New Data Insights from the Phase 3 Teprotumumab Trial (OPTIC) to be Presented at the American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS) Scientific Symposium

October 8, 2019

DUBLIN--(BUSINESS WIRE)--Oct. 8, 2019-- Additional results from the Phase 3 confirmatory clinical trial (OPTIC) of teprotumumab, an investigational medicine being developed by Horizon Therapeutics plc, will be presented at the American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS) 50th Anniversary 2019 Fall Scientific Symposium in San Francisco on Oct. 11.

The ASPORS meeting marks the first time that detailed secondary endpoint outcomes from the teprotumumab OPTIC trial related to diplopia (double vision), Graves' Ophthalmopathy (GO) Quality of Life and clinical activity score (CAS) will be presented. CAS is a 7-point scale that quantifies the pain, redness and swelling of various eye tissues. Posters about the perceptions and burden of thyroid eye disease (TED) will also be presented.

Presentation Details:

"Teprotumumab Infusions Reduce Proptosis in Thyroid-Eye Disease in a Randomized, Placebo-Controlled, Clinical (OPTIC) Study: Effectiveness on Diplopia and other Secondary Outcomes"

- **Speaker:** Raymond Douglas, M.D., Ph.D., director of the Orbital and Thyroid Eye Disease Program, Cedars-Sinai Medical Center
- **Session:** Thyroid Eye Disease
- **Date:** Friday, Oct. 11, 2019
- **Time:** 9:14 a.m. Pacific Time

"Physician Perceptions of Active Thyroid Eye Disease in the United States"

- **Lead Author:** Yao Wang, M.D., Cedars-Sinai Medical Center
- **Session:** Digital Poster and Video Viewing
- **Date:** Thursday, Oct. 10
- **Time:** 6:45 a.m. Pacific Time

"Impact of Thyroid Eye Disease on Patient Quality of Life as Perceived by US Ophthalmologists"

- **Lead Author:** Yao Wang, M.D., Cedars-Sinai Medical Center
- **Session:** Digital Poster and Video Viewing

- **Date:** Thursday, Oct. 10
- **Time:** 6:45 a.m. Pacific Time

About Thyroid Eye Disease

Thyroid eye disease (TED) is a serious, progressive and vision-threatening autoimmune disease with a limited window of activity that can last up to three years.[1,2,3] While TED often occurs in people living with hyperthyroidism or Graves' disease, it is a distinct disease that is caused by autoantibodies activating an IGF-1R-mediated signaling complex on cells within the orbit.[4,5] This leads to a cascade of negative effects, which may cause long-term, irreversible damage. Active TED lasts for up to three years and is characterized by inflammation and tissue expansion behind the eye.[1,6] As TED progresses, it causes serious damage – including proptosis (eye bulging), strabismus (misalignment of the eyes), and diplopia (double vision) – and in some cases can lead to blindness.[2,7] TED has only been shown to respond to pharmacotherapy while the disease is active and inflammation is ongoing.[8] Currently, patients must live with active TED until the disease becomes inactive – often left with permanent and vision-impairing consequences.[1,6]

About Teprotumumab

Teprotumumab is a fully human monoclonal antibody (mAb) and a targeted inhibitor of the insulin-like growth factor 1 receptor (IGF-1R). By targeting the IGF-1R signal, teprotumumab reduces inflammation and prevents excessive muscle and fat cell expansion behind the eye. The U.S. Food and Drug Administration (FDA) is currently evaluating teprotumumab's Biologics License Application (BLA) under Priority Review, a designation granted to applications for medicines that have the potential to provide significant improvements in the treatment of serious conditions. If approved, teprotumumab would be the first FDA-approved medicine for the treatment of active TED. Teprotumumab has also received Orphan Drug, Fast Track and Breakthrough Therapy designations from the FDA. The clinical development program for teprotumumab in the treatment of TED includes positive results from the Phase 3 OPTIC confirmatory clinical trial as well as positive Phase 2 results, which were published in The New England Journal of Medicine. The OPTIC trial was conducted at leading centers in the U.S., Germany and Italy, with co-principal investigators Raymond Douglas, M.D., Ph.D., Cedars-Sinai Medical Center; and George Kahaly, M.D., Ph.D., Johannes Gutenberg University Medical Center. Horizon is also conducting the OPTIC-X extension trial to gather further insight into the long-term efficacy and safety of teprotumumab.

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, follow us @HorizonNews on Twitter, like us on Facebook or explore career opportunities on LinkedIn.

References

1. Graves' Ophthalmopathy: VISA versus EUGOGO Classification, Assessment, and Management. *Journal of Ophthalmology.* 2015. https://www.hindawi.com/journals/joph/2015/249125/cta/. Accessed Feb 22, 2019.
2. The 2016 European Thyroid Association/European Group on Graves' Orbitopathy Guidelines for the Management of Graves' Orbitopathy. *European Thyroid Journal.*2 March 2016. https://www.ncbi.nlm.nih.gov/pubmed/27099835. Accessed Feb 22, 2019.
3. Shan SJ, Douglas RS. The Pathophysiology of Thyroid Eye Disease. *Journal of Neuro-Ophthalmology*. 2014; 34: 177-185.
4. Graves' Ophthalmopathy. *The New England Journal of Medicine.* 25 February 2010. https://www.nejm.org/doi/full/10.1056/NEJMra0905750. Accessed Feb 22, 2019.
5. Igs from patients with Graves' disease induce the expression of T cell chemoattractants in their fibroblasts. *The Journal of Immunology.* 15 January 2002. https://www.ncbi.nlm.nih.gov/pubmed/11777993. Accessed Feb 22, 2019.
6. Update on thyroid eye disease and management. *Clinical Ophthalmology.* 19 October 2009. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2770865/. Accessed Feb 22, 2019.
7. Clinical features of dysthyroid optic neuropathy: a European Group on Graves' Orbitopathy (EUGOGO) survey. *British Journal of Ophthalmology.* 11 October 2006. https://www.ncbi.nlm.nih.gov/pubmed/17035276. Accessed Feb 22, 2019.
8. Mamoojee Y, Pearce SHS. Natural History. In: Wiersinga WM, Kahaly GJ (eds): *Graves' Orbitopathy: A Multidisciplinary Approach – Questions and Answers.* Basel, Karger. 2017:93-104.

View source version on businesswire.com: https://www.businesswire.com/news/home/20191008005336/en/

Source: Horizon Therapeutics plc

Tina Ventura
Senior Vice President, Investor Relations
Investor-relations@horizontherapeutics.com

Ruth Venning
Executive Director, Investor Relations
Investor-relations@horizontherapeutics.com

U.S. Media Contact:
Matt Flesch
Vice President, Communications and Patient Advocacy
media@horizontherapeutics.com

Ireland Media Contact:
Gordon MRM
Ray Gordon
ray@gordonmrm.ie