



GSK
5 Crescent Drive
Philadelphia PA
19112
www.gsk.com

July 26, 2017

Subject: Discontinuation of TANZEUM® (albiglutide)

Dear Healthcare Provider,

After 3 years of providing TANZEUM (albiglutide) (30 mg and 50 mg for injection) as a treatment option for adults with type 2 diabetes mellitus, GSK has made the difficult decision to discontinue the commercial sale of TANZEUM.

This decision is not related to any known safety concern. GSK dedicated significant effort to educating HCPs on the safety and efficacy profile of TANZEUM for appropriate patients. However, even with this support, there has been limited prescribing of the medicine and, given the range of alternative treatments available, it has become harder and harder to make the impact for patients that we expected.

We expect that commercial supply will be depleted by July 2018. We are notifying you now to ensure you have sufficient time to transition any existing patients taking TANZEUM to an alternative therapy.

Suggested Actions:

1. Initiate discussions with patients currently on TANZEUM with a plan to transition all patients to an alternative therapy as appropriate by July 2018.
2. Do not initiate treatment with TANZEUM for any new patients.

This decision does not impact ongoing clinical studies for type 2 diabetes with TANZEUM. A separate communication will be distributed to clinical trial investigators with specifics related to ongoing studies.

GSK has also communicated this decision to the FDA.

We thank you for your support of TANZEUM as a treatment option for patients. If you have any questions, please contact our Customer Response Center at 1-888-825-5249.

Sincerely,

Philip Hornick, MD, PhD
VP, Therapeutic Area Head of Specialty, Rare Disease, Classic and Established Medicines
US Medical Affairs, GSK

Further Information

Reporting Adverse Events: If you become aware of an adverse event involving TANZEUM please contact:

- GSK at 1-888-825-5249 and/or
- FDA MedWatch program by phone at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm

This letter is not a comprehensive description of the risks with the use of TANZEUM. Please see full Prescribing Information, including Boxed Warning and Medication Guide, for TANZEUM on www.gsksource.com.

Additionally, please see Frequently Asked Questions on next page.

Discontinuation of TANZEUM® (albiglutide)

1. Why has GSK decided to discontinue manufacturing TANZEUM after announcing in November 2016 that the company would keep the product on the market in the US?

This has been a difficult decision for GSK. In 2016, following a review of opportunities that exist across the GSK portfolio, we announced an end to our direct sales force promotion for TANZEUM in the US. That decision has enabled us to shift investment to areas (such as respiratory) where greater long-term opportunities exist for us to support patients and strengthen our existing business. While we continued to invest in a small digital and direct mail marketing effort, we have seen a steady decline in the volume and market share of TANZEUM within the US. In the current marketplace, it is harder and harder to make the type of impact for patients that we would expect. Given the availability of multiple different treatment options to treat patients with type 2 diabetes, we have decided to cease any future research and development, manufacturing, supply, and sales activity for TANZEUM by July 2018.

2. How is this action patient-focused?

While this was a difficult decision, we feel patients can be well served by other companies with expansive diabetes portfolios who can make greater investments in patient education and support services than GSK.

We are announcing this decision well in advance to ensure that all healthcare professionals have considerable time to discuss alternative treatment options with their patients and switch patients as medically appropriate. This announcement will also enable healthcare professionals to start new patients on a different therapy moving forward.

3. What will the transition plan be? How will customers/patients be notified?

“Dear Doctor” letters will be sent electronically and via regular mail to healthcare professionals to advise them of this decision and of the one-year notice period available for them to transition any patients currently receiving albiglutide to alternative treatment as required.

We are also working closely with our distributors to ensure the medicine remains available to existing patients through the July 2018 timeframe.

GSK has updated both our consumer and HCP websites with this same information.

4. Has this decision been taken due to a safety concern with the medicine?

No, this decision has not been taken due to any safety concern.

5. What should healthcare professionals with patients on TANZEUM do?

We are advising healthcare providers to begin seeking alternative medicines for existing patients as soon as possible and to ensure all patients are started on a different therapy by the end of June 2018 at the latest.

In addition, we are advising that healthcare professionals no longer initiate any new patients on TANZEUM.

6. How is the company instructing patients with type 2 diabetes currently taking TANZEUM?

Patients should speak to their healthcare provider about their type 2 diabetes to learn more about alternative treatment options which may be suitable for them.

7. Why may HCPs and consumers continue to see promotion of TANZEUM (in journals, online, etc)?

With the recent decision to stop future research and development, manufacturing, and sale of TANZEUM in the US, GSK will immediately begin ceasing all forms of patient and healthcare professional marketing. However, it is possible that there may continue to be some lingering forms of promotion in the market as the promotion cancellation process completes.

TANZEUM.com, TANZEUMrems.com, and gsksource.com will be available for patients and healthcare professionals to access important information about TANZEUM through July 2018.

8. Does GSK have enough supply to meet patient demands up until the time of discontinuation?

Yes—we will ensure TANZEUM remains available to existing patients until at least the end of June 2018 so there is sufficient time for patients to meet with their treating physician and to identify and initiate a satisfactory treatment alternative, as appropriate.

9. What clinical programs are currently underway for TANZEUM?

In late 2016, GSK halted all uncommitted clinical development for TANZEUM. We are continuing those ongoing clinical studies including a Cardiovascular Outcomes Trial, a basal-bolus switch study (NCT02465515), and a study on new onset type 1 diabetes (NCT02284009), which are all expected to conclude by mid-2018. Clinical trial investigators have been informed of our intention to cease manufacturing, supply, and sales of TANZEUM.

10. What will happen if the Cardiovascular Outcomes Trial demonstrates a survival benefit of TANZEUM?

The Cardiovascular Outcomes Trial will complete in mid-2018. GSK remains highly committed to completing the ongoing HARMONY Cardiovascular Outcomes study, a postmarketing requirement. Our commitment to the fully recruited patients, investigators, and academic community is unwavering and we endeavour to advance medical science by adding to the body of evidence on the GLP-1 receptor agonist class effect in cardiovascular outcomes.

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