Media & Investor Release

Roche's Vabysmo prefilled syringe (PFS) approved in the EU for three retinal conditions that can cause blindness

- **Vabysmo PFS is the first and only prefilled syringe containing a bispecific antibody, offering a convenient alternative to currently available Vabysmo vials**
- **Vabysmo has demonstrated rapid and robust vision and anatomical improvements in neovascular age-related macular degeneration (nAMD), diabetic macular edema (DME) and retinal vein occlusion (RVO)**
- **The ready-to-use Vabysmo PFS is co-packaged with the only CE-marked needle specifically designed for intravitreal injection**

Basel, 13 December 2024– Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Medicines Agency has approved Vabysmo® (faricimab) 6.0 mg single-dose prefilled syringe (PFS) for use in the treatment of neovascular or 'wet' age-related macular degeneration (nAMD), diabetic macular edema (DME) and macular edema following retinal vein occlusion (RVO). Together, these three conditions affect more than nine million people in the European Union (EU) and can have a devastating impact – physically, emotionally, and economically – on those affected, their families and caregivers.[1-5]

"Approval of the Vabysmo prefilled syringe in the EU offers a convenient way for ophthalmologists to administer this treatment for people with three of the most common causes of vision loss," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "This simplified administration may thereby help reduce the treatment burden for patients and retina specialists."

The Vabysmo PFS provides ophthalmologists with the first and only CE-labelled needle for intravitreal injection. Vabysmo PFS delivers the same medicine as the currently available 6.0 mg Vabysmo vials in an alternative, ready-to-use format.[6] More than five million doses of Vabysmo have been distributed globally since its initial US approval in 2022.[6-11] Vabysmo PFS was first approved for nAMD, DME and RVO by the United States Food and Drug Administration in July 2024.[7] Vabysmo PFS will be the European Union's first and only prefilled syringe containing a bispecific antibody to treat retinal conditions that can cause blindness.

About Vabysmo® (faricimab)

Vabysmo is the first bispecific antibody approved for the eye.[7,8,12] It targets and inhibits two signalling pathways linked to a number of vision-threatening retinal conditions by neutralising angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A). Ang-2

and VEGF-A contribute to vision loss by destabilising blood vessels, causing new leaky blood vessels to form and increasing inflammation. By blocking pathways involving Ang-2 and VEGF-A, Vabysmo is designed to stabilise blood vessels.[12,13] Vabysmo is approved in more than 100 countries around the world, including the United States (US), Japan, the United Kingdom and the European Union (EU) for people with neovascular or 'wet' age-related macular degeneration and diabetic macular edema, and in more than 30 countries, including the US, EU and Japan, for people with macular edema following retinal vein occlusion. Review by other health authorities is ongoing.[6-11]

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 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 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 is the first United States Food and Drug Administration-approved refillable eye implant for neovascular or 'wet' age-related macular degeneration that continuously delivers a customised formulation of ranibizumab over a period of months.[14,15] 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.[7,8,12,13] Vabysmo is approved around the world for people living with nAMD, diabetic macular edema and macular edema following retinal vein occlusion.[6-11] 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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