New Real-World Data Show High Rate of Patient Adherence to TEPEZZA® (teprotumumab-trbw) for Thyroid Eye Disease (TED)

November 12, 2021

-- Analysis to be presented during AAO 2021 demonstrates 90% of patients finished full course of TEPEZZA therapy (eight infusions), indicating strong patient adherence --

DUBLIN--(BUSINESS WIRE)--Nov. 12, 2021-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced findings of a real-world adherence analysis of TEPEZZA for the treatment of TED at the American Academy of Ophthalmology Annual Meeting (AAO 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]

The analysis found that over 90% (n=995) of people who were prescribed TEPEZZA for TED went on to complete all eight infusions, indicating a high level of adherence to TEPEZZA in clinical practice. The study evaluated 1,101 people living with TED (71% female, mean age 58 years) who started treatment with TEPEZZA prior to July 2020. Non-compliance was low at approximately 1% (n=15). Only 8% (n=84) reported that they discontinued because of adverse events (AEs). The most common AEs reported in patients who discontinued due to an AE were consistent with observations in the TEPEZZA clinical trials.

“When considering treatment options, it is critical to balance desired efficacy with the potential for adverse events or other factors that may hinder adherence to treatment,” said Roger A. Dailey, M.D., F.A.C.S., study investigator and professor of ophthalmology, oculofacial plastic surgery and dermatology, Casey Aesthetic Facial Surgery Center at Oregon Health & Science University’s Casey Eye Institute. “These results, which show patients are committed to finishing this therapy for Thyroid Eye Disease, should give physicians further confidence in medical management of this devastating condition.”

“It is encouraging to see the high rate of adherence that we observed in the clinical trials has continued in real world clinical practice, and that there were very few discontinuations due to adverse events,” said Jeffrey W. Sherman, M.D., FACP, executive vice president, chief medical officer, Horizon. “These results provide important insights as physicians make treatment decisions with their patients. We know from our clinical trials the importance of completing all infusions as prescribed, as patients who completed the full course of therapy saw reduced eye bulging, improved double vision, and less eye pain, redness and swelling.”

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. TED begins with an acute (active) phase where inflammatory signs and symptoms, such as eye pain, swelling, proptosis (eye bulging) and diplopia (double vision), progress over time.[1,4] The disease then enters a chronic phase where inflammation is no longer present or has markedly diminished, but significant signs and symptoms may remain. 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 ≥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 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20211112005612/en/

Investors:
Tina Ventura
Senior Vice President, Investor Relations
Investor-relations@horizontherapeutics.com

Ruth Venning
Executive Director, Investor Relations
Investor-relations@horizontherapeutics.com

U.S. Media:
Rachel Vann
Director, Product Communications
media@horizontherapeutics.com

Ireland Media:
Gordon MRM
Ray Gordon
ray@gordonmrm.ie

Source: Horizon Therapeutics plc