Media & Investor Release

CHMP recommends EU approval of Roche's Susvimo, the first continuous delivery treatment for neovascular age-related macular degeneration (nAMD)

- **Susvimo is the first and only continuous delivery treatment that offers an alternative to standard of care eye injections for nAMD**
- **Positive recommendation is based on data from the LADDER, Archway and Portal studies showing Susvimo maintained vision equivalent to monthly intravitreal ranibizumab injections[1-3]**
- **By continuously delivering medicine into the eye through the Contivue® refillable implant, Susvimo may help people with nAMD maintain their vision with as few as two treatments per year[1-3]**
- **nAMD is a leading cause of blindness in people over the age of 60 and affects 1.7 million in the European Union (EU)[4]**

Basel, 24 July 2026 - Roche (SIX: RO, ROP; OTCQX: RHHBY) announced today that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of Susvimo® (ranibizumab injection) 100 mg/mL for the treatment of neovascular age-related macular degeneration (nAMD).[5] Susvimo is intended for continuous release into the vitreous using the Contivue implant.[6] A final decision is expected from the European Commission in the near future.

"The positive CHMP recommendation for Susvimo brings us closer to offering a new treatment option for people in Europe who currently face the burden of frequent eye injections," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "By requiring only two refills per year, Contivue with Susvimo offers a continuous drug delivery approach intended to reduce the frequency of clinic visits, with data from clinical trials supporting maintenance of vision up to seven years."

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 through which Susvimo is delivered, and four ancillary devices to initially fill, insert, refill and remove the implant (if required). Contivue provides continuous delivery of Susvimo directly to the eye.[6]

The positive recommendation 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 maintenance of vision 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]

Contivue has been specifically engineered for use with Susvimo.[6] 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.

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.[7-9] It develops when new and abnormal blood vessels grow uncontrolled under the macula, causing swelling, bleeding and/or fibrosis.[9] 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.[7,10,11]

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.[6]

Contivue with Susvimo delivers a customised formulation of ranibizumab, Susvimo, over time.[6] 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 diseases.[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 nAMD, diabetic macular edema (DME) and diabetic retinopathy (DR).[14]

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

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.

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.

References

[1] Khanani et al. First-Time Long-Term Efficacy and Safety Outcomes of PDS Patients Enrolled in the Ladder Phase 2 Trial of PDS for nAMD Followed for up to ~7 Years. 4-7 September, EURETINA 2025.
[2] Holekamp NM, Campochiaro PA, Chang MA, et al. Archway Randomized Phase 3 Trial of the Port Delivery System with Ranibizumab for Neovascular Age-Related Macular Degeneration. Ophthalmology. 2022;129(3):295-307. doi:10.1016/j.ophtha.2021.09.016
[3] Kitchens J, et al. Five Year Outcomes in nAMD Patients Enrolled in the Archway Study and Treated With the PDS. Presented at: The American Society of Retina Specialists (ASRS) 2025 Annual Meeting; 2025 August 01; Long Beach, California, United States.

[4] Li et al. Retinal diseases in Europe. Prevalence, incidence and healthcare needs. August 2017 [Internet; cited July 2026]. Available from: https://euretina.org/resource/euretina-whitebook-on-prevalence-incidence-and-healthcare-needs-for-retinal-diseases-in-europe/
[5] Roche data on file.
[6] Roche. Roche receives CE mark for Contivue, its Port Delivery Platform containing Susvimo, for neovascular age-related macular degeneration (nAMD). September 4, 2025. [Internet; cited July 2026]. Available from: https://www.roche.com/media/releases/med-cor-2025-09-04
[7] BrightFocus Foundation. Macular Degeneration Facts & Figures. [Internet; cited July 2026]. Available from: https://www.brightfocus.org/macular/facts-figures/
[8] Pennington KL, DeAngelis MM. Epidemiology of age-related macular degeneration (AMD): associations with cardiovascular disease phenotypes and lipid factors. Eye Vis (Lond). 2016;3:34. doi:10.1186/s40662-016-0063-5
[9] Little K, Ma JH, Yang N, Chen M, Xu H. Myofibroblasts in macular fibrosis secondary to neovascular age-related macular degeneration - the potential sources and molecular cues for their recruitment and activation. EBioMedicine. 2018;38:283-291. doi:10.1016/j.ebiom.2018.11.029
[10] Wong WL, Su X, Li X, et al. Global prevalence of age-related macular degeneration and disease burden projection for 2020 and 2040: a systematic review and meta-analysis. Lancet Glob Health. 2014;2(2):e106-e116. doi:10.1016/S2214-109X(13)70145-1
[11] Connolly E, Rhatigan M, O'Halloran AM, et al. Prevalence of age-related macular degeneration associated genetic risk factors and 4-year progression data in the Irish population. Br J Ophthalmol. 2018;102(12):1691-1695. doi:10.1136/bjophthalmol-2017-311673
[12] Heier JS, Singh RP, Wykoff CC, et al. The angiopoietin/tie pathway in retinal vascular diseases: A review. Retina. 2021;41(1):1-19. doi:10.1097/IAE.0000000000003003
[13] European Medicines Agency. Lucentis (ranibizumab) Summary of Product Characteristics. May 2026. [Internet; cited July 2026]. Available from: https://www.ema.europa.eu/en/documents/product-information/lucentis-epar-product-information_en.pdf
[14] US Food and Drug Administration (FDA). Susvimo Prescribing Information. September 2025. [Internet; cited July 2026]. Available from: https://www.gene.com/download/pdf/susvimo_prescribing.pdf

Roche Global Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD
Phone: +41 79 407 72 58

Simon Goldsborough
Phone: +44 797 32 72 915

Kirti Pandey
Phone: +41 79 398 38 53

Dr Rebekka Schnell
Phone: +41 79 205 27 03

Lorena Corfas
Phone: +41 79 568 24 95

Karsten Kleine
Phone: +41 79 461 86 83

Yvette Petillon
Phone: +41 79 961 92 50

Irène Stephan
Phone: +41 79 377 83 75

Roche Investor Relations

Dr Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Dr Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com