Media & Investor Release

European Commission approves Roche's Susvimo® for the treatment of neovascular age-related macular degeneration (nAMD)

- **By continuously delivering medicine into the eye through the Contivue refillable implant, Susvimo is the first and only continuous delivery treatment that offers an alternative to standard-of-care eye injections for nAMD[1-3]**
- **Susvimo helps people with nAMD maintain their vision with as few as two treatments per year[1-3]**
- **Data from the Phase III Archway study showed that Susvimo maintained vision equivalent to monthly intravitreal ranibizumab injections[2]**
- **nAMD is a leading cause of vision loss in adults over 60 and affects approximately 1.7 million people across the European Union[4,5]**

Basel, 21 September 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the European Commission has approved Susvimo® (ranibizumab 100 mg/mL solution for injection) for the treatment of neovascular age-related macular degeneration (nAMD), a leading cause of vision loss in people over the age of 60.[5,6]

"The European Commission approval of Susvimo now provides this continuous delivery option to people in Europe with neovascular age-related macular degeneration," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "Many nAMD patients are unable to extend their dosing interval beyond every eight weeks, and 40% discontinue treatment within two years. By offering patients continuous delivery through a refillable implant, Susvimo offers a unique alternative to frequent eye injections that can help maintain vision while significantly reducing the treatment burden."

In 2025, Roche was granted a CE mark for its Port Delivery Platform, known as Contivue® in the European Union (EU), which comprises the eye implant that delivers Susvimo and four ancillary devices to initially fill, insert, refill, and remove the implant (if required).[7] Contivue provides continuous delivery of Susvimo directly into the eye. Susvimo has been specifically developed for use with Contivue. Roche is evaluating other molecules in the pipeline that could potentially be used with the Port Delivery Platform to increase efficacy and/or durability, with the future aim of providing multiple treatment options to patients using Contivue.

"In clinical practice, we see firsthand how the fear of vision loss is compounded by the burden of frequent clinic visits," said Frank Holz, Professor and Chairman of the Department of Ophthalmology at the University of Bonn, Germany. "By continuously delivering medicine

directly into the eye, Contivue with Susvimo allows patients to maintain their vision with as few as two treatments a year."

The approval is based on data from three clinical studies in nAMD: one pivotal Phase III study, Archway, and two supportive studies, the Phase II Ladder study and the open-label long-term extension study Portal.[1-3] Data from Archway showed patients treated with Susvimo achieved and maintained vision outcomes equivalent to monthly intravitreal (IVT) ranibizumab injections, with longer-term data in Portal showing vision was maintained for up to seven years.[2,3] With two refills per year, approximately 95% of patients treated with Susvimo required no supplemental/additional anti-vascular endothelial growth factor (anti-VEGF) treatment.[3] Susvimo was generally well tolerated over the longer term.[1-3]

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. Neovascular or 'wet' AMD (nAMD) is an advanced form of the disease that can cause rapid and severe vision loss if left untreated.[8-10] It develops when new and abnormal blood vessels grow uncontrolled under the macula, causing swelling, bleeding and/or fibrosis.[10] 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.[5,8,11]

About Contivue with Susvimo (Port Delivery Platform with ranibizumab)

The Contivue devices include a refillable implant surgically inserted into the eye during a one-time, outpatient procedure. Contivue also includes four ancillary devices to initially fill, insert, refill, and remove the implant.[7]

Contivue with Susvimo delivers a customised formulation of ranibizumab, Susvimo, over time.[7] 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.[12] The customised formulation of ranibizumab, Susvimo, delivered by Contivue with Susvimo is different from the ranibizumab IVT injection, a medicine marketed as Lucentis® (ranibizumab injection)*, which is approved to treat nAMD and other retinal disorders.[13]

In the US, the devices (refillable eye implant and ancillary devices) and medicine (customised formulation of ranibizumab) are approved by the Food and Drug Administration (FDA) as a single product, called Susvimo for the treatment of nAMD, diabetic macular edema (DME) and diabetic retinopathy (DR).[14]

Contivue with Susvimo is also approved for the treatment of nAMD in Switzerland and Thailand.

About Roche in Ophthalmology

At Roche, we are on a mission to save and restore eyesight. Over 330 million people around the world are blind, or living with vision loss, creating a profound personal and socioeconomic burden.[15] With the broadest pipeline in Ophthalmology, we continue to invest at scale to redefine what is medically possible in eye care.

Our comprehensive ophthalmology pipeline integrates diverse targets, advanced delivery systems, cell and gene therapies, and AI-augmented imaging capabilities, 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.

About Roche

Roche (SIX: RO, ROP; OTCQX: RHHBY) is a healthcare company uniquely placed to prevent, stop and cure diseases by uniting leading science and technology across diagnostics, medicines and digital solutions.

Roche was founded in Basel, Switzerland in 1896 and today is a leading provider of transformative medicines and diagnostics for millions of people in over 150 countries around the world. It is dedicated to tackling healthcare challenges that place the greatest strain on patients, families, communities and healthcare systems. Across its Diagnostics and Pharmaceutical divisions, Roche focuses on areas including oncology, neurology, cardiovascular and metabolic diseases, ophthalmology, infectious diseases and immunology with the aim of providing real and positive change for patients, the people they love and the professionals who care for them.

Genentech in the United States is a fully owned subsidiary in the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, a major innovator in the Japanese therapeutic antibody market.

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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