Toujeo® (insulin glargine) – Expanded indication

- On November 26, 2019, the FDA approved Sanofi's Toujeo (insulin glargine), to improve glycemic control in adults and pediatric patients 6 years and older with diabetes mellitus (DM).
    - Previously, Toujeo was approved for the same indication in adults.
    - Toujeo is not recommended for the treatment of diabetic ketoacidosis.
- The FDA approval of the expanded indication for Toujeo was based on studies in adults with DM and a 26-week, open-label study of 463 pediatric patients with type 1 DM. Patients were randomized to basal-bolus treatment with Toujeo or Lantus® (insulin glargine).
    - At week 26, the difference in HbA_1c reduction from baseline between Toujeo and Lantus was 0.02% (95% CI: -0.16%, 0.20%) and met the prespecified noninferiority margin of 0.3%.
- The recommended starting dose of Toujeo in insulin-naïve pediatric and adult patients with type 1 DM is approximately one-third to one-half of the total daily insulin dose given subcutaneously (SC) once daily. As a general rule, 0.2 to 0.4 units of insulin per kilogram of body weight can be used to calculate the initial total daily insulin dose.
- The recommended starting dose of Toujeo in insulin-naive pediatric and adult patients with type 2 DM is 0.2 units per kilogram of body weight SC once daily.
- The dosage of Toujeo should be individualized and titrated based on the individual's metabolic needs, blood glucose monitoring results, and glycemic control goal.
- The dose of Toujeo should be titrated no more frequently than every 3 to 4 days.