



New TEPEZZA® (teprotumumab-trbw) Data to be Presented at the American Academy of Ophthalmology (AAO) 2021 Annual Meeting

October 12, 2021

-- Highlights include a poster presentation about real-world adherence to TEPEZZA and an oral presentation sharing data from the OPTIC-X extension trial in people with Thyroid Eye Disease (TED) who have low-level inflammation --

DUBLIN--(BUSINESS WIRE)--Oct. 12, 2021-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced new TEPEZZA data will be presented at the American Academy of Ophthalmology Annual Meeting ([AAO 2021](#)) in New Orleans and virtually, Nov. 12-15, 2021. TEPEZZA is the first and only medicine approved by the U.S. Food and Drug Administration (FDA) for the treatment of TED – a serious, progressive and potentially vision-threatening rare autoimmune disease.¹

Data being presented at AAO 2021 [include](#):

TEPEZZA data:

- **Title:** Real-World Adherence with Teprotumumab in TED
 - **Session:** PO026, R. Douglas
 - **Date:** Sunday, Nov. 14, 9:15 a.m. CT (e-poster also available on demand)
- **Title:** Teprotumumab Efficacy in TED Patients with Low Inflammation as Measured by Clinical Activity Score
 - **Session:** PA059, R. Douglas
 - **Date:** Monday, Nov. 15, 10:45 a.m. CT (e-poster also available on demand)

TED data:

- **Title:** TED and Healthcare Resource Utilization
 - **Session:** PO028, A. Kossler
 - **Date:** Sunday, Nov. 14, 9:37 a.m. CT (e-poster also available on demand)
- **Title:** Development of Health State Utilities for TED
 - **Session:** PO295, K. Cockerham
 - **Date:** On demand (e-poster)

Horizon will also host a product theater on Sunday, Nov. 14 at 4:10 p.m. CT titled “Impact of TEPEZZA (teprotumumab-trbw): Real-world Cases in Thyroid Eye Disease” featuring Andrew R. Harrison, M.D., Director of Oculoplastic and Orbital Surgery and Co-Director, Center for Thyroid Eye Disease, University of Minnesota.

About Thyroid Eye Disease (TED)

TED is a serious, progressive and potentially vision-threatening rare autoimmune disease.¹ TED often occurs in people living with Graves' disease, but is a distinct disease that is caused by autoantibodies activating an IGF-1R-mediated signaling complex on cells within the retro-orbital space.^{2,3} This leads to a cascade of negative effects, which may cause long-term, irreversible damage. As TED progresses, the serious damage it can cause includes proptosis (eye bulging), strabismus (misalignment of the eyes) and diplopia (double vision) – and in some cases can lead to blindness.^{4,5}

About TEPEZZA

INDICATION

TEPEZZA is indicated for the treatment of Thyroid Eye Disease.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Infusion Reactions: TEPEZZA may cause infusion reactions. Infusion reactions have been reported in approximately 4% of patients treated with TEPEZZA. Reported infusion reactions have usually been mild or moderate in severity. Signs and symptoms may include transient increases in blood pressure, feeling hot, tachycardia, dyspnea, headache and muscular pain. Infusion reactions may occur during an infusion or within 1.5 hours after an infusion. In patients who experience an infusion reaction, consideration should be given to premedicating with an antihistamine, antipyretic, or corticosteroid and/or administering all subsequent infusions at a slower infusion rate.

Preexisting Inflammatory Bowel Disease: TEPEZZA may cause an exacerbation of preexisting inflammatory bowel disease (IBD). Monitor patients

with IBD for flare of disease. If IBD exacerbation is suspected, consider discontinuation of TEPEZZA.

Hyperglycemia: Increased blood glucose or hyperglycemia may occur in patients treated with TEPEZZA. In clinical trials, 10% of patients (two-thirds of whom had preexisting diabetes or impaired glucose tolerance) experienced hyperglycemia. Hyperglycemic events should be managed with medications for glycemic control, if necessary. Monitor patients for elevated blood glucose and symptoms of hyperglycemia while on treatment with TEPEZZA. Patients with preexisting diabetes should be under appropriate glycemic control before receiving TEPEZZA.

Adverse Reactions

The most common adverse reactions (incidence $\geq 5\%$ and greater than placebo) are muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dysgeusia, headache and dry skin.

For additional information on TEPEZZA, please see [Full Prescribing Information](#) at [TEPEZZAhcp.com](#).

About Horizon

Horizon is focused on the discovery, development and commercialization of medicines that address critical needs for people impacted by rare, autoimmune and severe inflammatory diseases. Our pipeline is purposeful: we apply scientific expertise and courage to bring clinically meaningful therapies to patients. We believe science and compassion must work together to transform lives. For more information on how we go to incredible lengths to impact lives, please visit www.horizontherapeutics.com and follow us on [Twitter](#), [LinkedIn](#), [Instagram](#) and [Facebook](#).

References

1. Barrio-Barrio J, et al. Graves' Ophthalmopathy: VISA versus EUGOGO Classification, Assessment, and Management. *Journal of Ophthalmopathy*. 2015;2015:249125.
2. Weightman DR, et al. Autoantibodies to IGF-1 Binding Sites in Thyroid Associated Ophthalmopathy. *Autoimmunity*. 1993;16(4):251-257.
3. Pritchard J, et al. Immunoglobulin Activation of T Cell Chemoattractant Expression in Fibroblasts from Patients with Graves' Disease Is Mediated Through the Insulin-Like Growth Factor 1 Receptor Pathway. *J Immunol*. 2003;170:6348-6354.
4. Bartalena L, Kahaly GJ, Baldeschi L, et al. The 2021 European Group on Graves' Orbitopathy (EUGOGO) Clinical Practice Guidelines for the Medical Management of Graves' Orbitopathy [published online ahead of print]. *Eur J Endocrinol*. 2021 Jul 1:EJE-21-0479.R1. doi: 10.1530/EJE-21-0479.
5. McKeag D, et al. Clinical features of dysthyroid optic neuropathy: a European Group on Graves' Orbitopathy (EUGOGO) survey. *Br J Ophthalmol*. 2007;91:455-458.

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