



## *Investor Update*

Basel, 22 March 2018

### **FDA approves Lucentis (ranibizumab injection) 0.3 mg prefilled syringe for diabetic macular edema and diabetic retinopathy**

- ◆ **First and only prefilled syringe treatment option FDA-approved to treat all forms of diabetic retinopathy in people with or without diabetic macular edema (DME)**
- ◆ **Diabetic retinopathy is the leading cause of blindness among adults aged 20-74 in the United States<sup>1</sup>**
- ◆ **Prefilled syringe options are now FDA-approved for all Lucentis indications**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) approved the Lucentis® (ranibizumab injection) 0.3 mg prefilled syringe (PFS) as a new method of administering the medicine to treat all forms of diabetic retinopathy. In April 2017, Lucentis 0.3 mg became, and remains, the first and only FDA-approved medicine to treat all forms of diabetic retinopathy in people with or without diabetic macular edema (DME), a complication of the eye disease that causes swelling in the back of the eye. Diabetic retinopathy is the leading cause of blindness among working age adults and affects nearly 7.7 million people in the U.S.<sup>1,2</sup> The Lucentis 0.3 mg PFS is now the first syringe prefilled with an anti-vascular

## *Downloads*

↓ PDF

## *Services*

- Investor Relations team
- Send e-mail
- 📡 Subscribe to Roche Investor updates
- Finance information tool
- Ad hoc announcements

endothelial growth factor (VEGF) agent FDA-approved to treat both diabetic retinopathy and DME.

“Diabetic retinopathy is a serious condition that affects millions of people in the U.S.,” said Sandra Horning, M.D., Chief Medical Officer and Head of Global Product Development. “Today’s approval of the Lucentis 0.3 mg prefilled syringe reinforces our commitment to advancing therapy for those impacted by this vision-threatening disease.”

The Lucentis 0.3 mg PFS, which is made of borosilicate glass and is packaged in a single-use sterile, sealed tray, 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 snap off the syringe cap, attach the injection needle to the syringe and adjust the dose prior to administration.

The Lucentis 0.3 mg PFS is expected to be available in the second quarter of 2018.

The Lucentis 0.5 mg PFS, FDA-approved in October 2016, is indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO) and myopic choroidal neovascularisation (mCNV).

### **About Diabetic Retinopathy and Diabetic Macular Edema**

Diabetic retinopathy is the most common cause of vision loss in people with diabetes, which affects approximately 30 million people in the U.S.<sup>3</sup> 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.<sup>1</sup>

Diabetic macular edema (DME), which affects approximately 750,000 people in the U.S., is one of the vision-threatening complications of diabetic retinopathy, in which chronic damage occurs to the fine blood vessels of the retina, the light-sensitive tissue at the back of the eye necessary for good vision.<sup>4,5</sup>

### **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 neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), diabetic retinopathy (DR) and myopic choroidal neovascularisation (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 neovascular (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 neovascularisation (CNV).

### **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 neovascular age-related macular degeneration (AMD), diabetic macular edema (DME), diabetic retinopathy (DR), geographic atrophy (GA) and other retinal diseases. Roche is also investigating platforms for sustained ocular drug delivery. 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 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 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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](http://www.roche.com).

All trademarks used or mentioned in this release are protected by law.

#### References

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)  
<https://www.cdc.gov/visionhealth/basics/ced/index.html>. Accessed February 7, 2018.
2. Prevent Blindness America. Diabetic Retinopathy. Available at [☐](http://www.visionproblemsus.org/diabetic-retinopathy/diabetic-retinopathy-definition.html)  
<http://www.visionproblemsus.org/diabetic-retinopathy/diabetic-retinopathy-definition.html>. Accessed February 7, 2018.
3. American Diabetes Association. Statistics About Diabetes. Available at [☐](http://www.diabetes.org/diabetes-basics/statistics/)  
<http://www.diabetes.org/diabetes-basics/statistics/>. Accessed February 7, 2018.
4. Bressler NM, Varma R, Doan Q, et al. Underuse of the Health Care System by Persons With Diabetes Mellitus and Diabetic Macular Edema in the United States. *JAMA Ophthalmology*. 2014 Feb;132(2):168-73.
5. Bhagat N, Grigorian RA, Tutela A, et al. Diabetic macular edema: pathogenesis and treatment. *Surv Ophthalmol*. 2009;54(1):1-32.

© 2022 F. Hoffmann-La Roche Ltd 14.01.2022