

FDA Approves Tanzeum (albiglutide) for Adults with Type 2 Diabetes

On April 15, 2014, the U.S. Food and Drug Administration (FDA) approved Tanzeum (albiglutide) in adults with type 2 diabetes. Tanzeum is a once-weekly subcutaneous injection indicated for the improvement of glycemic control, along with diet and exercise. It acts as a glucagon-like peptide-1 (GLP-1) receptor agonist, helping to normalize blood glucose levels. Tanzeum has been studied as monotherapy or in combination with other type 2 diabetes therapies, including metformin, glimepiride, pioglitazone, and insulin. It should not be used to treat patients with type 1 diabetes, those who have diabetic ketoacidosis, or as first-line therapy for patients who cannot be managed with lifestyle modifications such as diet and exercise.

Tanzeum has a Boxed Warning stating that thyroid C-cell tumors have been observed in rodent studies with GLP-1 receptor agonists at clinically relevant exposures. However, it is unknown whether Tanzeum causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC) in humans. Because of this, Tanzeum is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). The FDA is requiring post-marketing studies for Tanzeum including a clinical trial to evaluate dosing, efficacy, and safety in pediatric patients; an MTC case registry of at least 15 years duration to identify any increase in MTC incidence related to Tanzeum; and a cardiovascular outcomes trial (CVOT) to evaluate the cardiovascular risk of Tanzeum in patients with high baseline risk of cardiovascular disease. The FDA approved Tanzeum with a Risk Evaluation and Mitigation Strategy (REMS), consisting of a communication plan to inform health care providers about the risks associated with Tanzeum. In clinical trials, the most common adverse reactions included diarrhea, nausea, and injection site reactions.

References:

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- Rosenstock J, Reusch J, Bush M, Yang F, Stewart M. Potential of Albiglutide, a Long-Acting GLP-1 Receptor Agonist, in Type 2 Diabetes: A Randomized Controlled Trial Exploring Weekly, Biweekly, and Monthly Dosing. *Diabetes Care*. 2009; 32: 1880-1886.
- FDA approves Tanzeum to treat type 2 diabetes [news release]. Silver Spring, MD: April 15, 2014. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm393289.htm>

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