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News Release

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New Eylea™ 8 mg approved in EU

- The European Commission has granted marketing authorization in the European Union (EU) for new Eylea™ 8 mg (aflibercept 8 mg) for the treatment of neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME)
- Aflibercept 8 mg is the only drug that is approved for nAMD and DME for extended treatment intervals of up to 5 months

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Berlin, January 8, 2024 – The European Commission has granted marketing authorization in the European Union (EU) for new Eylea™ 8 mg (aflibercept 8 mg, 114.3 mg/ml solution for injection) 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 approved for administration at extended treatment intervals of up to every 4 months, following 3 initial monthly doses. In patients with stable visual outcomes, treatment intervals of up to 5 months may be considered. Eylea 8 mg is the only treatment in the EU that is approved for extended treatment intervals of up to 5 months in nAMD and DME.

“Eylea 8 mg is an important advancement in retinal care as it provides greater and longer lasting control of the disease. Doctors may extend their patients interval to 4 months, right after 3 initial monthly doses, based on their judgement,” said Jean-François Korobelnik, Professor of Ophthalmology and Head of the Department of Ophthalmology at University Hospital of Bordeaux in France and a trial investigator. “This then does not only mean less eye injections and doctor visits for patients but could also help to mitigate capacity constraints faced in clinical practices in Europe.”

“The approval of Eylea 8 mg in the European Union marks a significant milestone in addressing the high unmet need to reduce the patients’ burden of retinal disease,” said Dr. Michael Devoy, Chief Medical Officer of Bayer’s Pharmaceuticals Division. “Building on the standard of care therapy Eylea 2 mg, patients have now the opportunity to benefit from Eylea 8 mg.”

The EU approval is based on positive results from the PULSAR clinical trial in nAMD and the PHOTON trial in DME. Both studies met their primary endpoint of non-inferior best corrected visual acuity (BCVA) changes with aflibercept 8 mg with 12- or 16-week dosing regimens compared to aflibercept 2 mg (Eylea 40 mg/ml) with a fixed 8-week treatment interval at week 48. In these studies, the safety profile of aflibercept 8 mg was consistent with the well-established safety profile of Eylea (aflibercept 2 mg).

Aflibercept 8 mg was approved under the brand name Eylea HD by the United States Food and Drug Administration (FDA) in August 2023. Bayer has submitted regulatory applications for aflibercept 8 mg in additional markets. Aflibercept 8 mg is being jointly developed by Bayer and Regeneron. Regeneron maintains exclusive rights to Eylea (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 and Eylea 8 mg.

About PULSAR and PHOTON

PULSAR and PHOTON are randomized, double-masked, active-controlled pivotal trials. Both trials were conducted in multiple centers globally with similar designs and endpoints. The Phase III PULSAR trial in nAMD and Phase II/III PHOTON trial in DME evaluated the efficacy and safety of aflibercept 8 mg with 12- and 16-week dosing regimens versus Eylea (aflibercept 2 mg) dosed every 8 weeks, following initial monthly doses, with the primary endpoint of non-inferiority in terms of best corrected visual acuity (BCVA) at week 48. The two-year data mark the end of the masked study (week 96) with the option to extend treatment intervals up to 24 weeks and with an optional 1-year open-label extension for patients until week 156. Patients in both clinical trials were randomized at baseline to the three different arms. Across both studies, 1,164 patients were treated with aflibercept 8 mg. All patients in the aflibercept 8 mg arms were continuously evaluated under stringent, clinically relevant, patient focused dose regimen modification (DRM) criteria starting from week 16 throughout the study. In the first year, patients in the aflibercept 8 mg groups could have their dosing intervals shortened down to an every 8-

week interval if DRM criteria for disease progression were observed. Intervals could not be extended until the second year of the study. In the second year, patients in the aflibercept 8 mg groups could have their dosing intervals shortened or extended if DRM criteria were met. Patients in all Eylea (aflibercept 2 mg) groups maintained a fixed 8-week dosing regimen throughout their participation in the trials. The lead sponsors of the trials were Bayer for PULSAR and Regeneron for PHOTON.

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. 196 million people worldwide are living with AMD – it is anticipated that this figure will increase to 288 million by 2040. Approximately 10-15% of people with AMD will develop the advanced form nAMD.

Diabetic macular edema (DME) is a common complication in eyes of people living with diabetes. DME occurs when high levels of blood sugar lead 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 is affecting around 21 million people globally.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its 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 2022, the Group employed around 101,000 people and had sales of 50.7 billion euros. R&D expenses before special items 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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