Media & Investor Release

FDA approves Roche's Vabysmo prefilled syringe (PFS) for three leading causes of vision loss

- **Vabysmo PFS is the first and only syringe prefilled with an FDA-approved bispecific antibody to treat retinal conditions that can cause blindness**
- **Designed to simplify administration, Vabysmo PFS provides retina specialists a ready-to-use option**
- **Vabysmo PFS will be available for people living with nAMD, DME and RVO**

Basel, 05 July 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today the United States Food and Drug Administration (US FDA) has approved the 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 close to 80 million people globally.[1-4] The Vabysmo PFS will become available to United States (US) retina specialists and their patients in the coming months.

"We are pleased that the US FDA has approved the Vabysmo PFS for people living with neovascular age-related macular degeneration, diabetic macular edema and retinal vein occlusion, which are some of the leading causes of vision loss," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "While many retina specialists are already using Vabysmo as a first-line treatment, this new offering should make it even simpler to administer, thereby enhancing the treatment experience for both physicians and patients."

Vabysmo PFS delivers the same medicine as the currently available Vabysmo vials in an alternative, ready-to-use format. Vabysmo will continue to be available in a 6.0 mg vial.[5]

Vabysmo is the first and only bispecific antibody approved for the eye and has demonstrated rapid and robust vision improvements and retinal drying in nAMD, DME and RVO.[5-13] Retinal drying is an important clinical measure, as swelling from excess fluid in the back of the eye is associated with distorted and blurred vision.[14]

To date, Vabysmo is approved in more than 95 countries for nAMD and DME, and in several countries, including the US and Japan, for RVO.[5,7,15-18] Review by other health authorities across the globe is ongoing. More than four million doses of Vabysmo have been distributed globally since its initial US approval in 2022.[18]

About Vabysmo® (faricimab)

Vabysmo is the first bispecific antibody approved for the eye.[5-7] 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.[6,19] Vabysmo is approved in more than 95 countries around the world, including the United States (US), Japan, the United Kingdom and the European Union for people living with neovascular or 'wet' age-related macular degeneration and diabetic macular edema and in several countries, including the US and Japan, for retinal vein occlusion.[5,7,15-19] Review by other regulatory authorities is ongoing.

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 gene therapies and treatments across multiple vision-threatening conditions, including 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 was approved by the United States Food and Drug Administration in 2021.[20] 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.[5-7,19] Lucentis® (ranibizumab injection)* was the first treatment approved to improve vision in people with certain retinal conditions.[21]

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.

In recognising our endeavour to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow

Jones Sustainability Indices for the fifteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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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