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News Release

Not intended for U.S. and UK Media

Aflibercept 8 mg application for macular edema following retinal vein occlusion accepted for review in China

- China's National Medical Products Administration (NMPA) has accepted for review the application for aflibercept 8 mg (114.3 mg/ml solution for injection) for the treatment of macular edema following retinal vein occlusion (RVO)
- The filing is supported by positive results from the global Phase III QUASAR study
- In QUASAR, aflibercept 8 mg dosed less frequently showed comparable visual acuity gains and anatomical outcomes to monthly Eylea™ (aflibercept) 2 mg at week 64

Berlin, August 13, 2026 – Bayer today announced that the National Medical Products Administration (NMPA) in China has accepted for review the application for aflibercept 8 mg (114.3 mg/ml solution for injection) to treat patients with visual impairment due to macular edema following retinal vein occlusion (RVO) including central, branch, and hemiretinal vein occlusion.

Reducing disease burden while maintaining vision outcomes

Macular edema following retinal vein occlusion is a significant cause of visual impairment worldwide, including in China, and can result in sudden and rapid vision loss.[1,2]

"For patients with macular edema due to retinal vein occlusion, treatment is essential to help preserve vision, but the usual monthly treatment frequency can be challenging to sustain," said Dr. Christian Rommel, Global Head of Research and Development at Bayer's Pharmaceuticals Division. "The QUASAR data show that aflibercept 8 mg could offer similar vision outcomes with fewer injections compared to monthly Eylea (aflibercept) 2 mg, which could make a meaningful difference in everyday care."

Evidence basis: Phase III QUASAR[3]

The submission to the NMPA is supported by positive results from the global randomized clinical Phase III trial QUASAR, which included patients from China. The study met its primary endpoint at week 36, demonstrating that patients receiving aflibercept 8 mg every 8 weeks (after 3 initial monthly injections) achieved comparable visual acuity gains and anatomical outcomes to those receiving the Eylea (aflibercept) 2 mg every 4 weeks. In both treatment arms dosing intervals could be extended based on dose regimen modification (DRM) criteria from week 32. Aflibercept 8 mg was well tolerated, and its safety profile was consistent with results from previous clinical trials.

Key results at end of study week 64, a key secondary endpoint[4]

At week 64, patients on aflibercept 8 mg (after 3 initial monthly injections) maintained visual acuity gains while needing about 3 fewer injections on average than those on Eylea 2 mg (8.5 vs. 11.7). More than 60% of patients receiving aflibercept 8 mg (after 3 initial monthly injections) were able to achieve a last assigned treatment interval of four months or longer, with 40% having a last assigned interval of five months.

Global and regional regulatory status

Eylea (aflibercept) 8 mg has been approved in the EU and other markets for the treatment of patients with macular edema following retinal vein occlusion (RVO) and is approved to date in 70 markets for the treatment of neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME). In more than 50 markets, Eylea 8 mg is the only anti-vascular endothelial growth factor-treatment (anti-VEGF) that is approved for extended treatment intervals of up to 6 months in nAMD and DME.

In China, Eylea 8 mg is approved for nAMD.

Collaboration and rights

Aflibercept (Eylea™) 2 mg and 8 mg (in the U.S. Eylea and Eylea HD) is jointly developed by Bayer and Regeneron.

- Regeneron holds exclusive rights in the United States.
- Bayer holds exclusive marketing rights outside the United States, where profits from sales are shared equally between the companies.

About RVO

Retinal vein occlusion (RVO) is a common retinal vascular disorder that currently affects 28 million adults globally[5] and can lead to sudden, rapid vision loss.[6] There are two main types of RVO – central retinal vein occlusion (CRVO) and branch retinal vein occlusion (BRVO). CRVO occurs when there is a blockage in the main vein of the retina at the optic nerve. BRVO occurs when the smaller, branch retinal veins are obstructed, and is up to six times more common than CRVO. Hemiretinal vein occlusion (HRVO) refers to the occlusion of a vein that drains one half of the retina. RVO can lead to a reduced oxygen supply to the retina, increasing the production of vascular endothelial growth factor (VEGF) and placental growth factor (PlGF). The blocked vein can cause fluid and blood to leak into the retina resulting in swelling and bleeding within the macula, the part of the eye responsible for sharp central vision and seeing fine detail. This swelling is called macular edema, and VEGF plays a major role in driving this pathology.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, “Health for all, Hunger for none,” the company’s products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2025, the Group employed around 88,000 people and had sales of 45.6 billion euros. R&D expenses amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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Bayer AG is a holding company with operating subsidiaries worldwide. References to "Bayer" or "the company" herein may refer to one or more subsidiaries as context requires.

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[1] Laouri M, *et al*. *Eye (Lond)* 2011;25:981–988

[2] The Royal College of Ophthalmologists. Clinical guidelines: Retinal Vein Occlusion (RVO). Available at: https://www.rcophth.ac.uk/wp-content/uploads/2015/07/Retinal-Vein-Occlusion-Guidelines-2022.pdf

[3] Gale R, presented at the *Angiogenesis Meeting 2025, Virtual Edition, February 8, 2025*

[4] Chaudhary V, *Presented at the Angiogenesis Meeting 2026, Virtual Edition, February 7, 2026*

[5] Song P, *et al*. *J Glob Health* 2019;9:010427

[6] The Royal College of Ophthalmologists. Clinical guidelines: Retinal Vein Occlusion (RVO). Available at: https://www.rcophth.ac.uk/wp-content/uploads/2015/07/Retinal-Vein-Occlusion-Guidelines-2022.pdf.