



## Horizon Therapeutics plc Announces TEPEZZA® (teprotumumab-trbw) Selected as a Winner of the R&D 100 Award

October 5, 2020

DUBLIN--(BUSINESS WIRE)--Oct. 5, 2020-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced that TEPEZZA® (teprotumumab-trbw) was selected as a [2020 R&D World R&D 100 Award](#) recipient in the Process/Prototyping category. 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).

"TEPEZZA is a testament to our focus on developing and manufacturing new medicines for people with rare diseases and we are honored that R&D World recognized the significance of this innovation," said Elizabeth H.Z. Thompson, Ph.D., group vice president, development and external search, research and development, Horizon. "In the eight months since FDA approval, TEPEZZA has already made a major difference in the lives of people who are impacted by Thyroid Eye Disease."

The R&D 100 Awards is the only science and technology competition that recognizes new commercial products, technologies and materials for their technological significance. It has been one of the most prestigious, global innovation award programs for more than 50 years.

### About Thyroid Eye Disease (TED)

TED is a serious, progressive and vision-threatening rare autoimmune disease.<sup>1</sup> TED often occurs in people living with hyperthyroidism or Graves' disease; however, it is a distinct disease that is caused by autoantibodies activating an IGF-1R-mediated signaling complex on cells within the retro-orbital space.<sup>2,3</sup> This leads to a cascade of negative effects, which may cause long-term, irreversible damage. 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.<sup>4,5</sup>

### 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  $\geq$ 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 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](#).

##### References

1. Barrio-Barrio J, et al. Graves' Ophthalmopathy: VISA versus EUGOGO Classification, Assessment, and Management. *Journal of Ophthalmopathy*. 2015;2015:1-16.
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. Ross DS, et al. The 2016 European Thyroid Association/European Group on Graves' Orbitopathy Guidelines for the Management of Graves' Orbitopathy. *Eur Thyroid J*. 2016;5(1):9-26.
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/20201005005226/en/): <https://www.businesswire.com/news/home/20201005005226/en/>

U.S. Media Contact:

Geoffrey Curtis

Executive Vice President, Corporate Affairs and Chief Communications Officer

[media@horizontherapeutics.com](mailto:media@horizontherapeutics.com)

Ireland Media Contact:

Ray Gordon

Gordon MRM

[ray@gordonmrm.ie](mailto:ray@gordonmrm.ie)

Source: Horizon Therapeutics plc