Media Release

Roche receives CE mark for Contivue, its Port Delivery Platform containing Susvimo, for neovascular age-related macular degeneration (nAMD)

- **Susvimo is under review with the EMA and once approved will be the first continuous delivery treatment for nAMD, affecting 1,7 million in the European Union[1]**
- **New seven-year data from the LADDER study show Contivue with Susvimo provides good visual outcomes with stable retinal anatomy over the longer term[2]**
- **With up to two refills per year, Contivue with Susvimo provides reliable, long-term vision outcomes and is approved in the US for nAMD, diabetic macular edema (DME) and diabetic retinopathy (DR)[2-5]**

Basel, 04 September 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has received the EU CE mark for its Port Delivery Platform containing Susvimo, which will now be known as Contivue® in the EU.[6] The device comprises the eye implant through which Susvimo is delivered, and four ancillary devices to initially fill, insert, refill, and remove the implant (if required).[6] Susvimo® (ranibizumab injection) 100 mg/mL is currently under review with the European Medicines Agency (EMA) for the treatment of nAMD.[6] With immediate and predictable durability, Contivue with Susvimo provides continuous delivery of a customised formulation of ranibizumab directly to the eye.[6]

“Susvimo offers people living with nAMD the opportunity to maintain their vision with as few as two treatments per year,” said Levi Garraway, MD, PhD, Roche’s Chief Medical Officer and Head of Global Product Development. “Moreover, this sustained delivery brings substantial long-term clinical benefits, as demonstrated by the seven years of follow-up data from the LADDER study.”

Three clinical studies contribute to the EMA’s evaluation of efficacy and safety of Contivue with Susvimo 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. Data from Archway showed patients treated with Contivue with Susvimo achieved and maintained vision outcomes equivalent to monthly intravitreal (IVT) ranibizumab injections.[7]

New long-term data from the LADDER study, presented at the 25th EURETINA Congress in Paris, France, shows that Contivue with Susvimo provides good visual outcomes with stable retinal anatomy over the longer term.[2] In the 59 patients continuously treated with Contivue with Susvimo over seven years, best-corrected visual acuity (BCVA) was 70.4 letters at baseline and 63.2 letters at seven years, an average decline of only six letters approximately

over that time for patients who were at or near peak levels at the time of enrolment after receiving three intravitreal injections of standard of care.[2] Half of all patients had approximately 20/40 vision at seven years (Snellen visual acuity test). Contivue with Susvimo durability was maintained in approximately 95% of patients.[2]

“The seven-year results from the LADDER study powerfully demonstrate the long-term outcomes delivered by Contivue with Susvimo,” said study investigator Carl C. Awh, MD, FASR, Tennessee Retina, Nashville, TN, USA . “For patients with nAMD, the sustained drug delivery of Contivue with Susvimo may provide superior visual outcomes compared to the well-demonstrated average decline in vision associated with long-term intravitreal injections.”

The port delivery platform devices have been specifically engineered for use with a customized formulation of ranibizumab that is gradually released over time. Roche has several molecules in the pipeline with potential for use with the port delivery platform for continued growth and expansion.

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.[8-10] It develops when new and abnormal blood vessels grow uncontrolled under the macula, causing swelling, bleeding and/or fibrosis.[10] 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.[8, 11-12]

About Contivue with Susvimo (Port Delivery Platform with ranibizumab)

Contivue is a refillable eye implant surgically implanted into the eye during a one-time, outpatient procedure.[2-4,13] Contivue also includes four ancillary devices to initially fill, insert, refill, and remove the implant.

Contivue with Susvimo delivers a customised formulation of ranibizumab, Susvimo, over time.[5] 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.[2-4,14] 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.[15]

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).[2-4]

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, which is led by science and informed by insights from people with eye conditions. 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 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 US FDA-approved refillable eye implant for neovascular or 'wet' age-related macular degeneration (nAMD), DME and DR that continuously delivers a customised formulation of ranibizumab over a period of months.[3-4] 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.[16] Vabysmo is approved around the world for people living with nAMD, DME and macular edema following retinal vein occlusion.[14] Lucentis® (ranibizumab injection) was the first treatment approved to improve vision in people with certain retinal conditions.[15]

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.

References

[1] Li at al. Retinal diseases in Europe.Prevalence, incidence and healthcare needs. 2017 [Internet; cited August 2025]. Available from: https://euretina.org/resource/euretina-whitebook-on-prevalence-incidence-and-healthcare-needs-for-retinal-diseases-in-europe/
[2] 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.
[3] Roche. FDA approves Roche's Susvimo for diabetic retinopathy. 2025. [Internet;cited September 2025]. Available from: https://www.roche.com/media/releases/med-cor-2025-05-22
[4] Roche. FDA approves Roche's Susvimo as the first and only continuous delivery treatment for the leading cause of diabetes-related blindness. 2025. [Internet; cited September 2025]. Available from: https://www.roche.com/media/releases/med-cor-2025-02-04
[5]: US Food and Drug Administration (FDA). Highlights of prescribing information, Susvimo. 2021. [Internet; cited September 2025]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761197s000lbl.pdf.
[6]. Roche data on file
[7] Khanani 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.
[8] Facts & figures - macular degeneration. BrightFocus Foundation. May 15, 2025. [Internet; cited September 2025]. Available from: https://www.brightfocus.org/macular/facts-figures/.
[9] Pennington KL, DeAngelis MM. Epidemiology of age-related macular degeneration (AMD): Associations with cardiovascular disease phenotypes and lipid factors. Eye and Vision. 2016;3(1). doi:10.1186/s40662-016-0063-5.
[10] 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.
[11] Wong WL, et al. Global prevalence of age-related macular degeneration (AMD) and disease burden projection for 2020 and 2040: a systematic review and meta-analysis. Lancet Global Health. 2014;2:106–16.
[12] Connolly E, et al. Prevalence of AMD associated genetic risk factors and four-year progression data in the Irish population. British Journal of Ophthalmology. 2018 Feb;102:1691-95
[13] Holekamp N, et al. Archway randomised phase III trial of the PDS with ranibizumab for neovascular age-related macular degeneration (nAMD). Ophthalmology. 2021
[14] Heier JS, et al. The angiopoietin/tie pathway in retinal vascular diseases: A review. The Journal of Retinal and Vitreous Diseases. 2021;41:1-19.
[15] US FDA. Highlights of prescribing information, Lucentis. 2014. [Internet; cited September 2025]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/125156s0069s0076lbl.pdf.
[16] United States (US) Food and Drug Administration (FDA). Highlights of prescribing information, Vabysmo. 2024. [Internet; cited September 2025]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761235s005lbl.pdf.

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