

FDA approves Roche's Lucentis (ranibizumab injection) for diabetic retinopathy, the leading cause of blindness among working age adults in the United States

Basel, 18 April 2017

- ◆ **First and only medicine approved to treat all forms of diabetic retinopathy**
- ◆ **Granted Priority Review Designation by the FDA based on analysis of results from a National Institutes of Health (NIH)-funded collaborative group study**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the US Food and Drug Administration (FDA) approved Lucentis® (ranibizumab injection) 0.3 mg for the monthly treatment of withal forms of diabetic retinopathy. The most common cause of vision loss in people with diabetes, diabetic retinopathy is the leading cause of blindness among adults aged 20 to 74¹ and affects nearly 7.7 million people in the US.² With this approval, Lucentis becomes the first and only FDA-approved medicine to treat diabetic retinopathy in people who have been diagnosed either with or without diabetic macular edema (DME), a complication of diabetic retinopathy that causes swelling in the back of the eye. In February 2015, Lucentis received FDA approval for the treatment of diabetic retinopathy in people with DME based on data from the pivotal RIDE and RISE Phase III clinical trials.

The FDA granted Lucentis Priority Review for the treatment of diabetic retinopathy without DME based on an analysis of the Diabetic Retinopathy Clinical Research Network's (DRCR.net) Protocol S study. This NIH-funded study compared Lucentis treatment to panretinal laser treatment in diabetic retinopathy patients both with and without DME. In the analysis that supported this approval, patients with and without DME in the Lucentis group experienced improvements in the severity of their retinopathy. Adverse events were consistent with those seen in previous studies.

"Diabetic retinopathy is the leading cause of vision loss among working-aged adults in the US between the ages of 20-and 74. We are very pleased that Lucentis is now FDA-approved to treat retinopathy in people with and without DME," said Sandra Horning, MD, Chief Medical Officer and Head of Global Product Development. "In multiple clinical studies, Lucentis demonstrated a significant improvement of patients' diabetic retinopathy, and it is the first and only anti-VEGF therapy approved to treat all forms of diabetic retinopathy."

Priority Review Designation is granted to medicines that the FDA has determined to have the potential to provide significant improvements in the safety and effectiveness of the treatment of a serious disease. The FDA previously granted Lucentis Breakthrough Therapy Designation for diabetic retinopathy in 2014 based on the pivotal RIDE and RISE Phase III clinical trials. Breakthrough designation is intended to expedite the development and review of medicines with early evidence of potential clinical benefit in serious diseases and to help ensure that patients receive access to medicines as soon as possible.

Diabetes affects more than 29 million people in the US.³ The longer a person has diabetes, especially if it is poorly controlled, the higher the risk of developing diabetic retinopathy and vision loss. Diabetic retinopathy occurs when blood vessels in the retina become damaged. This can cause vision loss or distortion when the abnormal vessels leak blood or fluid into the eye.¹

About Protocol S

The Diabetic Retinopathy Clinical Research Network's (DRCR.net) Protocol S study was a randomised, active-controlled study comparing Lucentis to a type of laser therapy called panretinal or scatter photocoagulation (PRP) in 305 patients with proliferative diabetic retinopathy, including those with and without diabetic macular edema (DME). In the Lucentis group, patients received a baseline 0.5 mg intravitreal injection followed by three monthly intravitreal injections, after which treatment was guided by pre-specified re-treatment criteria.

In the analysis that supported the approval, 37.8 percent (n=56/148) of patients in the Lucentis group without baseline DME had a two-step or better improvement in their diabetic retinopathy and 28.4 percent (n=42/148) had a three-step or better improvement at two years, according to the Early Treatment Diabetic Retinopathy Study Diabetic Retinopathy Severity Scale (ETDRS-DRSS).

In Lucentis-treated patients with baseline DME, 58.5 percent (n=24/41) had a two-step or better improvement in their diabetic retinopathy and 31.7 percent (n=13/41) had a three-step or better improvement at two years. Adverse events were similar to those seen in other Lucentis trials.

The DRCR.net is funded by the National Eye Institute, part of the National Institutes of Health. The DRCR.net is a collaborative multicenter dedicated to facilitating multicenter clinical research of diabetic retinopathy, DME and associated conditions, and supports the identification, design and implementation of multicenter clinical research initiatives focused on diabetes-induced retinal disorders. The DRCR.net was formed in September 2002 and currently includes over 115 participating sites with over 400 physicians throughout the US. The Protocol S study was supported, in part, by Roche as part of the company's ongoing commitment to supporting independent research and collaboration to advance science.

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**Samsung v. Regeneron
IPR2023-00442
U.S. Pat. 10,130,681
Exhibit 2258**

About Lucentis

Lucentis is a vascular endothelial growth factor (VEGF) inhibitor designed to bind to and inhibit VEGF-A, a protein that is believed to play a critical role in the formation of new blood vessels (angiogenesis) and the hyperpermeability (leakiness) of the vessels. Lucentis is FDA-approved for the treatment of patients with wet age-related macular degeneration (AMD), macular edema after retinal vein occlusion (RVO), diabetic macular edema (DME), diabetic retinopathy and myopic choroidal neovascularization (mCNV).

Lucentis was developed by Roche. The company retains commercial rights in the US and Novartis has exclusive commercial rights for the rest of the world.

Outside the US, Lucentis is approved in more than 110 countries to treat patients with wet AMD, for the treatment of DME, and due to macular edema secondary to both branch retinal vein occlusion (BRVO), central retinal vein occlusion (CRVO) and visual impairment due to choroidal neovascularization (CNV).

About Roche in Ophthalmology

Roche's vision for ophthalmology is to bring innovative therapeutics to patients with eye diseases. Currently, the company is investigating platforms for sustained drug delivery and has also initiated Phase III clinical trials for patients with geographic atrophy (GA), an advanced form of AMD. Additional focus includes using bispecific antibodies to simultaneously address multiple targets.

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 for improving patient access to medical innovations by working with all relevant stakeholders. Twenty-nine 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 eight 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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3. American Diabetes Association. Statistics About Diabetes. Available at <http://www.diabetes.org/diabetes-basics/statistics/>. Accessed March 7, 2017.