



New Real-World Analysis of TEPEZZA® (teprotumumab-trbw) Use Indicates a Small Percentage of People Receive a Second Course of Treatment

October 22, 2022

-- Analysis presented at American Thyroid Association Annual Meeting (ATA 2022) shows during a two-year period, 4.9% of patients who completed a full course of TEPEZZA were later prescribed a second course --

DUBLIN--(BUSINESS WIRE)--Oct. 22, 2022-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced new data from a real-world analysis of TEPEZZA presented at the 91st Annual Meeting of the ATA. TEPEZZA is the first and only medicine approved by the U.S. Food and Drug Administration (FDA) for the treatment of Thyroid Eye Disease (TED) – a serious, progressive and potentially vision-threatening rare autoimmune disease.¹

Evidence has indicated that due to the progressive nature of TED, the disease may reactivate, or flare. In a retrospective chart review, up to 15% of patients experienced a TED flare, regardless of treatment regimen. While many causes for reactivation are unknown, some triggers include pregnancy, stress and surgery.²

The real-world analysis assessed deidentified claims data from people living with TED who completed a full, uninterrupted course of TEPEZZA (8 infusions) in 2020 and then subsequently were prescribed a second course of treatment prior to July 2022. During this two-year period, 4.9% (286/5,845) of patients were prescribed a second course of TEPEZZA. 1.9% (110/5,845) of the total patients went on to initiate treatment by the end of the two-year period, with a mean time of 12 months between courses.³

“Treating an autoimmune condition like Thyroid Eye Disease that may worsen or flare over time is challenging,” said Shoaib Ugradar, M.D., The Jules Stein Eye Institute at University of California, Los Angeles (UCLA). “These data indicate that the need is low for additional treatment with TEPEZZA for those living with Thyroid Eye Disease who have completed an initial course. With continued analysis and research, we hope to come closer to identifying specific causes and indicators for additional treatment in order to better manage this debilitating, life-long condition.”

Horizon also announced results from a 2018 U.S. survey of endocrinologist and ophthalmologists comparing the impact of shorter versus longer duration TED in patients with a high Clinical Activity Score (CAS). The analysis looked at those with a CAS ≥ 3 , who had lived with TED for less than or equal to three years (n=192) versus over three years (n=115). Both shorter and longer duration groups reported comparable overall negative mental health impact (38.5% vs. 35.7%, respectively) and experience with anxiety and depression. They both also reported a similar negative effect of TED on their quality of life, as measured by a seven-point Likert scale, including social and daily activities.⁴

“Thyroid Eye Disease, regardless of years since diagnosis, can significantly impact a person's ability to look and feel like themselves and may affect daily tasks from reading to driving a car,” said Jeffrey W. Sherman, M.D., FACP, executive vice president, chief medical officer, Horizon. “These survey results emphasize the burden of disease for those living with Thyroid Eye Disease and underscore the need for appropriate care with treatment as soon as possible.”

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.^{5,6} This leads to a cascade of negative effects, which may cause long-term, irreversible damage, including blindness. Early signs and symptoms of TED may include dry eyes and grittiness; redness, swelling and excessive tearing; eyelid retraction; proptosis; pressure and/or pain behind the eyes; and diplopia.^{7,8}

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, dry skin, and menstrual disorders.

Please see [Full Prescribing Information](#) or visit TEPEZZAhcp.com for more information.

About Horizon

Horizon is a global biotechnology company 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, 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. Patel P, et al. Recurrent Thyroid Eye Disease. *Ophthalmic Plastic and Reconstructive Surgery*. 2015; 31:445-8.
3. Smith TJ, et al. Evaluation of United States Thyroid Eye Disease Patients Receiving an Additional Course of Teprotumumab Treatment over 2 years. Poster session presented at: Annual Conference of American Thyroid Association (ATA); 2022 October 19-23; Montreal, Quebec, Canada.
4. Smith TJ, et al. Sequelae of Shorter versus Longer Duration Inflammatory Thyroid Eye Disease. Poster session presented at: Annual Conference of American Thyroid Association (ATA); 2022 October 19-23; Montreal, Quebec, Canada.
5. Weightman DR, et al. Autoantibodies to IGF-1 Binding Sites in Thyroid Associated Ophthalmopathy. *Autoimmunity*. 1993;16(4):251-257.
6. 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.
7. 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. *Eur J Endocrinol*. 2021;185:G43-G67.
8. 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20221022005001/en/): <https://www.businesswire.com/news/home/20221022005001/en/>

Investors:

Tina Ventura

Senior Vice President, Chief Investor Relations Officer

Investor-relations@horizontherapeutics.com

U.S. Media:

Rachel Vann

Senior Director, Product Communications

media@horizontherapeutics.com

Ireland Media:

Gordon MRM

Ray Gordon

ray@gordonmrm.ie

Source: Horizon Therapeutics plc