

Basel, 08 September 2017

Roche provides update on first lampalizumab phase III study for geographic atrophy, an advanced form of age-related macular degeneration

- **Spectri study did not meet its primary endpoint of reducing mean change in geographic atrophy lesion area in patients treated with lampalizumab compared with sham treatment**
- **Safety profile was in line with previous lampalizumab trials and other intravitreal therapies**
- **Results from the second phase III study, Chroma, will be evaluated in November 2017**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the primary endpoint has not been met in Spectri, the first of two phase III studies evaluating the safety and efficacy of lampalizumab, an investigational medicine for the treatment of geographic atrophy (GA) due to age-related macular degeneration (AMD). Lampalizumab did not reduce mean change in GA lesion area compared to sham treatment at 1 year (48 weeks). Given the lack of efficacy, further dosing in patients will be interrupted until the results from the second phase III study are evaluated.

“Geographic atrophy is a progressive and irreversible disease that impairs vision, and there are currently no available treatments,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Global Head of Product Development. “While this result is disappointing, we will continue to evaluate results from Spectri to get a clearer understanding of the data as we await the results of our second phase III study, Chroma, anticipated in November.”

About the Spectri and Chroma Studies^{1, 2}

The phase III trials, called Spectri (GX29185; NCT02247531) and Chroma (GX29176; NCT02247479), are identically-designed, double-masked, randomised, global studies evaluating the efficacy and safety of a 10 mg dose of lampalizumab administered every 4 or 6 weeks by intravitreal injection, versus sham injections in people with GA due to AMD. Together, the studies enrolled more than 1,800 participants in more than 275 sites in over 20 countries.

The primary objective of the studies is to demonstrate a difference in mean change in GA lesion area in patients treated with lampalizumab compared to sham. This efficacy endpoint, evaluated at one year (week 48), is measured by fundus autofluorescence (FAF), an imaging technique used to provide information about the size and type of GA lesions in the macula. Secondary objectives of the studies, evaluated at two years (96 weeks), focus on assessing the impact of lampalizumab treatment on patients' visual function.

About lampalizumab

Lampalizumab is being investigated to determine its efficacy in reducing the progression of GA due to AMD. Lampalizumab is an antigen-binding fragment (Fab) of a humanised, monoclonal antibody directed against complement factor D (CFD). CFD is a rate-limiting enzyme in the activation and amplification of the alternative complement pathway (ACP), a component of the immune system. Dysfunction of the ACP has been linked to the pathogenesis of AMD through numerous genetic studies.^{3, 4, 5}

About geographic atrophy (GA)

GA is a progressive and irreversible form of AMD, affecting more than 5 million people worldwide.⁶ Visual impairment associated with GA tends to affect both eyes in many individuals.^{7, 8} People with GA report visual problems with activities of daily living – including reading, driving, recognising faces, and activities in dim or low light.^{9, 10, 11} GA represents a significant unmet medical need, as there are no approved therapies for this condition.

About Roche in ophthalmology

Roche is researching and developing new treatments for people living with a range of eye diseases that cause significant visual impairment and blindness, including GA, neovascular AMD, diabetic macular edema (DME), diabetic retinopathy (DR), and other retinal diseases.

Roche's ophthalmology medicines include Lucentis® (ranibizumab) in the US, which is indicated in the United States for the treatment of neovascular AMD, DME, DR with or without DME; macular edema secondary to retinal vein occlusion and myopic choroidal neovascularisation.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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