



## TANZEUM REMS

### FDA Required REMS Safety Information

- **Potential Risk of Medullary Thyroid Carcinoma (MTC)**
- **Risk of Acute Pancreatitis**

### Important Safety Notice

The FDA has required this safety update as part of the TANZEUM® REMS (Risk Evaluation and Mitigation Strategy) to inform healthcare providers about the following **serious risks of TANZEUM (albiglutide)**:

#### **Potential Risk of Medullary Thyroid Carcinoma (MTC)**

- Carcinogenicity of albiglutide could not be assessed in rodents, but other glucagon-like peptide-1 (GLP-1) receptor agonists have caused thyroid C-cell tumors in rodents at clinically relevant exposures. It is unknown whether TANZEUM causes thyroid C-cell tumors, including MTC in humans.
- Cases of MTC in patients treated with liraglutide, another GLP-1 receptor agonist, have been reported in the postmarketing period. The data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 receptor agonist use in humans.

#### **Acute Pancreatitis**

- In clinical trials, there were more cases of acute pancreatitis among patients treated with TANZEUM than among patients treated with comparators.

**TANZEUM is not recommended as first-line therapy for patients inadequately controlled on diet and exercise.**

A non-promotional factsheet, reviewed by the FDA, with more detailed safety information about these risks is enclosed.

**Indication:** TANZEUM is a GLP-1 receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Please visit [www.TANZEUMREMS.com](http://www.TANZEUMREMS.com) for more information.

This letter does not contain the complete safety profile for TANZEUM. Please see the enclosed Prescribing Information and Medication Guide.

**Reporting Adverse Events**

You are encouraged to report negative side effects of prescription drugs to GlaxoSmithKline (the Sponsor) at 1-888-825-5249 and/or the FDA [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

If you have any questions about the information contained in this letter or the use of TANZEUM, you may contact:

- US Medical Information Department at 1-877-356-8368

A handwritten signature in blue ink that reads "Philip Hornick". The signature is written in a cursive style with a large, stylized initial "P" and a long, sweeping underline that extends to the right.

Philip Hornick, MD, PhD, FESC  
Medical Affairs Therapy Area Head/Vice President - CVM  
Medical Affairs, North America