



New Combined Data from the Phase 2 and Phase 3 Teprotumumab Clinical Trials to be Presented during the American Thyroid Association Annual Meeting

October 24, 2019

DUBLIN--(BUSINESS WIRE)--Oct. 24, 2019-- New pooled data from the Phase 2 and Phase 3 clinical trials of teprotumumab, an investigational medicine being developed by Horizon Therapeutics plc (Nasdaq: HZNP), will be presented during an oral plenary presentation at the 89th Annual Meeting of the American Thyroid Association (ATA) in Chicago on Oct. 31. The U.S. Food and Drug Administration is currently evaluating under Priority Review a Biologics License Application (BLA) for teprotumumab in the treatment of active thyroid eye disease (TED). The Prescription Drug User Fee Act (PDUFA) goal date is March 8, 2020.

Two posters that highlight findings from a Horizon sponsored survey of endocrinologists will also be presented. The first poster illustrates endocrinologists' perceptions of the impact of TED on patient quality of life (QoL). The second poster discusses the treatment strategies used by endocrinologists to help manage this serious, progressive and vision-threatening disease in patients with TED.

Presentation Details:

Oral Presentation: Efficacy of Teprotumumab, an Insulin-like Growth Factor-1 Receptor Antagonist Antibody, in Patients with Active Thyroid Eye Disease: Pooled Results from Two Placebo-Controlled Trials

- **Speaker:** George J. Kahaly, M.D., Ph.D., professor of medicine and endocrinology and metabolism, Johannes Gutenberg University Medical Center
- **Session:** Highlighted Oral Abstracts Session
- **Date:** Thursday, Oct. 31, 2019
- **Time:** 8:50-10:05 a.m. Central Time

Poster: Impact of Thyroid Eye Disease on Patient Quality of Life as Perceived by US Endocrinologists

- **Study Author:** Anu Sharma, University of Utah School of Medicine
- **Date:** Thursday, Oct. 31, 2019

Poster: Trends in thyroid eye disease treatment among US endocrinologists

- **Study Author:** Anu Sharma, University of Utah School of Medicine
- **Date:** Friday, Nov. 1, 2019

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.^{6,1} 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.^{6,1}

About Teprotumumab

Teprotumumab is a fully human monoclonal antibody (mAb) and a targeted inhibitor of the insulin-like growth factor 1 receptor (IGF-1R). Teprotumumab has received Priority Review, 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

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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 Contacts:

Matt Flesch

Vice President, Communications and Patient Advocacy
media@horizontherapeutics.com

Rachel Vann

Associate Director, Product Communications
media@horizontherapeutics.com

Ireland Media Contact:

Gordon MRM

Ray Gordon
ray@gordonmrm.ie