



Real-World Experience Shows TEPEZZA® (teprotumumab-trbw) Was Effective in Treating People With Dysthyroid Optic Neuropathy (DON)

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-- Data presented at the North American Neuro-Ophthalmology Society (NANOS) Annual Meeting on March 11-16 in Orlando --

DUBLIN--(BUSINESS WIRE)--Mar. 12, 2023-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced results of an analysis of real-world treatment with TEPEZZA in Thyroid Eye Disease (TED) patients with DON, the majority of whom had not previously responded to other treatments. DON is a complication of TED characterized by thyroid-related impairment of visual function and can lead to permanent sight loss related to optic nerve compression.¹ 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.^{2,3}

This analysis summarizes real-world experience of people living with TED and DON who were treated with TEPEZZA between January 2020 and September 2022. During this period, 24 patients were identified from literature and the author's clinical experience with most (22 out of 24) receiving treatment with oral or intravenous steroids, surgery and/or radiation prior to TEPEZZA. After TEPEZZA treatment, meaningful improvement was observed in visual acuity in eyes with DON (mean lines of improvement of 3.7 – 23 patients, range 1-15, mean improvement in the mean deviation on visual field testing of -5.87 – 7 patients); proptosis (mean reduction of 4.4 mm – 19 patients); diplopia (mean improvement of 0.75 grade – 8 patients); and Clinical Activity Score (CAS) (mean reduction of 5.1 – 17 patients). Reported adverse events were consistent with TEPEZZA clinical trials and included fatigue, dysgeusia, hearing issues, nausea, hyperglycemia and muscle spasms.

"We know how devastating Thyroid Eye Disease can be for patients, and the risk of blindness in those with dysthyroid optic neuropathy is one of the most worrisome complications, especially when traditional therapies fail," said Madhura A. Tamhankar, M.D., study author and associate professor of ophthalmology and neurology at the Hospital of the University of Pennsylvania. "These data are encouraging for physicians looking for an option to treat patients at the highest risk of losing their sight and provide evidence that TEPEZZA can help improve symptoms and preserve visual acuity."

A recent health state [analysis](#) in *JAMA Ophthalmology* assessed the burden of TED, revealing people with moderate-to-severe disease experience substantial disutility in their day-to-day lives. In the study of over 100 general population participants, the worst impact on quality of life was associated with the most severe disease state (constant diplopia and large proptosis).⁴

"The spectrum and severity of Thyroid Eye Disease symptoms can vary greatly for people and often require significant intervention to avoid long-term repercussions and negative impact to everyday activity, especially when dysthyroid optic neuropathy is involved," said Mandeep Kaur, M.D., M.S., senior vice president, global medical affairs and outcomes research, Horizon. "This research underscores our ongoing commitment to ensuring patients receive appropriate care that can result in improved clinical outcomes."

About Thyroid Eye Disease (TED)

TED is a serious, progressive and potentially vision-threatening rare autoimmune disease.³ 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 controlled with medications for glycemic control, if necessary. Assess patients for elevated blood glucose and symptoms of hyperglycemia prior to infusion and continue to monitor while on treatment with TEPEZZA. Ensure patients with hyperglycemia or preexisting diabetes are under appropriate glycemic control before and while 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, weight decreased, nail disorders, and menstrual disorders.

Please see [Full Prescribing Information](#) or visit [TEPEZZAhcp.com](https://www.tepezza.com) for more information.

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, visit www.horizontherapeutics.com and follow us on [Twitter](#), [LinkedIn](#), [Instagram](#) and [Facebook](#).

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the potential benefits of TEPEZZA, the impact of additional data on treatment decisions and Horizon's plans for future clinical research. These forward-looking statements are based on Horizon's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to clinical trials, including the fact that prior results may not predict future clinical trial outcomes; regulatory obligations and oversight, including any changes in the legal and regulatory environment in which Horizon operates and those risks detailed from time-to-time under the caption "Risk Factors" and elsewhere in Horizon's filings and reports with the SEC. Horizon undertakes no duty or obligation to update any forward-looking statements contained in this press release as a result of new information.

References

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