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News Release

Not intended for U.S. and UK Media

Aflibercept 8 mg recommended for EU approval for third retinal indication

- Positive opinion of the Committee for Medicinal Products for Human Use (CHMP) is based on the outcomes from the clinical Phase III trial QUASAR in patients with macular edema following retinal vein occlusion (RVO) including branch, central and hemiretinal vein occlusion
- Aflibercept 8 mg demonstrated non-inferior visual acuity gains and robust fluid control with extended treatment intervals as well as fewer injections, compared to Eylea™ 2 mg monthly
- The decision of the European Commission is expected within the next weeks

Berlin, December 12, 2025 – The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended aflibercept 8 mg (114.3 mg/ml solution for injection) for marketing authorization in the European Union (EU) for the treatment of patients with visual impairment due to macular edema following retinal vein occlusion (RVO) including branch, central and hemiretinal vein occlusion. The European Commission's decision is anticipated within the coming weeks, which would mark the third indication for Eylea 8 mg.

"Following the approval of Eylea 8 mg for treatment intervals of up to six months in neovascular age-related macular degeneration and diabetic macular edema in the EU, today's recommendation marks a significant step towards advancing the treatment of retinal vein occlusion. Aflibercept 8 mg is set to enhance the standard of care, reducing the burden of frequent injections and clinic visits for patients experiencing macular edema due to retinal vein occlusion, without compromising efficacy and safety," 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 aflibercept 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 aflibercept 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 extend their treatment intervals to four months and longer, with 40% having a last assigned interval of five months.

The number of injections, a key secondary endpoint, was significantly reduced to 8.4 injections with aflibercept 8 mg administered every two months (after three initial monthly injections), compared to 11.7 with Eylea 2 mg 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. Additionally, aflibercept 8 mg was well tolerated, and its safety profile was consistent with results from previous clinical trials.

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.

Aflibercept 8 mg (in the United States: Eylea HD) is being jointly developed by Bayer and Regeneron. Regeneron maintains exclusive rights to Eylea 2 mg (aflibercept 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 QUASAR

The QUASAR trial is a global randomized, double-masked, active-controlled Phase III study evaluating the efficacy and safety of aflibercept 8 mg used with extended dosing intervals in treatment-naïve patients with macular edema secondary to retinal vein occlusion including branch retinal vein occlusion (BRVO), central retinal vein occlusion (CRVO), and hemiretinal vein occlusion (HRVO). The primary endpoint of this study is the

change in best corrected visual acuity (BCVA), as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) letter score, from baseline to week 36 of treatment. The study compared BCVA changes between patients who received aflibercept 8 mg every 8 weeks following either 3 or 5 initial monthly doses compared to aflibercept 2 mg every 4 weeks. Treatment intervals could be further adjusted based on treatment response continuously evaluated under clinically relevant dose regimen modification (DRM) criteria. Treatment intervals could be shortened by 4 weeks at any visit if patients met DRM criteria. Treatment intervals could be extended at dosing visits based on DRM criteria from week 32 (for the study arms with aflibercept 2 mg and aflibercept 8 mg following 3 initial monthly doses) or week 40 (for the study arm with aflibercept 8 mg following 5 initial monthly doses). Patients were treated up to week 60 followed by a monitoring period through week 64. The trial enrolled more than 800 patients from 27 countries.

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 superior vein that supplies one half of the retina. RVO leads 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 central field of vision, including visualizing fine details. 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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