Horizon Therapeutics plc
Conference Call
December 17, 2020

Tina Ventura
Senior Vice President, Investor Relations

Thank you, Josh. Good morning everyone and thank you for joining us.

On the call with me today are:

- **Tim Walbert**, Chairman, President and Chief Executive Officer;
- **Paul Hoelscher**, Executive Vice President, Chief Financial Officer; and
- **Andy Pasternak**, Executive Vice President, Chief Strategy Officer

Tim will discuss the announcement we made this morning, after which we will take your questions.

As a reminder, during today's call we will be making certain forward-looking statements, including statements about product supply, financial projections, development activities, and the expected timing and impact of future events. Our actual results could differ materially due to a number of factors, including the extent, duration and impact of the supply disruption, as well as other factors outlined in our latest Form 10-Q, and the 8-K we filed this morning with the Securities and Exchange Commission.

You are cautioned not to place undue reliance on these forward-looking statements and Horizon disclaims any obligation to update such statements.

In addition, on today's conference call, non-GAAP financial measures will be used. These non-GAAP financial measures are reconciled with the comparable GAAP financial measures in our latest earnings press release and other filings that are available on our investor website at www.horizontherapeutics.com.

I will now turn the call over to Tim.

Tim Walbert
Chairman, President and Chief Executive Officer

Thank you, Tina, and good morning, everyone.

This morning we announced that we expect a short-term disruption in the supply of TEPEZZA®, which is our biologic medicine for the treatment of Thyroid Eye Disease, or TED. This is due to recent Operation Warp Speed government-mandated COVID-19 vaccine production orders. We currently anticipate that this drug supply shortage will begin at the end of December and could last through the first quarter.

Let me provide some additional context regarding what has taken place at Catalent, our contract manufacturer for drug product. Catalent fills and finishes vials for TEPEZZA, as it does for many other injectable and infused medicines or vaccines. Operation Warp Speed per its authority provided by the Defense Production Act of 1950, recently ordered the prioritization of certain COVID-19 vaccine manufacturing, which resulted in the cancellation of previously guaranteed and contracted TEPEZZA drug product manufacturing lots in December. This was done so that manufacturing capacity could be instead used at Catalent for government-mandated orders to produce a COVID-19 vaccine. However, these manufacturing runs were required for us to maintain TEPEZZA supply for current demand as well as build inventory.

After being informed of the Operation Warp Speed mandate a few weeks ago, we quickly identified ways to potentially meet demand for existing patients. To offset the reduced slots allowed by Operation Warp Speed and Catalent, we accelerated our ongoing plans to increase the production scale of TEPEZZA drug product. In fact, as a result, Catalent was able to provide us one manufacturing slot this month, which we began earlier this week. With only one slot projected per month for the first quarter, we need increased scale manufacturing to meet patient demand versus the current several lots per month we have been producing at initial approved scale. As a result of this increased scale, we will need FDA approval of this lot and we will be submitting analysis and data from this lot to the FDA in January for their review and approval. The FDA has agreed to allow us to submit data on a rolling basis and indicated they will work with us to minimize drug shortage. Ultimately, the length of the TEPEZZA supply disruption will depend on whether this and future manufacturing slots are successfully completed at the increased scale as well as the decision by the U.S. Food and Drug Administration regarding this increased scale manufacturing process for TEPEZZA.

Additionally, we have been working with multiple government agencies to share the significant impact this drug shortage will have on patients and do everything in our power to mitigate this disruption. These organizations include:

- The FDA Commissioner's Office;
- Senior leadership of the FDA Center for Drug Evaluation and Research, or CDER;
- The Office of New Drugs within CDER;
- The Division of Ophthalmology within CDER;
- The FDA Drug Shortage Staff;
- The FDA Office of Pharmaceutical Quality;
- The FDA Office of Pharmaceutical Manufacturing Assessment;
- The Secretary of Health and Human Services' Office;
- Operation Warp Speed;
- The HHS Assistant Secretary for Preparedness and Response;
- BARDA;
- The Executive Office of the President; and
- The Office of the Vice President

While we are continuing to work closely with many of these organizations, particularly the FDA and Operation Warp Speed, to limit the length of the disruption and accelerate the availability of TEPEZZA supply, at this point we needed to inform patients and physicians about the upcoming supply disruption.

As things stand today, patients currently on TEPEZZA will be impacted and will need to temporarily stop their TEPEZZA treatment when the current supply runs out at the end of this month. Treatment for new patients planning to start TEPEZZA will be delayed. As we resume supply, our priority will be to enable patients who were already on treatment to resume therapy as quickly as possible. We are encouraging patients to reach out to their

physicians to discuss how to manage their Thyroid Eye Disease during this time period and we will be communicating with physicians and patients throughout the disruption via our patient services organization.

We launched TEPEZZA in January of this year. It's the first – and importantly, the only – approved treatment for Thyroid Eye Disease. That is why today's news is particularly disappointing – there are no other approved treatments available for these patients. Given the severity of this disease, the significant patient need, and the dramatic efficacy profile of this medicine, the demand for TEPEZZA was substantially higher than our original expectations. Before TEPEZZA received approval, we worked extensively to increase the production of TEPEZZA to meet demand levels significantly above our expectations, securing significant additional batches of drug substance with our contract manufacturer, AGC Biologics, and fill/finish slots with Catalent for drug product. Up until these manufacturing slots at Catalent were cancelled as a result of Operation Warp Speed actions, we had sufficient drug product supply to meet current demand and continue to build inventory.

We also understand that Catalent is setting up a new drug product manufacturing line, which it expects to have live in April, to accommodate COVID-19 vaccine production that should further alleviate supply constraints. We are also continuing to progress toward the planned addition of another product contract manufacturer in the second half of 2021. We initiated this process in the first quarter of this year.

We are delaying the start of our TEPEZZA chronic T-E-D trial, as well as our TEPEZZA exploratory trial in diffuse cutaneous systemic sclerosis. We currently expect to begin these trials in the second quarter of 2021, assuming that supply is back to normalized levels. If the chronic TED trial is initiated in the second quarter of 2021, we would continue to expect data readout in the first quarter of 2022.

As we noted in our release this morning, as a company, we are in an extremely strong financial position, with significant liquidity. We expect to have more than $2 billion in cash and cash equivalents at the end of this year. Given our current debt position of approximately $1 billion, this would result in a net cash position of more than $1 billion at year end. We do not expect the TEPEZZA supply disruption to impact the full-year 2020 guidance we provided on our third quarter call, including our previously announced TEPEZZA full-year net sales guidance of greater than $800 million. We do anticipate an impact to TEPEZZA net sales in 2021 given that we will not be able to supply TEPEZZA to the market at the start of the year. As per our normal process, we plan to issue full-year 2021 guidance when we report fourth-quarter 2020 results and would at the time expect to have additional information regarding TEPEZZA supply.

We certainly appreciate the efforts of Operation Warp Speed and the Administration are taking to accelerate COVID-19 vaccine production to save lives and put an end to this pandemic. At Horizon, we are committed to putting patients first and foremost, and in this respect, we are very pleased that COVID-19 vaccines will soon be available for the millions of people around the world who need them. At the same time, the impact this supply disruption will have on patients with TED is significant, particularly given the debilitating nature of this disease. We will do everything possible to provide support for TED patients and their physicians during this short-term disruption.

I will now open the call up for questions.

Tina Ventura
Senior Vice President, Investor Relations

Thank you, Josh. That concludes our call this morning. A replay of this call and webcast will be available in approximately two hours. Thank you for joining us.