Merilog™ (insulin aspart-szjj) – New first-time biosimilar approval

- On February 14, 2025, the FDA approved Sanofi-Aventis' Merilog (insulin-aspart-szjj), biosimilar to Novo Nordisk's Novolog® (insulin aspart).
    - Merilog is the first rapid-acting insulin biosimilar product approved by the FDA.
- Merilog and Novolog share the following indication: to improve glycemic control in adults and pediatric patients with diabetes mellitus.
- The approval of Merilog is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Novolog.
- Merilog is contraindicated:
    - During episodes of hypoglycemia
    - In patients with hypersensitivity to insulin aspart products or any of the excipients in Merilog.
- Warnings and precautions for Merilog include never share a Merilog Solostar prefilled pen between patients; hyperglycemia or hypoglycemia with changes in insulin regimen; hypoglycemia; hypoglycemia due to medication errors; hypersensitivity reactions; hypokalemia; and fluid retention and heart failure with concomitant use of PPAR-gamma agonists.
- The most common adverse reactions with Merilog use were hypoglycemia, allergic reactions, local injection site reactions, lipodystrophy, rash, and pruritus.
- The recommended dosage of Merilog is to inject subcutaneously within 5 to 10 minutes before a meal into the abdominal area, thigh, buttocks or upper arm. Individualize the dosage of Merilog based on the patient's metabolic needs, blood glucose monitoring results and glycemic control goal. Generally use Merilog in regimens with an intermediate- or long-acting insulin.
- Sanofi Aventis' launch plans for Merilog are pending. Merilog will be available as 100 units/mL (U-100) solution in a 10 mL multiple-use vial and a 3 mL single-patient-use SoloStar® prefilled pen.