Admelog® (insulin lispro) – New drug approval

- On December 11, 2017, the FDA announced the approval of Sanofi's Admelog (insulin lispro) injection to improve glycemic control in adults and pediatric patients 3 years and older with type 1 diabetes mellitus (T1DM) and adults with type 2 diabetes mellitus (T2DM).

- Admelog is a rapid-acting insulin which may be administered before meals to help control blood sugar levels after eating. It can also be used in insulin pumps to meet both background and mealtime insulin needs.

    — Admelog was approved as a follow-on insulin similar to Humalog® and is not a biosimilar product.

- The safety and efficacy of Admelog was based on studies of Admelog in 1012 patients with T1DM and T2DM as well as studies of another insulin lispro product of 1809 patients with T1DM and T2DM.

    — Overall, Admelog demonstrated non-inferiority to a comparator insulin lispro product in mean hemoglobin A1c (HbA1c) reduction.
    — Studies of another lispro product demonstrated efficacy in mean HbA1c reduction.

- Admelog is contraindicated during episodes of hypoglycemia and in patients who are hypersensitive to insulin lispro or to any of the excipients.

- Other warnings and precautions of Admelog include never share an Admelog SoloStar® pen or syringe between patients, hyperglycemia or hypoglycemia with changes in insulin regimen, hypoglycemia, hypoglycemia due to medication errors, hypokalemia, fluid retention and heart failure with concomitant use of PPAR-gamma agonists, and hyperglycemia and ketoacidosis due to insulin pump device malfunction.

- Adverse reactions associated with Admelog include hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, pruritus, and rash.

- Admelog may be administered by subcutaneous injection, continuous subcutaneous infusion (insulin pump), and intravenous infusion.

    — The dose of Admelog should be individualized and adjusted based on route of administration, the individual's metabolic needs, blood glucose monitoring results, and glycemic control goal.
    — If changing patients from another insulin lispro product to Admelog, the dose of Admelog should be the same as the other insulin lispro product.
    — Refer to the Admelog drug label for additional dosing information.

- Sanofi's launch plans for Admelog are pending. Admelog will be available as 100 units/mL (U-100) 10 mL multiple-dose vials and 3 mL single patient use SoloStar prefilled pens.