

Roche's faricimab meets primary endpoint in two global phase III studies and shows potential to extend time between treatments up to 16 weeks for people with neovascular age-related macular degeneration

- **Faricimab given at intervals of up to every 16 weeks demonstrated non-inferior visual acuity gains compared to aflibercept given every eight weeks, potentially reducing the frequency of injections and overall burden of treatment**
- **Nearly half of people were treated with faricimab every 16 weeks during the first year – the first time this level of durability has been achieved in a phase III study of an injectable eye medicine for neovascular age-related macular degeneration**
- **Faricimab is the first investigational bispecific antibody designed for the eye and targets two distinct pathways – via angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A) – that drive a number of retinal conditions**
- **Faricimab was generally well-tolerated in both studies, with no new or unexpected safety signals identified**

Basel, 25 January 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced positive topline results from two identically designed global phase III studies, TENAYA and LUCERNE, evaluating its investigational bispecific antibody, faricimab, in people living with neovascular or “wet” age-related macular degeneration (nAMD). Both studies met their primary endpoint and showed that people receiving faricimab injections at fixed intervals of up to every 16 weeks achieved visual acuity outcomes that were non-inferior to those receiving aflibercept injections every eight weeks. Nearly half (45%) of people in both studies were treated with faricimab every 16 weeks during the first year. This is the first time this level of durability has been achieved in a phase III study of an injectable eye medicine for nAMD. In both studies, faricimab was generally well-tolerated, with no new or unexpected safety signals identified.

Neovascular AMD affects around 20 million people globally and is the leading cause of blindness in those aged 60 and older.^{1,2,3} Current standards of care, injections that inhibit vascular endothelial growth factor (VEGF), have significantly reduced the rates of vision loss due to nAMD.⁴ However, VEGF is not the only pathway involved in the development and progression of this complex condition.⁴ With anti-VEGF monotherapies, people with nAMD have to visit their ophthalmologist as often as monthly for eye injections to help maintain vision gains and/or prevent vision loss.⁵ This high treatment burden can lead to under-treatment and potentially less than optimal vision outcomes.⁶ It has been more than 15 years since a medicine with a new mechanism of action has been approved to treat nAMD.⁷ Faricimab is the first bispecific antibody designed for the eye.⁸ It targets two distinct pathways – via angiopoietin-2 (Ang-2) and VEGF-A – that drive a number of retinal conditions, including nAMD.⁸

“These results show the potential of faricimab as a new class of medicine that could extend time between treatments for people living with neovascular age-related macular degeneration,” said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “We have now seen positive

and consistent results in four phase III studies for faricimab across both neovascular age-related macular degeneration and diabetic macular edema. We look forward to submitting these data to global regulatory authorities, with the aim of bringing this promising treatment option to patients as soon as possible.”

The findings from TENAYA and LUCERNE build on [positive topline results](#) from the phase III YOSEMITE and RHINE studies, announced in December 2020, which support the potential of faricimab as a treatment option for diabetic macular edema, a leading cause of vision loss among working-age adults.⁹ Detailed results from all four studies will be presented in February at [Angiogenesis, Exudation, and Degeneration 2021](#), a medical symposium presented by Bascom Palmer Eye Institute of the University of Miami Miller School of Medicine, and submitted for approval to health authorities around the world, including the U.S. Food and Drug Administration and European Medicines Agency.

About the TENAYA and LUCERNE studies^{10,11}

TENAYA (NCT03823287) and LUCERNE (NCT03823300) are two identical, randomised, multicentre, double-masked, global phase III studies, evaluating the efficacy and safety of faricimab compared to aflibercept in 1,329 people living with neovascular age-related macular degeneration (671 in TENAYA and 658 in LUCERNE). The studies each have two treatment arms: faricimab 6.0 mg administered at fixed intervals of every eight, 12 or 16 weeks, selected based on objective assessment of disease activity at weeks 20 and 24; aflibercept 2.0 mg administered at fixed eight-week intervals. In both arms, sham injections were administered at study visits when treatment injections were not scheduled, to maintain the masking of investigators and participants.

The primary endpoint of the studies is the average change in best-corrected visual acuity (BCVA) score (the best distance vision a person can achieve – including with correction such as glasses – when reading letters on an eye chart) from baseline through week 48. Secondary endpoints include: safety; the percentage of participants in the faricimab arm receiving treatment every eight, 12 and 16 weeks; the percentage of participants achieving a gain, and the percentage avoiding a loss, of 15 letters or more in BCVA from baseline over time; and change in central subfield thickness from baseline over time.

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.¹ Neovascular or “wet” AMD (nAMD) is an advanced form of the disease that can cause rapid and severe vision loss.^{12,13} It develops when new and abnormal blood vessels grow uncontrolled under the macula, causing swelling, bleeding and/or fibrosis.¹³ 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.^{1,2,3}

About faricimab

Faricimab is the first investigational bispecific antibody designed for the eye.⁸ It targets two distinct pathways

– via angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A) – that drive a number of retinal conditions.⁸ Ang-2 and VEGF-A contribute to vision loss by destabilising blood vessels, causing new leaky blood vessels to form and increasing inflammation.⁴ By simultaneously blocking both pathways involving Ang-2 and VEGF-A, faricimab is designed to stabilise blood vessels, potentially improving vision outcomes for longer for people living with retinal conditions.⁴

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, covering early and late stage products, which is led by science and informed by insights from people with eye diseases. Our late stage pipeline includes two potential first-of-a-kind treatments, Port Delivery System with ranibizumab (PDS) and faricimab, which are being evaluated in a number of retinal conditions including neovascular age-related macular degeneration, diabetic macular edema and diabetic retinopathy. PDS is a permanent refillable eye implant that continuously delivers a customised formulation of ranibizumab over a period of months, potentially reducing the treatment burden associated with frequent eye injections.¹⁴ Faricimab is the first investigational bispecific antibody designed for the eye.⁸ It targets two distinct pathways – via angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A) – that drive a number of retinal conditions, to stabilise blood vessels, potentially improving vision outcomes for longer.^{4,8} Our early stage pipeline includes gene therapies and treatments for geographic atrophy and other vision-threatening diseases, including rare and inherited conditions.

Applying our extensive experience, we have already brought breakthrough ophthalmic treatments to people living with vision loss through Lucentis[®] (ranibizumab injection), the first treatment approved to improve vision in people with certain retinal conditions.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people’s lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make

a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 billion. 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.

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