Media & Investor Release

FDA approves Roche's Susvimo for diabetic retinopathy

- **Susvimo can help people with diabetic retinopathy (DR) maintain their vision and prevent progression to blindness with only one treatment every nine months**
- **Susvimo's innovative technology via the Port Delivery Platform may offer an alternative to regular eye injections in the US**
- **Diabetic retinopathy affects almost 10 million people in the US and is the third FDA-approved indication for Susvimo, which is also approved for treating neovascular or 'wet' age-related macular degeneration and diabetic macular edema**

Basel, 22 May 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 retinopathy (DR), a potentially blinding condition that affects almost 10 million people in the US and more than 100 million people globally.[1,2] It is the first and only FDA-approved continuous delivery treatment shown to maintain vision in people with DR with just one refill every nine months.[3,4] Susvimo is now available to US retina specialists and their patients with DR who have previously responded to at least two anti-vascular endothelial growth factor (VEGF) injections.

"The approval of Susvimo for diabetic retinopathy expands treatment options for patients, offering predictable and immediate durability after implantation with only one treatment every nine months," said Levi Garraway, MD, PhD, Chief Medical Officer and Head of Global Product Development. "Many patients with common retinal conditions seek alternative treatment options like Susvimo that can help preserve vision with longer intervals between treatments than regular eye injections."

"Susvimo is a compelling new treatment for patients at risk of vision loss from progression of diabetic retinopathy," said vitreoretinal surgeon, Carl Awh, M.D., Tennessee Retina, Tennessee. "I am delighted to have this far more durable treatment available for my patients."

The FDA decision was based on positive one-year results from the phase III Pavilion study. People with DR who received Susvimo refilled every nine months achieved superior improvements on the Diabetic Retinopathy Severity Scale (DRSS).[4] This means there was a reduction in the severity of eye damage caused by diabetes, compared with those under monthly clinical observation who were treated with anti-VEGF injections as needed based on disease progression.[4] Additionally, none of the participants receiving Susvimo required supplemental treatment at one year.[4] Safety was consistent with the known safety profile for Susvimo.[4]

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.[5,6] The Port Delivery Platform is a refillable eye implant surgically inserted into the eye during a one-time, outpatient procedure, which introduces medicine directly into the eye, addressing certain retinal conditions that can cause vision loss.[5,6]

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 retinopathy

Accounting for approximately 5% of all cases of visual impairment, diabetic retinopathy (DR) occurs when damage to the blood vessels and the formation of new blood vessels causes blood and/or fluid to leak into the retina - a part of the eye that sends information to the brain, enabling sight.[7,8] This leads to swelling, as well as blockage of the blood supply to some areas of the retina.[9] As the condition progresses, vision becomes impaired.[8] DR affects approximately 103 million people globally, resulting in blindness in almost five million people.[2,10]

About the Pavilion study[11]

Pavilion (NCT04503551) is a multicentre, randomised, US-based phase III study evaluating the efficacy, safety and pharmacokinetics of Susvimo® (Port Delivery Platform with ranibizumab) 100 mg/mL refilled every nine months compared with people under monthly clinical observation, in 174 people with non-proliferative diabetic retinopathy (DR) without centre-involved diabetic macular edema. Participants were randomised 5:3 to receive either Susvimo with refills every nine months or monthly clinical observation, respectively. In the Susvimo arm, participants received two loading doses of intravitreal ranibizumab, before Susvimo implantation at week 4. The primary endpoint was the proportion of participants with at least a two-step improvement from baseline on the Early Treatment Diabetic Retinopathy Study-Diabetic Retinopathy Severity Scale at week 52. Following the primary analysis, participants initially in the clinical observation arm received two ranibizumab loading doses before Susvimo implantation at week 64.

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.[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.[12]

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.[13] 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 System 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), diabetic macular edema (DME) and diabetic retinopathy (DR) that continuously delivers a customised formulation of ranibizumab over a period of months.[3,6] 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.[14-16] Vabysmo is approved around the world for people living with nAMD, DME and macular edema following retinal vein occlusion.[16-21] Lucentis® (ranibizumab injection)* was the first treatment approved to improve vision in people with certain retinal conditions.[13]

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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