Horizon Therapeutics plc Trading Halted Today; FDA Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) Meeting to Discuss Teprotumumab for Thyroid Eye Disease

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DUBLIN--(BUSINESS WIRE)--Dec. 13, 2019-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced that NASDAQ has halted trading of the Company's common stock. As per the U.S. Food and Drug Administration (FDA) guidelines for new molecular entities (NMEs), the FDA Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) is holding a meeting today from 8 a.m. to 4 p.m. ET to discuss teprotumumab, an investigational medicine for the treatment of Thyroid Eye Disease (TED). Teprotumumab is an investigational medicine and its safety and efficacy have not been established.

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 inflammation subsides, after which they are 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). 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 2 clinical study, which were published in The New England Journal of Medicine, as well as positive results from the Phase 3 OPTIC confirmatory clinical trial. 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.

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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