Horizon Therapeutics plc Announces Data from the TEPEZZA® (teprotumumab-trbw) Phase 4 Clinical Trial in Patients with Chronic/Low CAS Thyroid Eye Disease (TED) to be Presented at the Upcoming Endocrine Society (ENDO) Annual Meeting

June 5, 2023

-- TEPEZZA Phase 4 trial results to be shared in an oral presentation on Saturday, June 17 at 3:30 p.m. CT --

-- Two patients will share their real-world experience living with TED and being treated with TEPEZZA on Friday, June 16 at 10:15 a.m. CT --

DUBLIN--(BUSINESS WIRE)--Jun. 5, 2023-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced new data will be presented at the annual meeting of the Endocrine Society (ENDO 2023) in Chicago, June 15-18. 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) regardless of disease activity or duration. TED is a serious, progressive, debilitating and potentially vision-threatening rare autoimmune disease.¹

Horizon presentations include:

- **Title:** Efficacy and Safety Results from the Randomized, Placebo-Controlled Multicenter Trial with Teprotumumab in Chronic-Low Clinical Activity Score Thyroid Eye Disease Patients
  - **Session:** Oral Presentation, 10388, R Douglas
  - **Date:** Saturday, June 17, 3:30 p.m. CT

- **Title:** A Randomized, Quadruple-masked, Placebo-controlled, Multicenter Trial to Evaluate the Efficacy and Safety of Teprotumumab in Patients with Chronic (Inactive/Low CAS) Thyroid Eye Disease
  - **Session:** P81, SAT-459, R Douglas
  - **Date:** Saturday, June 17, 1-2 p.m. CT

- **Title:** Hearing-related Issues Associated with Graves’ Disease, Thyroid Eye Disease and Treatment with Teprotumumab
  - **Session:** P81, SAT-465, TJ Smith
  - **Date:** Saturday, June 17, 1-2 p.m. CT

- **Title:** Hearing-Related Adverse Events in Teprotumumab Oncology Clinical Trials
  - **Session:** P81, SAT-475, TJ Smith
  - **Date:** Saturday, June 17, 1-2 p.m. CT

- **Title:** Teprotumumab Pooled Efficacy from the European Study Sites Participating in the Phase 2, OPTIC (Phase 3) and OPTIC-X Pivotal Trials
  - **Session:** P81, SAT-463, G Kahaly
  - **Date:** Saturday, June 17, 1-2 p.m. CT

- **Title:** Inactive Thyroid Eye Disease Patient Journey
  - **Session:** P81, SAT-470, TJ Smith
  - **Date:** Saturday, June 17, 1-2 p.m. CT

- **Title:** The Epidemiology of Thyroid Eye Disease in Olmsted County, Minnesota
  - **Session:** P54, FRI-549, K Rachmasari
  - **Date:** Friday, June 16, 12-1 p.m. CT

Horizon will host a product theater on Friday, June 16 at 12 p.m. CT in ENDOExpo Theater 3, titled “Thyroid Eye Disease (TED): Early Diagnosis, Referral, and Treatment” with Todd W. Frieze, M.D., FACP, FACE, ECNU, Duke University Health System.

Additionally, two people living with TED will join Malini Gupta, M.D., ECNU, FACE, Director of G2Endo, for a discussion on their journey to diagnosis and experience being treated with TEPEZZA. The event, “As Seen on TV: Real Patients Share Their Thyroid Eye Disease (TED) Treatment Experience,” will be held in the Exhibit Hall on Friday, June 16 at 10:15 a.m. CT.

“We look forward to bringing these valuable findings and unique patient perspectives to an audience well-positioned to detect the earliest signs and symptoms of Graves’ disease and Thyroid Eye Disease,” said Jeffrey W. Sherman, M.D., FACP, executive vice president, chief medical officer, Horizon. “The ENDO meeting provides an important opportunity to share results from the TEPEZZA Phase 4 clinical trial, which met its primary endpoint and demonstrated significant proptosis improvement in people who have lived with Thyroid Eye Disease for many years and have low
About Thyroid Eye Disease (TED)

TED is a serious, progressive, debilitating 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, 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.\(^4,5\)

About TEPEZZA

INDICATION

TEPEZZA is indicated for the treatment of Thyroid Eye Disease regardless of Thyroid Eye Disease activity or duration.

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 ≥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 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.

References


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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:
Eimear Rigby
Associate Director, Corporate Communications
erigby@horizontherapeutics.com

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