Horizon Therapeutics plc to Resupply Market With TEPEZZA® (teprotumumab-trbw) for the Treatment of Thyroid Eye Disease (TED) Beginning in April

March 30, 2021

DUBLIN--(BUSINESS WIRE)--Mar. 30, 2021-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced that the U.S. Food and Drug Administration (FDA) has approved a prior approval supplement (PAS) to the previously approved Biologics Licensing Application (BLA) giving Horizon authorization to manufacture more TEPEZZA drug product resulting in an increased number of vials with each manufacturing slot. The company plans to resupply the market beginning in April, which will end the supply disruption that began in December 2020 following U.S. government orders prioritizing the manufacturing of a COVID-19 vaccine.

"We commend the efforts of the FDA and the Biden Administration to accelerate COVID-19 vaccine production while working together with our team so that people living with Thyroid Eye Disease are able to resume or start treatment with TEPEZZA," said Tim Walbert, chairman, president and chief executive officer, Horizon. "We are pleased that patients who have had to struggle with the debilitating effects of Thyroid Eye Disease will soon have access again to TEPEZZA, the only FDA-approved medicine to treat this rare disease, and we appreciate their patience and understanding during this unfortunate disruption. We understand the ongoing need for vaccine production and hope that the Biden Administration continues to prioritize all patients who need access to medically necessary treatments."

Information for Patients

TED patients who have been affected by the TEPEZZA supply disruption should talk with their doctor about their plan for starting or resuming treatment and share the plan with their infusion center. Patients can contact their infusion center directly to schedule their infusions or call their Horizon Patient Access Liaison (PAL) if they have questions about the process of starting or resuming treatment. To enroll in Horizon Patient Services, please call 1-833-583-7399 Monday to Friday, 8 a.m. through 8 p.m. ET. Additional information for patients is available on Horizon's website.

Information for Health Care Professionals

Physicians with questions should call or email Horizon Medical Information at 1-866-479-6742 or medicalinformation@horizontherapeutics.com.

Additional TEPEZZA Information

The Company continues to expect full-year 2021 TEPEZZA net sales of more than $1.275 billion, which assumes the successful completion of future committed manufacturing slots for TEPEZZA at its third-party manufacturer, Catalent. The company expects its TEPEZZA clinical trial in chronic TED and exploratory trial in diffuse cutaneous systemic sclerosis to start mid-year 2021 and anticipates data from the chronic TED trial mid-year 2022. In addition, Horizon is making progress with its second drug product manufacturer and is on track to begin shipping TEPEZZA supply from this manufacturer, following U.S. FDA approval, by year end.

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 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.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to the anticipated end of the TEPEZZA supply disruption; the timing of availability of TEPEZZA to patients; and business and other statements that are not historical facts. 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, the risk of future supply disruptions, whether as a result of additional government orders or other issues at Horizon's third party manufacturers; impacts of the COVID-19 pandemic and actions taken to slow its spread; 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.

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