# Media & Investor Release

## FDA approves Roche's Susvimo as the first and only continuous delivery treatment for the leading cause of diabetes-related blindness

- **Susvimo is the first and only continuous delivery treatment that offers an alternative to regular eye injections to treat diabetic macular edema (DME)**
- **With as few as two treatments per year, Susvimo may help people with DME maintain their vision**
- **Approval marks the second indication for Susvimo in addition to neovascular or 'wet' age-related macular degeneration (nAMD)**

Basel, 04 February 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the US Food and Drug Administration (FDA) has approved Susvimo® (ranibizumab injection) 100 mg/mL for the treatment of diabetic macular edema (DME), a leading cause of vision loss in adults with diabetes, affecting more than 29 million adults worldwide.[1-3] Susvimo is the first and only FDA-approved treatment shown to maintain vision in people with DME with fewer treatments than standard-of-care eye injections.[4-6] Susvimo is now available to US retina specialists and their patients with DME.

"Susvimo presents a unique, convenient treatment alternative to routine eye injections for people with a potentially blinding diabetic eye condition," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "As the global prevalence of diabetic macular edema continues to grow, today's FDA approval for Susvimo reflects our dedication to innovation and enhancing the patient experience."

"I am excited to offer Susvimo to my patients living with diabetic macular edema who want an option with longer intervals between treatments due to their busy personal and professional lives," said vitreoretinal surgeon, Jordan Graff, MD, Barnet Dulaney Perkins Eye Center, Arizona, US. "Having completed dozens of Susvimo surgeries in my patients with wet, or neovascular, age-related macular degeneration (nAMD), I've seen first-hand how Susvimo, with its continuous delivery of medication, can help preserve vision with fewer treatments. I look forward to broadening Susvimo's impact to even more patients in my clinic."

The FDA decision was based on positive one-year results from the phase III Pagoda study, which showed that Susvimo demonstrated sustained vision improvements in people with DME, with safety consistent with the known safety profile for Susvimo.[7] In Pagoda, people with DME who received Susvimo refilled every six months achieved non-inferior improvements in vision compared with those receiving monthly 0.5 mg ranibizumab intravitreal injections (9.6 eye chart letters, similar to gaining two more lines on an eye chart, compared to 9.4 letters, respectively).[7]

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Susvimo provides continuous delivery of a customised formulation of ranibizumab via the Port Delivery Platform, while other currently approved treatments may require eye injections as often as once per month.[6,8] Susvimo was first approved by the FDA for the treatment of nAMD in 2021.[9] Discussions with other global regulatory agencies are ongoing.

Roche is focused on saving people's eyesight from the leading causes of vision loss through pioneering therapies and has the broadest retina pipeline in ophthalmology, which is led by science and informed by insights from people with eye conditions.

## About diabetic macular edema (DME)

Affecting around 29 million people globally, DME is a vision-threatening retinal condition associated with blindness and decreased quality of life when left untreated.[1-3,10] DME occurs when damaged blood vessels leak into and cause swelling in the macula – the central area of the retina responsible for the sharp vision needed for reading and driving.[11,12] The number of people with DME is expected to grow as the prevalence of diabetes increases.[13]

## About the Pagoda study[14]

Pagoda (NCT04108156) is a multicentre, randomised, active treatment-controlled, non-inferiority US-based phase III study evaluating the efficacy, safety and pharmacokinetics of Susvimo® (Port Delivery Platform with ranibizumab) refilled every six months compared with monthly ranibizumab 0.5 mg intravitreal injections, in 634 people with diabetic macular edema. Participants were randomised 3:2 to receive either Susvimo refilled every six months or continued monthly intravitreal ranibizumab injections. In the Susvimo arm, participants received four loading doses of intravitreal ranibizumab, before Susvimo implantation at week 16. The primary endpoint of the study is a change in best-corrected visual acuity 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 60 and week 64. Following primary analyses, participants who were initially randomised to intravitreal injections received Susvimo, with refills every 24 weeks.

## About Susvimo® (Port Delivery Platform with ranibizumab) in the US

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.[8] 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.[15]

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.[16] Roche is also developing DutaFabs – the next generation of

bispecific antibodies designed for increased efficacy and durability – tailored for continuous delivery via the Port Delivery implant.

## 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 conditions. Our pipeline includes innovative treatments across different modalities, such as antibodies, and gene and cell therapies targeting multiple vision-threatening conditions, including retinal vascular and diabetic eye diseases, geographic atrophy, and autoimmune conditions, such as thyroid eye disease and uveitic macular edema.

Applying our extensive experience, we have brought breakthrough ophthalmic treatments to people living with vision loss. Susvimo® (previously called Port Delivery Platform with ranibizumab) 100 mg/mL for intravitreal use via ocular implant is the first US Food and Drug Administration-approved refillable eye implant for neovascular or 'wet' age-related macular degeneration (nAMD) and diabetic macular edema (DME) that continuously delivers a customised formulation of ranibizumab over a period of months.[4,8] 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.[17-19] Vabysmo is approved around the world for people living with nAMD, DME and macular edema following retinal vein occlusion.[19-24] Lucentis® (ranibizumab injection)* was the first treatment approved to improve vision in people with certain retinal conditions.[16]

## 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.
For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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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