Horizon Therapeutics plc Announces Short-Term TEPEZZA® (teprotumumab-trbw) Supply Disruption Due to Government-Mandated (Operation Warp Speed) COVID-19 Vaccine Production

December 17, 2020

- Conference Call Today at 8 a.m. ET -

DUBLIN--(BUSINESS WIRE)--Dec. 17, 2020-- Horizon Therapeutics plc (Nasdaq: HZNP) announced that it expects a short-term disruption in TEPEZZA (teprotumumab-trbw) supply as a result of recent government-mandated COVID-19 vaccine production orders related to Operation Warp Speed that have dramatically restricted capacity available for the production of TEPEZZA at its drug product contract manufacturer, Catalent. Operation Warp Speed, per its authority provided through the Defense Production Act of 1950, recently ordered the prioritization of certain COVID-19 vaccine manufacturing at Catalent, resulting in the cancellation of previously guaranteed and contracted TEPEZZA drug product manufacturing slots in December, which were required to maintain TEPEZZA supply. To offset the reduced slots allowed by Operation Warp Speed and Catalent, the Company accelerated plans to increase the production scale of TEPEZZA drug product. The Company currently anticipates that this drug supply shortage will begin at the end of December and could last through the first quarter. The length of the TEPEZZA supply disruption will depend on whether future manufacturing slots are successfully completed as well as decisions by the U.S. Food and Drug Administration (FDA) regarding this increased scale manufacturing process of TEPEZZA. The Company expects to submit data in January from the first increased scale manufacturing lot to the FDA for its review and approval.

TEPEZZA is a biologic approved for the treatment of Thyroid Eye Disease (TED), which is a rare, serious, progressive and vision-threatening autoimmune disease.[1] There are no FDA-approved alternative treatments for TED.

“We appreciate the efforts Operation Warp Speed and the Administration are taking to accelerate the COVID-19 vaccine production to save lives and put an end to the pandemic,” said Tim Walbert, chairman, president and chief executive officer, Horizon. “We understand the impact that the TEPEZZA supply disruption will have on patients with TED and physicians who treat them. Our job is to support these patients and physicians and we will continue to work closely with the FDA and Operation Warp Speed to limit the length of this disruption and accelerate the availability of TEPEZZA drug product supply.”

The Company does not anticipate the short-term supply disruption to impact its full-year 2020 financial guidance, including its previously announced full-year 2020 TEPEZZA guidance of more than $800 million in net sales. The Company expects to have more than $2 billion of cash and cash equivalents at Dec. 31, 2020. The Company also plans to delay the start of its planned TEPEZZA clinical trial in chronic TED and the TEPEZZA exploratory trial in diffuse cutaneous systemic sclerosis until the second quarter of 2021, assuming commercial drug product supplies have normalized by that time. Assuming the chronic TED trial is initiated in the second quarter of 2021, the Company would continue to anticipate data in the first quarter of 2022.

Consistent with past practice, the Company expects to issue 2021 guidance in connection with its fourth-quarter 2020 earnings call when the Company expects to have additional information regarding TEPEZZA supply.

Information for patients
Beginning today, Horizon is delaying new patients starting on TEPEZZA. The Company will be communicating with TEPEZZA patients currently on therapy and the physicians who treat them. The Company’s priority will be to resume therapy for those patients as quickly as possible. If patients have additional questions, please contact Horizon Patient Services at 1-833-469-8331.

Information for healthcare professionals
Physicians with questions should call 1-866-479-6742 [Option 1] or email medicalinformation@horizontherapeutics.com.

Call Information
At 8 a.m. EST/1 p.m. IST today, the Company will host a live webcast to discuss the TEPEZZA supply disruption. The live webcast and a replay may be accessed at http://ir.horizontherapeutics.com. Please connect to the Company's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. A replay of the webcast will be available approximately two hours after the live webcast.

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.

References

1. Barrio-Barrio J, et al. Graves' Ophthalmopathy: VISA versus EUGOGO Classification, Assessment and Management. *Journal of Ophthalmopathy*. 2015;2015:1-16.

Forward-Looking Statements
This press release contains forward-looking statements, including, but not limited to, statements related to the anticipated impact of recent government orders on TEPEZZA supply, Horizon's financial and operating results, and planned clinical trials; expectations regarding the length of TEPEZZA supply disruptions; Horizon's full-year 2020 financial guidance and guidance with respect to 2020 TEPEZZA sales; Horizon's expected cash position at December 31, 2020; expected financial performance and operating results in future periods; development and commercialization plans; expected timing of clinical trials and results 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 that further TEPEZZA manufacturing run cancellations, whether as a result of additional government orders or other issues at Horizon's third party manufacturers, or failed manufacturing runs could exacerbate and prolong TEPEZZA supply disruptions; Horizon's actual future financial and operating results may differ from its expectations or goals; Horizon's ability to successfully commercialize and grow net sales from existing medicines, including TEPEZZA; uncertainty regarding the impact of the TEPEZZA supply disruption on TEPEZZA's long-term commercial potential; whether the FDA grants accommodations to alleviate TEPEZZA supply constraints and increase production; impacts of the COVID-19 pandemic and actions taken to slow its spread; risks relating to Horizon's ability to successfully implement its business strategies; risks inherent in developing novel medicine candidates and existing medicines for new indications; risks associated with regulatory approvals; competition, including potential generic competition; the ability to protect intellectual property and defend patents; 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.

About Horizon
Horizon is focused on researching, developing and commercializing medicines that address critical needs for people impacted by rare and rheumatic 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.

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