Tanzeum™ (albiglutide) is a once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist approved for use in the United States as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.1

About Tanzeum

- Tanzeum belongs to the class of incretin mimetic therapies. These therapies mimic the action of a class of hormones, often referred to as incretins, which help lower blood glucose levels.2,3
- GLP-1 receptor agonists specifically help lower blood glucose when levels are elevated (glucose-dependent mechanism of action).4
- Tanzeum is made up of two copies of recombinant modified human GLP-1 fused in tandem to recombinant human albumin. Tanzeum has an extended half-life of five days and is indicated as a weekly injectable medicine.5

About Diabetes

Type 2 diabetes is a complex and progressive disease.6 Despite a number of available management options, approximately 50 percent of patients do not have their blood glucose under control.7,8

Mode of Administration*

The injector pen was developed in parallel with and used in the albiglutide Phase III clinical trial program (Harmony). Tanzeum has been developed for once-weekly self-administration by patients at any time of the day without regard to meals, and will be administered using an injector pen supplied with a 5mm 29-gauge thin-walled needle.1

Tanzeum is a lyophilised (freeze-dried) product, which requires reconstitution prior to subcutaneous injection.1

[*Further instructions on administration can be found in the ‘Instructions for Use’ section of the Prescribing Information for Tanzeum.1]

Clinical Trials

The clinical development program for Tanzeum (albiglutide) by GSK includes the Harmony studies, comprising eight Phase III studies involving over 5,000 adult patients diagnosed with type 2 diabetes. The Harmony program evaluated Tanzeum alone or in combination with or against commonly-used classes of type 2 diabetes treatment, including insulin, in patients at different stages of the disease, as well as those with renal impairment.

[Individual study results are outlined in the accompanying Harmony Clinical Trials Factsheet]
**Indications and Usage**

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.

**Limitations of Use:**
- Not recommended as first-line therapy for patients inadequately controlled on diet and exercise.
- Has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.
- Not for patients with pre-existing severe gastrointestinal disease.
- Has not been studied in combination with prandial insulin.

**Important Safety Information**

**BOXED WARNING: RISK OF THYROID C-CELL TUMORS**

Thyroid C-cell tumors have been observed in rodent studies with glucagon-like peptide-1 (GLP-1) receptor agonists at clinically relevant exposures. It is unknown whether Tanzeum causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans. 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).

**WARNINGS AND PRECAUTIONS**

- **Pancreatitis:** Discontinue promptly if suspected. Do not restart if confirmed. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- **Hypoglycemia:** Can occur when used in combination with insulin secretagogues (e.g. sulfonylureas) or insulin. Consider lowering sulfonylurea or insulin dosage when starting Tanzeum.
- **Hypersensitivity Reactions:** Discontinue Tanzeum if suspected. Monitor and treat promptly per standard of care until signs and symptoms resolve.
- **Renal Impairment:** Monitor renal function in patients with renal impairment reporting severe adverse gastrointestinal reactions.
- **Macrovascular Outcomes:** There have been no clinical trials establishing conclusive evidence of macrovascular risk reduction with Tanzeum or any other antidiabetic drug.

**ADVERSE REACTIONS**

Adverse reactions, reported in ≥10% of patients treated with Tanzeum and more frequently than in patients on placebo, were upper respiratory tract infection, diarrhea, nausea, and injection site reaction.

[**For all information regarding safety and warnings please refer to the Prescribing Information for Tanzeum**]
References

1 Tanzeum Full Prescribing Information, GlaxoSmithKline 2014. [Published version TBC]