FDA approves Roche’s Lucentis (ranibizumab injection) for treatment of diabetic retinopathy in people with diabetic macular edema

- First eye medicine approved for treatment of diabetic retinopathy with diabetic macular edema
- Granted Breakthrough Therapy Designation and Priority Review by FDA
- Diabetic macular edema can occur at any stage of diabetic retinopathy, a leading cause of blindness in American adults.¹
- Fourth Lucentis indication for treatment of serious eye diseases since 2006

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) approved Lucentis® (ranibizumab injection) for the treatment of diabetic retinopathy (DR), in people with diabetic macular edema (DME). DME impacts nearly 750,000 Americans, about 10 percent of people with DR.

The FDA granted Lucentis Breakthrough Therapy Designation and Priority Review for this indication based on results from the RISE and RIDE Phase III clinical trials.

“While there are various options for treating diabetic macular edema, before today none were approved showing improvement in retinopathy,” said Sandra Horning, M.D., chief medical officer and head of Global Product Development. “With today’s approval, people with diabetic macular edema now have a FDA-approved medicine that showed meaningful improvements in retinal damage from diabetes, in addition to the established improvement in vision.”

Almost 29 million Americans have diabetes.² The longer people have diabetes, especially if it is poorly managed, the higher their risk for developing DR. It is caused by elevated blood sugar levels damaging the fine blood vessels of the retina, the light-sensitive tissue at the back of the eye necessary for good vision.
DR with DME is a common diabetic eye disease and a leading cause of blindness in American adults under 55. DR with DME can lead to conditions that threaten vision.

The FDA designates Breakthrough Therapy to a medicine if it is intended to treat a serious or life-threatening disease and if preliminary clinical research suggests it may provide substantial improvement on clinically significant endpoints over existing therapies.

The FDA grants Priority Review to medicines that, if approved, would have the potential to provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.

In 2012, Lucentis was the first medicine approved by the FDA for the treatment of DME. Lucentis has also been an important option for patients with wet age-related macular degeneration (wet AMD) since 2006 and macular edema following retinal vein occlusion (RVO) since 2010.

About RISE and RIDE
RISE and RIDE are two identically-designed, parallel, double-masked, sham treatment-controlled trials in 759 patients with DR and DME at baseline who were randomized into three groups to receive monthly treatment with 0.3 mg Lucentis, 0.5 mg Lucentis or sham injection. The primary outcome in RISE and RIDE was visual acuity gain at 24 months for DME patients.

The safety and efficacy of Lucentis for the treatment of DR with DME was assessed over three years in patients with baseline DR severity scores ranging from 10 to 75 in the study eye (on the ETDRS diabetic retinopathy severity scale). Secondary and exploratory outcomes were evaluated at 24 months. At Month 24, a higher proportion of patients had observed a three-step or better improvement of their disease compared to sham, as determined by color fundus photography. The safety in the RISE and RIDE Phase III trials was consistent with previous studies.

In the third year of the studies, patients from the control group had the option to cross over to receive monthly treatment with 0.5 mg Lucentis; patients originally randomized to 0.3 mg or 0.5 mg Lucentis continued to receive the same dose and all patients were followed for 12 additional months. The 0.3 mg dose of Lucentis is approved for both DME and for DR in people with diabetic macular edema.
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 wet AMD, macular edema following RVO, DME and DR in people with DME. Genentech has conducted eight key clinical trials with Lucentis. The medicine has been studied in 21 clinical trials worldwide in more than 9,080 patients.

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.


**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**

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. 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](http://www.roche.com).

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References:
1 Facts About Diabetic Eye Disease, National Eye Institute, National Institutes of Health. Available at: https://www.nei.nih.gov/health/diabetic/retinopathy