of Zomacton (somatropin), for the replacement of endogenous growth hormone (GH) in adults with GH deficiency (GHD).
    - Previously, Zomacton was only indicated for the treatment of pediatric patients who have growth failure due to inadequate secretion of endogenous GH.
- GHD in adults is characterized by metabolic dysfunction, reduced physical strength and activity, altered lipid metabolism and increases in body fat. Adult GHD can be a continuation of childhood onset GHD or have an onset in adulthood resulting primarily from trauma, surgery or radiation to the head.
    - Adult GHD occurs in approximately 1 - 2 adults per 100,000.
- The approval of Zomacton for adult GHD is based on two studies in 98 patients with adult-onset GHD and two studies in 67 adult patients with childhood-onset GHD. Patients were randomized to another somatropin product or placebo for 6 months, followed by 12 months of treatment with another somatropin product. The primary efficacy measures were body composition (lean body mass and fat mass) and lipid parameters.
    - In patients with adult-onset GHD, treatment with another somatropin product vs. placebo resulted in an increase in mean lean body mass (2.59 vs. -0.22 kg; $p < 0.001$) and a decrease in body fat (-3.27 vs. 0.56 kg; $p < 0.001$). Similar changes were seen in childhood-onset GHD patients.
    - Serum concentrations of high-density lipoprotein cholesterol had normalized by the end of 18 months of treatment with the other somatropin product (mean change of 13.7 mg/dL and 11.1 mg/dL for the adult-onset and childhood-onset groups, respectively; $p < 0.001$).
- The recommended dosage of Zomacton for adult patients is administered subcutaneously in one of two methods:
    - Non-weight based: Initiate Zomacton with a dose of approximately 0.2 mg/day (range, 0.15 mg/day - 0.3 mg/day) and increase the dose every 1 - 2 months by increments of approximately 0.1 mg/day - 0.2 mg/day, according to individual patient requirements based on the clinical response and serum insulin-like growth factor 1 concentrations.
    - Weight based: Initiate Zomacton at 0.006 mg/kg daily and increase the dose according to individual patient requirements to a maximum of 0.0125 mg/kg daily.
    - Refer to Zomacton's drug label for further information about dosing and titration in adult patients and for pediatric dosing information.