FDA News Release

FDA approves Afrezza to treat diabetes

For Immediate Release

June 27, 2014

Release

This press release, issued June 27, 2014, was modified June 30, 2014 to correct language related to the administration of the drug. The correction was made to the first paragraph.

Español (/web/20170311085255/https://www.fda.gov/NewsEvents/Newsroom/ComunicadosdePrensa/ucm403113.htm)

The U.S. Food and Drug Administration today approved Afrezza (insulin human) Inhalation Powder, a rapid-acting inhaled insulin to improve glycemic control in adults with diabetes mellitus. Afrezza is a rapid-acting inhaled insulin that is administered at the beginning of each meal.

An estimated 25.8 million (18.8 million diagnosed and 7.0 million undiagnosed) people in the United States or approximately 8.3 percent of the population–have diabetes. Over time, high blood sugar levels can increase the risk for serious complications, including heart disease, blindness and nerve and kidney damage.

"Afrezza is a new treatment option for patients with diabetes requiring mealtime insulin," said Jean-Marc Guettier, M.D., director of the Division of Metabolism and Endocrinology Products in the FDA's Center for Drug Evaluation and Research. "Today's approval broadens the options available for delivering mealtime insulin in the overall management of patients with diabetes who require it to control blood sugar levels."

The drug's safety and effectiveness were evaluated in a total of 3,017 participants–1,026 participants with type 1 diabetes and 1,991 patients with type 2 diabetes. The efficacy of mealtime Afrezza in adult patients with type 1 diabetes patients was compared to mealtime insulin aspart (fast-acting insulin), both in combination with basal insulin (long-acting insulin) in a 24 week study. At week 24, treatment with basal insulin and mealtime Afrezza provided a mean reduction in HbA1c (hemoglobin A1c or glycosylated hemoglobin, a measure of blood sugar control) that met the pre-specified non-inferiority margin of 0.4 percent. Afrezza provided less HbA1c reduction than insulin aspart, and the difference was statistically significant. Afrezza was studied in adults with type 2 diabetes in combination with oral antidiabetic drugs; the efficacy of mealtime Afrezza in type 2 diabetes patients was compared to placebo inhalation in a 24 week study. At week 24, treatment with Afrezza plus oral antidiabetic drugs provided a mean reduction in HbA1c that was statistically significantly greater compared to the HbA1c reduction observed in the placebo group.

Afrezza is not a substitute for long-acting insulin. Afrezza must be used in combination with long-acting insulin in patients with type 1 diabetes, and it is not recommended for the treatment of diabetic ketoacidosis, or in patients who smoke.

Afrezza has a Boxed Warning advising that acute bronchospasm has been observed in patients with asthma and chronic obstructive pulmonary disease (COPD). Afrezza should not be used in patients with chronic lung disease, such as asthma or COPD because of this risk. The most common adverse reactions associated with Afrezza in clinical trials were hypoglycemia, cough, and throat pain or irritation.

The FDA approved Afrezza with a Risk Evaluation and Mitigation Strategy, which consists of a communication plan to inform health care professionals about the serious risk of acute bronchospasm associated with Afrezza.

The FDA is requiring the following post-marketing studies for Afrezza:

- a clinical trial to evaluate pharmacokinetics, safety and efficacy in pediatric patients;
- a clinical trial to evaluate the potential risk of pulmonary malignancy with Afrezza (this trial will also assess cardiovascular risk and the long-term effect of Afrezza on pulmonary function);
- two pharmacokinetic-pharmacodynamic euglycemic glucose-clamp clinical trials, one to characterize dose-response and one to characterize within-subject variability.

Afrezza is manufactured by MannKind Corporation, Danbury, Connecticut.

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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