

FDA approves new type 2 diabetes drug

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Tanzeum is injected once a week and appears to help control blood sugar levels, agency says.

(HealthDay)—Millions of Americans with type 2 diabetes have a new treatment option with the U.S. Food and Drug Administration's approval Tuesday of a once-weekly injectable drug, Tanzeum.

The FDA described Tanzeum (albiglutide) as a "glucagon-like peptide-1 (GLP-1) receptor agonist—a hormone that helps normalize patients' blood sugar levels.

Tanzeum "can be used alone or added to existing treatment regimens to control [blood sugar](#) levels in the overall management of [diabetes](#)," Dr. Curtis Rosebraugh, director of the Office of Drug Evaluation II in the FDA's Center for Drug Evaluation and Research, said in an agency news release.

The FDA's approval of the drug was based on eight [clinical trials](#) that included more than 2,000 people with type 2 diabetes. Those who took Tanzeum showed improvements in [blood sugar control](#). The drug has

also been studied for use in combination with other diabetes medications such as metformin, glimepiride, pioglitazone (Actos) and insulin.

The most common side effects seen with Tanzeum were nausea and/or reactions at the site of injection, the FDA said.

The drug, which is manufactured by GlaxoSmithKline, is not approved to treat Type 1 diabetes, the FDA noted.

The drug will carry a boxed warning stating that the use of some GLP-1 receptor agonists have been associated with thyroid tumors in rodents. The FDA said Tanzeum should not be prescribed for patients with a personal or family history of a type of thyroid cancer called medullary thyroid carcinoma (MTC), or for patients with Multiple Endocrine Neoplasia syndrome type 2. Patients with this disease have tumors in more than one gland in their body and are at increased risk for MTC.

Dr. Spyros Mezitis is an endocrinologist at Lenox Hill Hospital in New York City. He said Tanzeum joins a list of other approved injectable diabetes medicines, including Victoza (liraglutide), Byetta (exenatide) and Bydureon (exenatide extended release).

"Post-marketing clinical trials are planned to examine cardiovascular effects, use in pediatric patients, and possible increase in pancreatitis or medullary thyroid cancer," Mezitis said. "The results of these clinical trials will determine which GLP-1 agonists will be more useful" to patients.

According to the FDA, about 24 million people in the United States have [type 2 diabetes](#), which accounts for more than 90 percent of all diabetes cases diagnosed in the United States. Over time, the high [blood sugar levels](#) produced by diabetes can increase the risk for serious complications, including heart disease, blindness, and nerve and kidney

damage.

More information: The U.S. National Institute of Diabetes and Digestive and Kidney Diseases has more about [type 2 diabetes](#).

The FDA has more about [this approval](#).

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