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FDA Approves Genentech's Lucentis (Ranibizumab Injection) for Diabetic Retinopathy, the Leading Cause of Blindness Among Working Age Adults in the United States

- **First and only medicine FDA-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**

South San Francisco, CA -- April 17, 2017 --

Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), today announced that the U.S. Food and Drug Administration (FDA) approved Lucentis® (ranibizumab injection) 0.3 mg for the monthly treatment of all 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 74[1] and affects nearly 7.7 million people in the U.S.[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 U.S. 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, M.D., 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 benenfit 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 U.S.[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 randomized, 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 network 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 U.S. The Protocol S study was supported, in part, by Genentech as part of the company's ongoing commitment to supporting independent research and collaboration to advance science.

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 Genentech, a member of the Roche Group. The company retains commercial rights in the U.S. and Novartis has exclusive commercial rights for the rest of the world.

Outside the U.S., 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).

Lucentis Important Safety Information

Patients should not use Lucentis if they have an infection in or around the eye or are allergic to Lucentis or any of its ingredients. Lucentis is a prescription medication given by injection into the eye and it has side effects. Some Lucentis patients have had detached retinas and serious infections inside the eye. If the eye becomes red, sensitive to light, or painful, or if there is a change in vision, patients should call or visit an eye doctor right away.

Some patients have had increased eye pressure before and within one hour of an injection.

Uncommonly, Lucentis patients have had serious, sometimes fatal problems related to blood clots, such as heart attacks or strokes. Fatal events were seen more often in patients with diabetic macular edema and diabetic retinopathy with Lucentis compared with patients who did not receive Lucentis.

Serious side effects include inflammation inside the eye and, rarely, problems related to the injection procedure such as cataracts. These side effects can make vision worse.

The most common eye-related side effects are increased redness in the white of the eye, eye pain, small specks in vision and increased eye pressure. The most common non-eye-related side effects are nose and throat infections, headache, lung/airway infections, and nausea.

Patients may report side effects to the FDA at (800) FDA-1088 or

http://www.fda.gov/medwatch. Patients may also report side effects to Genentech at (888) 835-2555.

For additional safety information, please see Lucentis full Prescribing Information, available here: http://www.gene.com/download/pdf/lucentis_prescribing.pdf

About Genentech in Ophthalmology

Genentech's vision for ophthalmology is to bring innovative therapeutics to people with eye diseases. Currently, the company is conducting Phase III clinical trials for people with geographic atrophy (GA), an advanced form of AMD, as well as investigating platforms for sustained ocular drug delivery and a treatment for giant cell arteritis, a form of vasculitis that can lead to blindness. Additional focus includes using bispecific antibodies to simultaneously address multiple targets for patients with AMD and diabetic eye disease.

About Genentech Access Solutions

Access Solutions is part of Genentech's commitment to helping people access the Genentech medicines they are prescribed, regardless of their ability to pay. The team of in-house specialists at Access Solutions is dedicated to helping people navigate the access and reimbursement process, and to providing assistance to eligible patients in the United States who are uninsured or cannot afford the out-of-pocket costs for their medicine. To date, the team has helped more than

1.4 million patients access the medicines they need. Please contact Access Solutions (866) 4ACCESS/(866) 422-2377 or visit http://www.Genentech-Access.com for more information.

About Genentech

Founded 41 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, California. For additional information about the company, please visit http://www.gene.com.

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[1] U.S. Centers for Disease Control and Prevention. Common Eye Disorders: Diabetic Retinopathy. Available at https://www.cdc.gov/visionhealth/basics/ced/index.html. Accessed March 7, 2017.

[2] Prevent Blindness America. Diabetic Retinopathy. Available at http://www.visionproblemsus.org/diabetic-retinopathy/diabetic-retinopathy-definition.html. Accessed March 7, 2017.

[3] American Diabetes Association. Statistics About Diabetes. Available at http://www.diabetes.org/diabetes-basics/statistics/. Accessed March 7, 2017.