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News Release

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Aflibercept 8 mg to treat macular edema following retinal vein occlusion submitted for approval in Japan

- Submission for marketing authorization to the Ministry of Health, Labour and Welfare (MHLW) in Japan for aflibercept 8 mg for the treatment of patients with macular edema following retinal vein occlusion (RVO)
- Submission is based on positive results from the global phase III QUASAR study
- Aflibercept 8 mg demonstrated non-inferior visual acuity gains when given less frequently, compared to Eylea™ 2 mg monthly

Berlin, May 9, 2025 – Bayer has submitted an application to the Japanese Ministry of Health, Labour and Welfare (MHLW) seeking approval of aflibercept 8 mg (114.3 mg/ml solution for injection) for the treatment of patients with macular edema following retinal vein occlusion (RVO) including central, branch and hemiretinal vein occlusion. In Japan, this would be the third indication for aflibercept 8 mg supporting the blockbuster status of Eylea™.

The submission to the MHLW is supported by favorable outcomes from the global randomized, double-masked, active-controlled phase III QUASAR study. The study was conducted in RVO patients from 27 countries, including Japan. This study achieved its primary endpoint at week 36, showing that patients treated with aflibercept 8 mg every 8 weeks (following 3 or 5 initial monthly doses) achieved visual acuity improvements that were non-inferior to patients receiving the current standard treatment, Eylea™ 2 mg (aflibercept 2 mg) every 4 weeks.

“Japan is an important market for Bayer in ophthalmology and today's submission marks a significant step towards enhancing patient care in retinal vein occlusion,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization, and Member of the Pharmaceuticals Leadership Team at Bayer. “Following approval in Japan, aflibercept 8 mg may offer extended treatment intervals for patients affected by macular edema due to retinal vein occlusion, thereby reducing the burden of frequent injections and clinic visits."

The QUASAR clinical study demonstrated that approximately 90% of patients on aflibercept 8 mg maintained their extended 8-week dosing intervals through 36 weeks, and almost 70% of patients (in the group with 3 initial monthly dosing) had a last assigned dosing interval of 12 weeks. Importantly, fluid reduction – an indicator of disease control – was similar with extended dosing intervals of aflibercept 8 mg compared with monthly doses of Eylea 2 mg. Additionally, aflibercept 8 mg was well tolerated, and its safety profile was consistent with previous clinical trials.

Eylea 8 mg has been approved to date in more than 50 markets for the treatment of neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME). Further regulatory applications for Eylea 8 mg in additional markets are ongoing.

Eylea 8 mg is the only anti-vascular endothelial growth factor-treatment (anti-VEGF) that is approved for extended treatment intervals of up to 5 months for both, nAMD and DME, in the EU and UK. In February 2025, Bayer submitted an application to EMA to expand treatment intervals to up to 6 months with Eylea 8 mg for the treatment of nAMD and DME based on clinical evidence from the PULSAR and PHOTON studies.

Eylea 8 mg (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 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. 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 a swelling and bleeding of the macula, the centre of the retina responsible for fine vision. 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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js (2025-0069e)