Media & Investor Release

Roche to reintroduce Susvimo in the US for people with neovascular age-related macular degeneration (nAMD)

- **The FDA has approved updates to Susvimo, which will be available to US retina specialists and patients with nAMD in the coming weeks**
- **Susvimo offers the first alternative to regular eye injections that are standard of care for nAMD, which impacts 20 million people worldwide and can cause blindness if left untreated**
- **By continuously delivering medicine to the eye through a refillable implant, Susvimo is the first and only approved nAMD treatment shown to maintain vision with two refills a year**

Basel, 08 July 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the reintroduction of Susvimo® (ranibizumab injection) 100 mg/mL for intravitreal use via ocular implant for the treatment of people in the United States (US) with neovascular or 'wet' age-related macular degeneration (nAMD), following the end of a voluntary recall. The US Food and Drug Administration (FDA) has approved a post-approval supplement to the Biologics License Application for Susvimo, reflecting component-level updates made to the ocular implant and refill needle. Roche will work to make Susvimo available in the US to retina specialists and their patients with nAMD in the coming weeks.

"We are pleased to reintroduce Susvimo, a unique therapeutic approach shown to provide an effective alternative to regular eye injections by preserving vision with two refills per year in Phase III study patients with neovascular age-related macular degeneration," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Susvimo's return to the retina community reflects our unwavering commitment to provide innovative retinal treatments, and lays the groundwork for future advancements."

Susvimo provides continuous delivery of a customised formulation of ranibizumab via the Port Delivery Platform, while other currently approved treatments may require multiple eye injections per year.[1-3]

The Susvimo implant is surgically inserted into the eye during a one-time, outpatient procedure and is refilled once every six months using a specifically designed needle, which introduces a customised formulation of ranibizumab directly into the device.[1,4] Susvimo was approved by the FDA in 2021.[4] The following year, Roche voluntarily recalled the ocular implant, insertion tool and initial fill kit in the US following test results that showed some implants did not perform to Roche's standards. Roche has since updated the Susvimo implant

and refill needle, and testing confirmed that they now meet these performance standards.[5] Manufacturing process improvements were also implemented.[5]

Roche is committed to making this innovative drug delivery system available around the world. This is one of multiple options Roche continues to develop to meet the needs of people living with nAMD and other prevalent eye conditions, including diabetic macular edema.

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.[6] Neovascular or 'wet' AMD (nAMD) is an advanced form of the disease that can cause rapid and severe vision loss if left untreated.[7,8] It develops when new and abnormal blood vessels grow uncontrolled under the macula, causing swelling, bleeding and/or fibrosis.[8] 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.[6,9,10]

About Susvimo® (Port Delivery System with ranibizumab)

Susvimo 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.[1] 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.[11]

The customised formulation of ranibizumab delivered by 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 US Food and Drug Administration in 2006.[3]

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, which is led by science and informed by insights from people with eye diseases. Our pipeline includes gene therapies and treatments across multiple vision-threatening conditions, including diabetic eye diseases, geographic atrophy and autoimmune conditions, such as thyroid eye disease and uveitic macular edema.

Applying our extensive experience, we have already brought breakthrough ophthalmic treatments to people living with vision loss. Susvimo® (previously called Port Delivery System

with ranibizumab) 100 mg/mL for intravitreal use via ocular implant was approved by the United States (US) Food and Drug Administration in 2021.[4] Vabysmo® (faricimab) is the first bispecific antibody approved for the eye, which targets and inhibits two signalling pathways linked to a number of vision-threatening retinal conditions by neutralising angiopoietin-2 and vascular endothelial growth factor-A.[12,13] Vabysmo is approved around the world for people living with neovascular or 'wet' age-related macular degeneration and diabetic macular edema, and in several countries, including the US and Japan, for macular edema following retinal vein occlusion.[5,14-18] Lucentis® (ranibizumab injection)* was the first treatment approved to improve vision in people with certain retinal conditions.[3]

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavour to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the fifteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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.

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