RXADVANCE
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CLINICAL UPDATE

Brand Name	Semglee™
Generic Name	insulin glargine injection
Drug Manufacturer	Mylan

Clinical Update

Clinical Update: FDA Approves Semglee™ (insulin glargine injection) for Type 1 and Type 2 Diabetes.
FDA approval date: June 11, 2020

Overview

Semglee™ (insulin glargine) is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.

The U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for Semglee™ (insulin glargine injection), in vial and pre-filled pen presentations, to control high blood sugar in adults with type 2 diabetes and adult and pediatric patients with type 1 diabetes. Semglee™ has an identical amino acid sequence to Sanofi's Lantus® and is approved for the same indications.

Efficacy

The approval for Semglee™ was based on a comprehensive analytical, pre-clinical, and clinical program (including the INSTRIDE studies) which confirmed the PK/PD, efficacy, safety, and immunogenicity of Semglee™ in comparison to Lantus® in patients with type 1 and type 2 diabetes.

The INSTRIDE 1 and INSTRIDE 2 studies were randomized, confirmatory clinical trials designed to evaluate the efficacy and safety of Mylan's proposed insulin glargine, MYL-1501D, versus branded insulin glargine, Lantus®. INSTRIDE 1 was a 52-week noninferiority study in 558 T1DM patients, while INSTRIDE 2 was a 24-week study in 560 T2DM (including insulin-naïve) patients. In both studies, patients were randomized to receive either once daily MYL-1501D or Lantus® and the primary endpoint was change from baseline in HbA1c after 24 weeks. Secondary endpoints included glycemic endpoints like change from baseline in fasting plasma glucose and insulin dose, as well as safety endpoints like systemic reactions, device-related safety issues and immunogenicity. The safety, efficacy, and immunogenicity data from these studies in T1DM and T2DM patients indicated that there were no differences in the Semglee™ and Lantus® arms.

Safety

Semglee™ is not recommended for the treatment of diabetic ketoacidosis. It should not be used during episodes of hypoglycemia or if hypersensitive to insulin glargine or its excipients. Patients should be instructed to never share the prefilled pen even if the needle is changed. Hypoglycemia is the most common adverse reaction with insulin, including Semglee™ and it may be life-threatening. Severe, life-threatening generalized allergy, including anaphylaxis can occur with insulin products, including Semglee™. Monitor potassium levels for hypokalemia. Fluid retention and heart failure have been reported with concomitant use of thiazolidinediones and Semglee™.