Basaglar® (insulin glargine) – New Drug Approval

- On December 16, 2015, the FDA announced the approval of Eli Lilly and Boehringer Ingelheim’s Basaglar (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).
  - Basaglar is not recommended for treating diabetes ketoacidosis.
  - Basaglar is not approved as a biosimilar product.

- Basaglar is a long-acting human insulin analog with an identical amino acid sequence to Lantus® (insulin glargine).
  - Insulin glargine is also available under the brand names Lantus and Toujeo® (insulin glargine).

- Basaglar’s approval was based, in part, on the safety and effectiveness of Lantus and on two trials comparing Basaglar to a comparator insulin glargine product in T1DM and T2DM patients.
  - The data demonstrated that Basaglar was sufficiently similar to Lantus to scientifically justify reliance and to establish the safety and efficacy of Basaglar for its approved uses.

- Warnings and precautions for Basaglar include: never share a Basaglar KwikPen® between patients, hyperglycemia or hypoglycemia with changes in insulin regimen, hypoglycemia, mediation errors, hypersensitivity and allergic reactions, hypokalemia, and fluid retention and heart failure with concomitant use of PPAR-gamma agonists.

- Basaglar is contraindicated during episodes of hypoglycemia.

- The most common adverse events (> 5%) with Basaglar use were hypoglycemia, allergic reactions, injection sit reaction, lipodystrophy, pruritus, rash, edema, and weight gain.

- The dosing of Basaglar should be individualized based on the patient’s metabolic needs, blood glucose monitoring, glycemic control, type of diabetes, and prior insulin use.
  - Basaglar should be administered subcutaneously once daily at any time of day, but at the same time every day.
  - In patients with T1DM, Basaglar must be used concomitantly with short-acting insulin.

- Eli Lilly and Boehringer Ingelheim plan to launch Basaglar on December 15, 2016. Basaglar will be available as a 100 units/mL injection in a 3 mL prefilled Basaglar KwikPen delivery device.