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News Release

Not intended for U.S. and UK Media

Eylea™ 8 mg approved in the EU for third retinal indication

- The European Commission has granted marketing authorization in the European Union (EU) for Eylea™ 8 mg (aflibercept 8 mg) for the treatment of patients with macular edema following retinal vein occlusion (RVO) including branch, central and hemiretinal vein occlusion
- In addition to the positive efficacy and safety profile, Eylea 8 mg offers high durability as demonstrated at week 64 in the Phase III clinical trial QUASAR in which more than 60% of RVO patients treated with Eylea 8 mg achieved a last assigned treatment interval of four months or longer, with 40% having a last assigned interval of five months

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Berlin, January 16, 2026 – The European Commission has granted marketing authorization in the European Union (EU) for Eylea™ 8 mg (aflibercept 8 mg, 114.3 mg/ml solution for injection) for the treatment of patients with visual impairment due to macular edema following retinal vein occlusion (RVO) including branch, central and hemiretinal vein occlusion. RVO is the third indication for Eylea 8 mg.

“Retinal vein occlusion often presents with sudden vision loss and affects older people who are still of working age. Early diagnosis and treatment are essential to help prevent irreversible vision loss; however, the treatment burden of frequent injections can be challenging for patients. In the Phase III clinical trial QUASAR, Eylea 8 mg demonstrated in the key secondary endpoint that it can meaningfully reduce the number of injections while maintaining visual acuity and providing a favorable safety profile,” said Richard Gale, Professor of Ophthalmology Hull York Medical School (HYMS), University of York, and Consultant Medical Ophthalmologist, and one of the trial investigators.

In the early treatment phase of RVO, treatment is intensive, with intravitreal injections usually administered in monthly intervals (every 4 weeks). In the QUASAR trial,

Eylea 8 mg achieved non-inferior functional and anatomic outcomes compared to Eylea 2 mg, with three times fewer patients requiring monthly intervals (every 4 weeks), despite patients in all treatment arms having the option to extend dosing intervals. Patients treated with Eylea 8 mg (after 3 initial monthly injections) not only maintained their visual acuity but required an average of 2-3 fewer injections than those receiving Eylea 2 mg (8.4 vs. 11.7) by week 64. Importantly, fluid reduction – an indicator of disease control – was similar with extended dosing intervals of aflibercept 8 mg compared with dosing intervals of Eylea 2 mg. The study results also showed that Eylea 8 mg was well tolerated, and its safety profile was consistent with results from previous clinical trials.

“Eylea 8 mg represents a new treatment option for patients with macular edema due to retinal vein occlusion, addressing the demand for more durable therapies. The recent approval in the European Union expands the range of retinal indications for Eylea 8 mg – now encompassing wet age-related macular degeneration, diabetic macular edema, and retinal vein occlusion,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer.

The QUASAR clinical study met its primary endpoint at week 36, demonstrating that patients receiving Eylea 8 mg every 2 months (after 3 or 5 initial monthly injections) achieved non-inferior visual acuity gains and robust fluid control compared to those receiving Eylea 2 mg (aflibercept 2 mg) monthly. Additional submitted data show that visual acuity was maintained with Eylea 8 mg, and unparalleled durability was demonstrated through the end of the study at week 64. More than 60% of patients receiving aflibercept 8 mg were able to achieve a last assigned treatment interval of four months and longer, with 40% having a last assigned interval of five months.

Eylea 8 mg has been approved to date in more than 60 markets for the treatment of neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME).

Eylea 8 mg is the first and only anti-vascular endothelial growth factor-treatment (anti-VEGF) that is approved for extended treatment intervals of up to 6 months both in nAMD and DME in the EU and UK.

Eylea 8 mg (in the United States: Eylea HD) is being jointly developed by Bayer and Regeneron. Regeneron maintains exclusive rights to Eylea 2 mg and Eylea HD in the United States. Bayer has licensed the exclusive marketing rights outside the United States, where the companies share equally the profits from sales of Eylea 2 mg and Eylea 8 mg.

About RVO

Retinal vein occlusion (RVO) is a chronic condition that currently affects 28 million adults globally and can lead to sudden, rapid vision loss. 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 supplies 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 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements
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