FDA News Release

FDA approves Admelog, the first short-acting "follow-on" insulin product to treat diabetes

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Release

The U.S. Food and Drug Administration today approved Admelog (insulin lispro injection), a short-acting insulin indicated to improve control in blood sugar levels in adults and pediatric patients aged 3 years and older with type 1 diabetes mellitus and adults with type 2 diabetes mellitus. Admelog is the first short-acting insulin approved as a “follow-on” product (submitted through the agency’s 505(b)(2) pathway).

According to the **Centers for Disease Control and Prevention (https://www.cdc.gov/)**, more than 30 million people in the U.S. have diabetes, a chronic disease that affects how the body turns food into energy and the body’s production of natural insulin. Over time, diabetes increases the risk of serious health complications, including heart disease, blindness, and nerve and kidney damage. Improvement in blood sugar control through treatment with insulin, a common treatment, can reduce the risk of some of these long-term complications.

“One of my key policy efforts is increasing competition in the market for prescription drugs and helping facilitate the entry of lower-cost alternatives. This is particularly important for drugs like insulin that are taken by millions of Americans every day for a patient’s lifetime to manage a chronic disease,” said FDA Commissioner Scott Gottlieb, M.D. “In the coming months, we’ll be taking additional policy steps to help to make sure patients continue to benefit from improved access to lower cost, safe and effective alternatives to brand name drugs approved through the agency’s abbreviated pathways.”

Admelog was approved through an abbreviated approval pathway under the Federal Food, Drug, and Cosmetic Act, called the 505(b)(2) pathway. A new drug application submitted through this pathway may rely on the FDA’s finding that a previously approved drug is safe and effective or on published literature to support the safety and/or effectiveness of the proposed product, if such reliance is scientifically justified. The use of abbreviated pathways can reduce drug development costs so products can be offered at a lower price to patients. In the case of Admelog, the manufacturer submitted a 505(b)(2) application that relied, in part, on the FDA’s finding of safety and effectiveness for **Humalog (https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=020563)** (insulin lispro injection) to support approval. The applicant demonstrated that reliance on the FDA’s finding of safety and effectiveness for Humalog was scientifically justified and provided Admelog-specific data to establish the drug’s safety and efficacy for its approved uses. The Admelog-specific data included two phase 3 clinical trials which enrolled approximately 500 patients in each.

Admelog is a short-acting insulin product, which can be used to help patients with diabetes control their blood sugar. Short-acting insulin products are generally, but not always, administered just before meals to help control blood sugar levels after eating. These types of insulin products can also be used in insulin pumps to meet both background insulin needs as well as mealtime insulin needs. This is in contrast to long-acting insulin products, like insulin glargine, insulin degludec and insulin detemir, which are generally used to provide a background level of insulin to control blood sugars between meals, and are administered once or twice a day. While both types of insulin products can play important roles in the treatment of types 1 and 2 diabetes mellitus, patients with type 1 diabetes require both types of insulin while patients with type 2 diabetes may never need a short-acting insulin product.

“With today’s approval, we are providing an important short-acting insulin option for patients that meets our standards for safety and effectiveness,” said Mary T. Thanh Hai, M.D., deputy director of the Office of New Drug Evaluation II in the FDA’s Center for Drug Evaluation and Research.

Admelog can be administered by injection under the skin (subcutaneous), subcutaneous infusion (i.e., via insulin pump), or intravenous infusion. Dosing of Admelog should be individualized based on the route of administration and the patient’s metabolic needs, blood glucose monitoring results and glycemic control goal.

The most common adverse reactions associated with Admelog in clinical trials was hypoglycemia, itching, and rash. Other adverse reactions that can occur with Admelog include allergic reactions, injection site reactions, and thickening or thinning of the fatty tissue at the injection site (lipodystrophy).

Admelog should not be used during episodes of hypoglycemia (low blood sugar) or in patients with hypersensitivity to insulin lispro or one of its ingredients. Admelog SoloStar prefilled pens or syringes must never be shared between patients, even if the needle is changed.

Patients or caregivers should monitor blood glucose in all patients treated with insulin products. Insulin regimens should be modified cautiously and only under medical supervision. Admelog may cause low blood sugar (hypoglycemia), which can be life-threatening. Patients should be monitored more closely with changes to insulin dosage, co-administration of other glucose-lowering medications, meal pattern, physical activity and in patients with renal impairment or hepatic impairment or hypoglycemia unawareness.

Accidental mix-ups between insulin products can occur. Patients should check insulin labels before injecting the insulin product.

Severe, life-threatening, generalized allergic reactions, including anaphylaxis, may occur.

Health care providers should monitor potassium levels in patients at risk of hyperkalemia, a serious and potentially life-threatening condition in which the amount of potassium in the blood is too high.

Admelog received tentative approval from the FDA on Sept. 1, 2017 and is now being granted final approval.

The approval of Admelog was granted to Sanofi-Aventis U.S.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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