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News Release

Not intended for U.S. and UK Media

Eylea™ 8 mg with extended 6-month treatment interval recommended for approval in EU

- Committee for Medicinal Products for Human Use (CHMP) opinion is based on the findings from the pivotal clinical trials PULSAR in neovascular (wet) age-related macular degeneration (nAMD) and PHOTON in diabetic macular edema (DME)
 - 28% of patients in DME and 24% of patients in nAMD had a last assigned treatment interval of 6 months at the end of three years
 - The decision of the European Commission is expected within the next weeks
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Berlin, May 23, 2025 – Bayer announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending a label extension for Eylea™ 8 mg (aflibercept 8 mg, 114.3 mg/ml solution for injection). This extension allows for expanded treatment intervals of up to 6 months for the treatment of two major retinal diseases, neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME) following approval by the European Commission. The decision of the European Commission is expected within the next few weeks and if approved, Eylea 8 mg would be the only anti-vascular endothelial growth factor (VEGF) treatment in the EU with treatment intervals of up to 6 months for both nAMD and DME.

“Following approval of the European Commission, extended treatment intervals with Eylea 8 mg of up to 6 months can significantly reduce the frequency of injections and visits to the clinic for patients,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer. “These extended intervals, combined with the unique product profile of Eylea 8 mg, position it to become a new standard of care for retinal diseases.”

The CHMP opinion is based on positive three-year results from open-label extension studies of the pivotal clinical trials PULSAR, in nAMD and PHOTON, in DME. In both extension studies patients randomized to Eylea 8 mg at baseline maintained their visual and anatomic improvements, with 24% of patients in nAMD and 28% of patients in DME having a last assigned dosing interval of 6 months at the end of three years.

The safety profile of Eylea 8 mg continued to be favorable in the third year in both studies and is consistent with the well-established safety profile of Eylea 2 mg. The long-term safety data did not show any new signals in both trials, including for patients switching from Eylea 2 mg to Eylea 8 mg. The rates for ocular treatment emergent adverse events were similar across all treatment groups.

Eylea™ 8 mg (aflibercept 8 mg) has been approved to date in more than 50 markets for the treatment of nAMD and 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 (after 3 initial monthly injections) for both nAMD and DME, in the EU and UK.

Eylea is a global market leader for the treatment of retinal eye diseases with anti-vascular endothelial growth factors (anti-VEGF), with more than 88 million applications and more than 12 million patient-years of experience worldwide.

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 nAMD and DME

Neovascular (wet) age-related macular degeneration (nAMD) is an eye disease that progresses rapidly and if left untreated can lead to vision loss in a few months. nAMD is one of the leading causes of irreversible blindness and vision impairment around the world. nAMD may affect people as they age. It occurs when abnormal blood vessels grow and leak fluid under the macula, the part of the eye responsible for sharp central vision and seeing fine detail. This fluid can damage and scar the macula, which can cause vision loss. 170 million people worldwide are living with AMD – it is anticipated that this

figure will increase to 288 million by 2040. Approximately 10% of people with AMD will develop the advanced form nAMD.

Diabetic macular edema (DME) is a common complication in the eyes of people living with diabetes. DME occurs when high levels of blood sugar leads to damaged blood vessels in the eye that leak fluid into the macula. This can lead to vision loss and, in some cases, blindness. Globally, 146 million people are currently living with diabetic retinopathy (DR), which can develop into a more serious condition which is diabetic macular edema. DME affects around 27 million people globally.

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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