Semglee® (insulin glargine) – New drug approval

- On June 11, 2020, Mylan and Biocon announced the FDA approval of Semglee (insulin glargine), to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus (T1DM) and in adults with type 2 diabetes mellitus (T2DM).
    - Semglee is not recommended for the treatment of diabetic ketoacidosis.
- Semglee has an identical amino acid sequence to Lantus® (insulin glargine) and is approved for the same indications.
- The efficacy of Semglee was demonstrated in an open-label, randomized, active-controlled study in 558 patients with T1DM. Patients received either Semglee or another insulin glargine product, in combination with mealtime insulin lispro. At week 24, treatment with Semglee was found to be non-inferior to that achieved with comparator insulin glargine product with regard to the mean change in hemoglobin A1c (HbA1c) over 24 weeks of treatment (treatment difference 0.03; 95% CI: -0.06, 0.12).
- In addition, the efficacy of Semglee was demonstrated in an open-label, randomized, active-controlled study in 560 patients with T2DM. Patients received either Semglee or another insulin glargine product, both administered in combination with oral antidiabetic drugs. At week 24, treatment with Semglee was found to be non-inferior to that achieved with comparator insulin glargine product with regard to the mean change in HbA1c over 24 weeks of treatment (treatment difference: 0.05; 95% CI: -0.11, 0.21).
- Semglee is contraindicated during episodes of hypoglycemia and in patients with hypersensitivity to insulin glargine or one of its excipients.
- Warnings and precautions for Semglee include never share a Semglee prefilled pen, syringe or needle between patients; hyperglycemia or hypoglycemia with changes in insulin regimen; hypoglycemia; medication errors; hypersensitivity and allergic reactions; hypokalemia; and fluid retention and heart failure with concomitant use of peroxisome proliferator-activated receptor (PPAR)-gamma agonists.
- Adverse reactions commonly associated with insulin glargine products include hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, pruritus, rash, edema and weight gain.
- In patients with T1DM, Semglee must be used concomitantly with short-acting insulin. The recommended starting dose of Semglee in patients with T1DM should be approximately one-third of the total daily insulin requirements. Short-acting, premeal insulin should be used to satisfy the remainder of the daily insulin requirements.
- The recommended starting dose of Semglee in patients with T2DM who are not currently treated with insulin is 0.2 units/kg or up to 10 units once daily. One may need to adjust the amount and timing of short-or rapid-acting insulins and dosages of other antidiabetic drugs.
- Refer to the Semglee drug label for additional dosing and administration recommendations.

Continued . . .

- Mylan/Biocon’s launch plans for Semglee are pending. Semglee will be available as 100 units/mL multiple-dose vials (10 mL) and single-patient-use prefilled pens (3 mL).