Media & Investor Release

Roche's Vabysmo gets CHMP recommendation for third indication retinal vein occlusion (RVO)

- **Positive recommendation is based on two Phase III studies. In addition to robust retinal drying with Vabysmo, these data show early and sustained vision improvements, which are non-inferior to aflibercept**
- **If approved, Vabysmo would be the first and only bispecific antibody treatment available for the nearly one million people with RVO in the European Union**
- **Vabysmo is already approved in the US and Japan for RVO and in more than 95 countries around the world for people living with nAMD and DME**

Basel, 28 June 2024 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for the extension of the Vabysmo® (faricimab) marketing authorisation to include the treatment of visual impairment due to macular edema secondary to retinal vein occlusion (RVO). A final decision regarding the approval is expected from the European Commission in the near future.

"This CHMP recommendation represents an important step towards bringing Vabysmo to even more patients living with vision loss in Europe," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Recognising the disruptive impact retinal vein occlusion can have on the everyday lives and independence of these patients, we hope that Vabysmo will offer a new treatment option that can effectively help preserve and improve their vision."

The CHMP decision is based on full 72-week data from the Phase III BALATON and COMINO studies evaluating Vabysmo in more than 1,200 people with macular edema due to branch and central RVO (BRVO and CRVO).[1,2] In both studies, Vabysmo demonstrated early and sustained vision improvements non-inferior to aflibercept, and robust retinal drying. Vabysmo was well tolerated and the safety profile was consistent with previous studies.[3] Current available treatments for RVO are typically given every one to two months. [4,5]

Vabysmo was first approved for RVO by the United States Food and Drug Administration in October 2023 and by the Japan Ministry of Health, Labour and Welfare in March 2024.[6-8] It is also approved in more than 95 countries around the world for people living with neovascular or 'wet' age-related macular degeneration (nAMD) and diabetic macular edema (DME).[6,8-11]

Roche has the broadest retina pipeline in ophthalmology. Led by science and informed by insights from people with eye conditions, Roche is committed to saving people's eyesight from the leading causes of vision loss through pioneering treatments.

About retinal vein occlusion (RVO)

RVO is the second most common cause of vision loss due to retinal vascular diseases. It affects an estimated 28 million adults globally, mainly those aged 60 or older, and can lead to severe and sudden vision loss.[12,13] The level of angiopoietin-2 (Ang-2) is elevated in RVO and it is thought that increased Ang-2 expression drives disease progression.[14,15] RVO typically results in sudden, painless vision loss in the affected eye because the vein blockage restricts normal blood flow in the affected retina, resulting in ischemia, bleeding, fluid leakage and retinal swelling called macular edema.[13,16,17] Currently, macular edema due to RVO is typically treated with repeated intravitreal injections of anti-vascular endothelial growth factor therapies.[16] There are two main types of RVO: branch RVO, which affects more than 23 million people globally and occurs when one of the four smaller 'branches' of the main central retinal vein becomes blocked; and central RVO, which is less common, affecting more than four million people worldwide, and occurs when the eye's central retinal vein becomes blocked.[12,17]

About the BALATON and COMINO studies[1,2]

BALATON (NCT04740905) and COMINO (NCT04740931) were two randomised, multicentre, global Phase III studies evaluating the efficacy and safety of Vabysmo® (faricimab) compared to aflibercept. For the first 20 weeks, patients were randomised 1:1 to receive six monthly injections of either Vabysmo (6.0 mg) or aflibercept (2.0 mg). From weeks 24-72, all patients received Vabysmo (6.0 mg) up to every four months using a treat-and-extend dosing regimen.

The BALATON study was conducted in 553 people with branch retinal vein occlusion. The COMINO study was conducted in 729 people with central retinal or hemiretinal vein occlusion.

The primary endpoint of each study was the change in best-corrected visual acuity from baseline at 24 weeks. Secondary endpoints included change in central subfield thickness and drying of retinal fluid from baseline over time up to week 24.

About the Vabysmo® (faricimab) clinical development programme

Roche has a robust Phase III clinical development programme for Vabysmo. The programme includes AVONELLE-X (NCT04777201), an extension study of TENAYA (NCT03823287) and LUCERNE (NCT03823300), evaluating the long-term safety and tolerability of Vabysmo in neovascular or 'wet' age-related macular degeneration (nAMD), and RHONE-X (NCT04432831), an extension study of YOSEMITE (NCT03622580) and RHINE (NCT03622593) evaluating the long-term safety and tolerability of Vabysmo in diabetic macular edema (DME).[18,19] Roche has also initiated several Phase IV studies, including the ELEVATUM (NCT05224102) study of Vabysmo in underrepresented patient populations with DME, the SALWEEN study of Vabysmo in a subpopulation of nAMD highly prevalent in Asia, and the POYANG (NCT06176352) study of Vabysmo in adult treatment-naive patients with choroidal neovascularisation secondary to pathologic myopia.[20-22] Roche has also initiated the VOYAGER (NCT05476926) study, a global real-world data collection platform, and supports

several other independent studies to further understand retinal conditions with a high unmet need.[23]

About Vabysmo® (faricimab)

Vabysmo is the first bispecific antibody approved for the eye. 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.[24] Vabysmo is approved in more than 95 countries around the world, including the United States, 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 RVO.[4,6-9] 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 U.S. Food and Drug Administration in 2021.[25] Vabysmo is approved around the world 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 macular edema following retinal vein occlusion.[4,6-9] Lucentis® (ranibizumab injection)* was the first treatment approved to improve vision in people with certain retinal conditions.[5]

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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