Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
www.bayer.com/en/media

News Release

Not intended for U.S. and UK Media

Eylea™ 8 mg with extended 6-month treatment interval approved in the EU

- The European Commission (EC) has approved Eylea 8 mg with extended treatment intervals of up to 6 months in 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 (VEGF) treatment in the EU with treatment intervals of up to 6 months for both patients with nAMD and DME

Berlin, June 27, 2025 – The European Commission (EC) has granted a label extension in the European Union (EU) for Eylea™ 8 mg (aflibercept 8 mg, 114.3 mg/ml solution for injection) with extended treatment intervals of up to 6 months for the treatment of two major retinal diseases, neovascular (wet) age-related macular degeneration (nAMD) and visual impairment due to diabetic macular edema (DME). Eylea 8 mg is the first and only anti-vascular endothelial growth factor (VEGF) treatment in the EU with treatment intervals of up to 6 months for both patients with nAMD and DME.

“Extended treatment intervals with Eylea 8 mg can significantly decrease the frequency of injections and clinic visits for patients without compromising efficacy,” stated Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer. “This translates to decreased burden of disease for patients and may enhance adherence to treatment. For ophthalmologists, it allows for greater capacity to treat additional patients. Given its distinctive product profile, Eylea 8 mg has the potential to establish a new standard of care for retinal diseases.”

The EC decision is based on additional positive results from the third year open-label extension phase of the pivotal clinical trials PULSAR in nAMD and PHOTON in DME. In

both extension phases (study weeks 96-156), patients originally randomized to Eylea 8 mg at week 0 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 at week 96. 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 60 markets for the treatment of nAMD and DME. Further regulatory applications for Eylea 8 mg in additional markets are ongoing.

Eylea is a global market leader for the treatment of retinal eye diseases with anti-vascular endothelial growth factors (anti-VEGF), with more than 89 million applications and more than 13 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.

Contact for media inquiries:
Jutta Schulze, phone +49 175 3002905
Email: jutta.schulze@bayer.com

Contact for investor inquiries:
Bayer Investor Relations Team, phone +49 214 30-72704
Email: ir@bayer.com
www.bayer.com/en/investors/ir-team

Find more information at https://pharma.bayer.com/
Follow us on Facebook: http://www.facebook.com/bayer

js (2025-0122E)

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.