

FDA approves Roche's Susvimo, a first-of-its-kind therapeutic approach for neovascular or "wet" age-related macular degeneration (nAMD)

- **Susvimo, previously called Port Delivery System with ranibizumab, is the first nAMD treatment in 15 years to provide an alternative to standard-of-care eye injections needed as often as once a month**
- **By continuously delivering medicine into the eye through a refillable implant, Susvimo may help people with nAMD maintain their vision with as few as two treatments per year**
- **Neovascular AMD impacts approximately 20 million people worldwide and is a leading cause of blindness in people over the age of 60**

Basel, 22 October 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has approved Susvimo™ (ranibizumab injection) 100 mg/mL for intravitreal use via ocular implant for the treatment of people with neovascular or "wet" age-related macular degeneration (nAMD) who have previously responded to at least two anti-vascular endothelial growth factor (VEGF) injections. Neovascular AMD is a potentially blinding condition that requires treatment with eye injections as often as once a month.^{1,2,3,4} Susvimo, previously called Port Delivery System with ranibizumab, is the first and only FDA-approved treatment for nAMD that offers as few as two treatments per year.^{5,6}

"Susvimo represents a major advancement in the treatment of retinal disease and is an important new option for patients with wet AMD," said Carl Regillo, M.D., Chief of Retina Service at Wills Eye Hospital in Philadelphia and an Archway study investigator. "With Susvimo, my patients now have an option that can help them maintain their vision as well as anti-VEGF injections, but on a more manageable twice-yearly treatment schedule."

Susvimo delivers ranibizumab continuously, offering people living with nAMD an alternative to anti-VEGF eye injections needed as often as once a month.^{3,4,5} The implant is surgically inserted into the eye during a one-time, outpatient procedure and refilled every six months.^{5,6} If necessary, supplemental ranibizumab treatment can be given to the affected eye while the Susvimo implant is in place.⁵

"We believe that Susvimo can help people with nAMD preserve their vision while potentially alleviating the treatment burden associated with current standards of care," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Susvimo's approval builds on Roche's long-standing commitment to people living with vision-threatening conditions."

The approval is based on positive results from the phase III Archway study primary analysis, which showed nAMD patients treated with Susvimo achieved and maintained vision gains equivalent to monthly ranibizumab injections – +0.2 and +0.5 eye chart letters from baseline, respectively – at weeks 36 and 40 of treatment. In addition, only 1.6% of Susvimo patients received supplemental ranibizumab treatment before their first refill, and more than 98% could go six months before their first refill.⁵

In the Archway study, Susvimo was generally well-tolerated, with a favourable benefit-risk profile. However, the Susvimo implant has been associated with a three-fold higher rate of endophthalmitis than monthly intravitreal injections of ranibizumab. Many of these events were associated with conjunctival retractions or erosions. Appropriate conjunctiva management and early detection with surgical repair of conjunctival retractions or erosions may reduce the risk of endophthalmitis. In clinical trials, 2.0% of patients receiving a ranibizumab implant experienced at least one episode of endophthalmitis. The most common adverse events (AEs) were conjunctival haemorrhage, conjunctival hyperaemia, iritis and eye pain.⁶ The safety profile of Susvimo in the clinical trial setting is well understood and will continue to be monitored closely.⁵

Roche has a robust phase III clinical development programme for Susvimo, including the Portal, Pagoda, Pavilion and Velodrome studies. Portal is an extension study evaluating the long-term safety and efficacy of Susvimo in nAMD.⁷ Pagoda is evaluating Susvimo for the treatment of people with diabetic macular edema (DME), while Pavilion is a study of Susvimo in diabetic retinopathy without DME.^{8,9} Velodrome is evaluating Susvimo refilled every nine months in nAMD.¹⁰ Susvimo is also currently under review for the treatment of nAMD by the European Medicines Agency (EMA).

Susvimo will be available in the United States in the coming months.

Roche's late-stage ophthalmology portfolio also includes faricimab, a bispecific antibody under FDA and EMA review for the treatment of nAMD and DME. The FDA is additionally reviewing faricimab for the treatment of diabetic retinopathy.

About the Archway Study^{5,11,12}

Archway (NCT03677934) was a randomised, multicentre, open-label phase III study evaluating the efficacy and safety of Susvimo™ (ranibizumab injection) 100 mg/mL for intravitreal use via ocular implant administered via the Susvimo eye implant, refilled every six months at fixed intervals, compared to monthly intravitreal injections of ranibizumab 0.5 mg in 415 people living with neovascular or “wet” age-related macular degeneration (nAMD). Patients enrolled in Archway were responders to prior treatment with anti-vascular endothelial growth factor (VEGF) therapy. In both study arms, patients were treated with at least three anti-VEGF injections within the six months prior to their Archway screening visit. The primary endpoint of the study was the change in best-corrected visual acuity (BCVA) score (the best distance vision a person can achieve – including with correction such as glasses – when reading letters on an eye chart) from baseline at the average of Week 36 and Week 40. Secondary endpoints include safety, overall change in vision (BCVA) from baseline and change from baseline in centre point thickness over time.

According to pre-specified study criteria, Susvimo was shown to be non-inferior and equivalent to monthly ranibizumab injections. On average, patients had received five prior ranibizumab injections before their first study treatment visit. In the Susvimo arm of the study, patients gained an average of 0.2 eye chart letters in visual acuity from baseline compared with 0.5 eye chart letters for the monthly ranibizumab arm. During the first treatment interval, before the first scheduled refill, 1.6% of Susvimo patients assessed (n=4/246) received supplemental ranibizumab treatment, and 98.4% of patients (n=242/246) did not receive supplemental treatment.

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About neovascular age-related macular degeneration

Age-related macular degeneration (AMD) is a condition that affects the part of the eye that provides sharp, central vision needed for activities like reading.¹³ Neovascular or “wet” AMD (nAMD) is an advanced form of the disease that can cause rapid and severe vision loss.^{1,2} It develops when new and abnormal blood vessels grow uncontrolled under the macula, causing swelling, bleeding and/or fibrosis.² Worldwide, around 20 million people are living with nAMD – the leading cause of vision loss in people over the age of 60 – and the condition will affect even more people around the world as the global population ages.^{13, 14, 15}

About Susvimo (ranibizumab injection) 100 mg/mL for intravitreal use via ocular implant
Susvimo™ (ranibizumab injection) 100 mg/mL for intravitreal use via ocular implant is a refillable eye implant surgically inserted into the eye during a one-time, outpatient procedure. Susvimo continuously delivers a customised formulation of ranibizumab over time.⁵ Susvimo is indicated for intravitreal use via the Susvimo eye implant only.⁶ Ranibizumab is a vascular endothelial growth factor (VEGF) inhibitor designed to bind to and inhibit VEGF-A, a protein that has been shown to play a critical role in the formation of new blood vessels and the leakiness of the vessels.⁴

Susvimo is different from the ranibizumab intravitreal injection, a medicine marketed as Lucentis®* (ranibizumab injection), which is approved to treat neovascular or “wet” age-related macular degeneration (nAMD) and other retinal diseases. Lucentis®** was first approved for nAMD by the FDA in 2006.¹⁶

About Roche in Ophthalmology

Roche is focused on saving people’s eyesight from the leading causes of vision loss through pioneering therapies. Through our innovation in the scientific discovery of new potential drug targets, personalised healthcare, molecular engineering, biomarkers and continuous drug delivery, we strive to design the right therapies for the right patients.

We have the broadest retina pipeline in Ophthalmology, covering early- and late-stage products, which is led by science and informed by insights from people with eye diseases. Our late-stage pipeline includes faricimab, a potential first-of-a-kind treatment being evaluated in a number of retinal conditions including neovascular age-related macular degeneration (nAMD), diabetic macular edema and diabetic retinopathy. Faricimab is the first investigational bispecific antibody designed for the eye.¹⁷ It targets two distinct pathways – via angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A) – that drive a number of retinal conditions, to stabilise blood vessels, potentially improving vision outcomes for longer.^{4,17} Our early-stage pipeline includes gene therapies and treatments for geographic atrophy and other vision-threatening diseases, including rare and inherited conditions.

Applying our extensive experience, we have already brought breakthrough ophthalmic treatments to people living with vision loss through Lucentis®* (ranibizumab injection), the first treatment approved to improve

vision in people with certain retinal conditions, and Susvimo™ (ranibizumab injection) 100 mg/mL for intravitreal use via ocular implant, the first FDA-approved refillable eye implant for nAMD that continuously delivers a customised formulation of ranibizumab over a period of months.

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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

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. More than 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. Moreover, for the twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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.

*Lucentis® (ranibizumab injection) was developed by Genentech, a member of the Roche Group. Genentech retains commercial rights in the United States and Novartis has exclusive commercial rights for the rest of the world.

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

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