

Friday, Oct 14, 2016

FDA Approves Genentech's Lucentis® (Ranibizumab Injection) Prefilled Syringe

- **Lucentis prefilled syringe offers a ready-to-use option to deliver treatment with fewer steps**
- **First anti-VEGF prefilled syringe FDA-approved to treat people with wet age-related macular degeneration and people with macular edema after retinal vein occlusion**

South San Francisco, CA -- October 14, 2016 --

Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), today announced that the U.S. Food and Drug Administration (FDA) approved the Lucentis® (ranibizumab injection) 0.5 mg prefilled syringe (PFS) as a new method of administering the medicine. Like the Lucentis 0.5 mg vial, the 0.5 mg PFS is approved to treat people with wet age-related macular degeneration (AMD) and macular edema after retinal vein occlusion (RVO). The Lucentis PFS is the first syringe prefilled with an anti-VEGF medicine FDA-approved to treat two eye conditions.

“The FDA approval of the Lucentis prefilled syringe marks a new milestone in our ongoing commitment to people affected by vision-threatening eye diseases,” said Sandra Horning, M.D., chief medical officer and head of Global Product Development. “With the PFS, physicians will have a new option for administering Lucentis to the hundreds of thousands of people in the U.S. diagnosed with either wet AMD or macular edema after RVO.”

The Lucentis PFS allows physicians to eliminate several steps in the preparation and administration process, including disinfecting the vial, attaching a filter needle, drawing the medicine from the vial using the needle, removing the filter needle from the syringe and replacing with an injection needle. With the Lucentis PFS, physicians attach the injection needle to the syringe and adjust the dose prior to administration.

The Lucentis 0.5 mg PFS is expected to be available in early 2017.

About Wet AMD

Age-related macular degeneration (AMD) is a disease that impacts the part of the eye that provides sharp, central vision and is a leading cause of blindness in people age 60 and over.¹ Wet AMD is an advanced form of the disease that can cause rapid and severe vision loss.² Approximately 11 million people in the United States have some form of AMD and, of those, about 1.1 million have wet AMD.^{3,4}

Wet AMD is caused by growth of abnormal blood vessels, also known as choroidal neovascularization (CNV) or ocular angiogenesis, under the macula. These vessels leak fluid and blood and cause scar tissue that destroys the central retina. This process results in a deterioration of sight over a period of months to years.

Lucentis was approved to treat wet AMD in 2006.

About RVO

RVO affects more than one million people in the U.S.⁵ and is the second-most common cause of vision loss due to retinal vascular disease,⁶ which can develop over a long period of time or occur suddenly. It occurs when the normal blood flow through a retinal vein becomes blocked, causing swelling (edema) and hemorrhages in the retina, which may result in vision loss. Sudden blurring or vision loss in all or part of one eye is common with RVO, although loss of vision can develop over a long period of time. RVO typically affects patients who are more than 50 years old, and the incidence increases with age. People with a history of high blood pressure, hypertension, diabetes and atherosclerosis are at an increased risk for developing RVO.

There are two main types of RVO: branch-RVO, which affects an estimated 887,000 people, and central-RVO, which affects an estimated 265,000 people in the U.S.⁵ Branch-RVO, which is three times more common than central-RVO,⁷ occurs when one of the smaller veins emptying into the main vein of the eye becomes blocked. Usually, the blockage occurs at the site where an artery and a vein cross, and affects only a portion of the retina. Central-RVO, the less common form of RVO, occurs when the main vein of the eye (located at the optic nerve) becomes blocked.

Lucentis was approved to treat macular edema after RVO in 2010.

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) and diabetic retinopathy (DR) in people with DME. Lucentis safety and efficacy has been studied in more than 9,000 patients, across eight pivotal and 23 clinical trials.

Lucentis was developed by Genentech. 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 100 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) and central retinal vein occlusion (CRVO).

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.

Uncommonly, Lucentis patients have had serious, sometimes fatal problems related to blood clots, such as heart attacks or strokes.

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

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.

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.

Lucentis is for prescription use only.

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 investigating platforms for sustained drug delivery and is conducting Phase III clinical trials for people with geographic atrophy (GA), an advanced form of AMD and giant cell arteritis, a form of vasculitis that can lead to blindness. Additional focus includes using bispecific antibodies to simultaneously address multiple targets.

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 40 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>.

¹ Macular Degeneration Partnership. What is Macular Degeneration? Available at: <http://www.amd.org/what-is-amd.html>. Accessed June 17, 2016.

² Macular Degeneration Partnership. Wet AMD. Available at: <http://www.amd.org/what-is-macular-degeneration/wet-amd/>. Accessed June 17, 2016.

³ BrightFocus Foundation. Macular Degeneration: Essential Facts. Available at: <http://www.brightfocus.org/macular/news/macular-essential-facts>. Accessed June 29, 2016

⁴ American Academy of Ophthalmology. What Is Macular Degeneration? Available at: <http://www.aao.org/eye-health/diseases/amd-macular-degeneration>. Accessed July 08, 2016.

⁵ Genentech data on file (Based on population-based studies/the Beaver Dam Eye Study 2000 and 2008 and the United States Census).

⁶ Rehak J, Rehak M. Branch retinal vein occlusion: pathogenesis, visual prognosis, and treatment modalities. *Curr Eye Res*. 2008;33:111-131.

⁷ Hamid S et al. Etiology and Management of Branch Retinal Vein Occlusion. *World Applied Sciences Journal* 6(1):94-99, 2009.