Media & Investor Release

Roche's Susvimo maintains vision over five years with two refills per year in people with neovascular age-related macular degeneration (nAMD)

- **Susvimo is the only continuous delivery treatment to provide reliable, long-term vision outcomes in nAMD, the leading cause of vision loss in people over the age of 60**
- **With two refills per year, Susvimo maintained vision and stabilised the retina for five years, with durability maintained in approximately 95% of patients**
- **Susvimo was well tolerated over five years and has a well-characterised safety profile**

Basel, 01 August 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today new, five-year efficacy, safety and durability data from the Phase III Portal study, a long-term extension of the Phase III Archway study, of Susvimo® (ranibizumab injection) for the treatment of people with nAMD.[1] Results show that Susvimo's immediate and predictable durability was sustained over five years, with approximately 95% of people receiving treatment every six months requiring no supplemental treatment before each refill. The data were presented at the American Society of Retina Specialists (ASRS) 2025 Annual Meeting in Long Beach, California, United States.

"These long-term results reinforce Susvimo's ability to maintain vision and retinal drying over a long period of time for people with nAMD, the leading cause of vision loss in people over age 60," said Levi Garraway, MD, PhD, Roche's chief medical officer and head of Global Product Development. "These robust data reinforce our confidence in Susvimo's unique therapeutic approach, providing an effective alternative to regular eye injections while preserving vision in a sustained manner."

"People with nAMD often experience suboptimal outcomes with real-world anti-VEGF treatment, largely due to the frequency of injections," said study investigator John Kitchens, M.D., Retina Associates of Kentucky, who presented the data at ASRS. "Continuous delivery of treatment with Susvimo may preserve vision in patients with nAMD for longer in real-world clinical use than IVT injections."

In the Portal study (n = 352), people originally treated with Susvimo in Archway continued to receive Susvimo refills every six months (Susvimo cohort; n = 220), while those originally treated with monthly intravitreal (IVT) ranibizumab injections in Archway received Susvimo and then refills every six months (IVT-Susvimo cohort; n = 132).

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Five-year results showed consistent and sustained disease control and retinal drying in a population who entered Archway with vision at or near peak levels after receiving an average of five intravitreal injections per standard of care. In the Susvimo cohort, best-corrected visual acuity (BCVA) was 74.4 letters at baseline and 67.6 letters at 5 years. In the IVT-Susvimo cohort, BCVA was 76.3 letters at baseline and 68.6 at 5 years. Half of all patients had better than 20/40 vision at five years (Snellen visual acuity test). Average central subfield thickness (CST) remained stable, with a 1.0 (95% CI: -13.1, 11.1) µm reduction from baseline in the Susvimo cohort, and a 10.3 (95% CI: -25.7, 5.0) µm reduction in the IVT-Susvimo cohort.

The cohort of people who entered the Portal study from Archway is the largest cohort of people with nAMD to be followed prospectively and continuously for five years in a clinical study.[1]

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. 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.

About the Archway study and its open-label extension study (Portal)[1,2]

Archway (NCT03677934) was a randomised, multicentre, open-label phase III study evaluating the efficacy and safety of Susvimo refilled every six months at fixed intervals, compared to monthly IVT ranibizumab 0.5 mg in 415 people living with nAMD. Patients were randomized 3:2 to Susvimo (n = 248) or IVT ranibizumab injections (n = 167). Patients enrolled in Archway were responders to prior treatment with anti-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, with an average of five anti-VEGF injections before randomization. The primary endpoint of the study was the change in BCVA score 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. Patients who completed the study at week 96 were eligible to enter the Portal open-label extension study. In Portal, people originally treated with Susvimo in Archway continued to receive Susvimo refills every six months (Susvimo cohort), while those originally treated with monthly intravitreal (IVT) ranibizumab injections in Archway received the Susvimo implant and then refills every six months (IVT-Susvimo cohort). Portal is ongoing.

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.[3] Neovascular or 'wet' AMD (nAMD) is an advanced form of the disease that can cause rapid and severe vision loss if left untreated.[4,5] It develops when new and abnormal blood vessels grow uncontrolled under the

macula, causing swelling, bleeding and/or fibrosis.[5] 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.[3,6,7]

About Susvimo® (Port Delivery System with ranibizumab)

Approved in the United States by the Food and Drug Administration (FDA) for nAMD, diabetic macular edema (DME) and diabetic retinopathy (DR), Susvimo is a refillable eye implant surgically inserted into the eye during a one-time, outpatient procedure.[8,9] Susvimo continuously delivers a customised formulation of ranibizumab over time.[8,9] Ranibizumab is a 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.[8-10]

The customised formulation of ranibizumab delivered by Susvimo is different from the ranibizumab IVT injection, a medicine marketed as Lucentis® (ranibizumab injection)*, which is approved to treat nAMD and other retinal diseases.[11]

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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