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News Release

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Long-term efficacy and safety of Eylea™ 8 mg with extended dosing intervals in wet age-related macular degeneration confirmed at three years

- Results from the open-label extension study of PULSAR show sustained visual acuity gains and fluid control in patients with neovascular (wet) age-related macular degeneration (nAMD) with Eylea™ 8 mg through three years
- The vast majority of patients randomized to Eylea 8 mg had a last assigned extended dosing interval of ≥ 3 months at the end of three years
- 40% of patients randomized to Eylea 8 mg had a last assigned dosing interval of ≥ 5 months, and 24% of patients had a last assigned dosing interval of 6 months at the end of three years
- Long-term safety profile of Eylea 8 mg continued to be favorable in the third year

Berlin, February 7, 2024 – Bayer and its collaboration partner Regeneron presented results from the open-label extension study of the clinical trial PULSAR in patients with neovascular (wet) age-related macular degeneration (nAMD) at three years, at the 22nd annual Angiogenesis meeting, Miami, USA. The data confirm the high durability of Eylea™ 8 mg (aflibercept 8 mg, 114.3 mg/ml solution for injection) as well as its long-term efficacy and safety at the end of three years.

Patients on Eylea 8 mg show sustained visual acuity gains and fluid control through three years. The vast majority of patients randomized to Eylea 8 mg had a last assigned dosing interval of ≥ 3 months at the end of three years. 40% of patients randomized to Eylea 8 mg had a last assigned dosing interval of ≥ 5 months, and 24% of 6 months at the end of three years. Robust reductions in mean central retinal thickness (CRT) from baseline were maintained with Eylea 8 mg through three years. The safety profile of Eylea 8 mg continued to be favorable in the third year.

“We are excited about the reassuring long-term data of Eylea 8 mg which spotlight that a substantial proportion of patients can experience benefits of long treatment intervals with just one injection of Eylea 8 mg every 6 months,” said Professor Tien Y. Wong, China. “Based on the positive data I am confident that Eylea 8 mg has the potential to become the new standard of care in retinal diseases.”

“With an aging population and a rising prevalence of wet age-related macular degeneration, there is an urgent need for more durable treatments,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization, and Member of the Pharmaceuticals Leadership Team at Bayer. “We are delighted that long-term results for Eylea 8 mg have demonstrated its potential in addressing this important need of patients, caregivers and ophthalmologists.”

Efficacy of Eylea 8 mg evaluated by mean change in best-corrected visual acuity (BCVA) was sustained through three years (week 156) compared to the start of the extension study (baseline at week 96).

The safety profile of Eylea 8 mg continued to be favorable through three years and is consistent with the well-established safety profile of Eylea 2 mg. The long-term safety data did not show any new signals for any of the treatment groups (patients randomized to Eylea 8 mg every 3 or 4 months (12 or 16 weeks) and patients switching from Eylea 2 mg to Eylea 8 mg). The rates for ocular treatment emergent adverse events were similar in all treatment groups. No cases of occlusive vasculitis were reported. Intraocular inflammation was low throughout the three years (2.4% in patients switched to Eylea 8 mg, and 1.9% in patients randomized at baseline to Eylea 8 mg).

These long-term data show the continued durable efficacy and safety of Eylea 8 mg. For patients and ophthalmologists this can mean reduced burden of disease with comparable efficacy and safety to the current standard of care Eylea 2 mg.

Eylea 8 mg is the only anti-VEGF treatment that is approved for treatment intervals of up to 5 months for both, nAMD and diabetic macula edema (DME), in the EU, UK and other markets.

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 the PULSAR extension study

The aim of the open-label extension study was to evaluate long-term efficacy, safety and durability of Eylea 8 mg in patients with neovascular (wet) age-related macular degeneration (nAMD) from week 96 until week 156. All patients previously treated with Eylea 2 mg could be switched to Eylea 8 mg every 12-weeks. For these switch patients (n = 208) no initial monthly doses of Eylea 8 mg were necessary. Patients (n = 417) that have already been treated with Eylea 8 mg at week 96 continued their last assigned interval. The majority of patients (90.2%) that were enrolled in the open-label extension study completed the study. Disease activity was monitored every 4 weeks through week 108, then continued every 12 weeks. Disease activity was assessed according to specified, clinically relevant disease regimen modification (DRM) criteria. In patients with no disease activity treatment interval was extended by 2-week increments with a maximum interval of 24 weeks (6 months). In patients with disease activity treatment interval was shortened by 2-week increments with a minimum interval of 8 weeks (2 months).

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 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 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 2023, the Group employed around 100,000 people and had sales of 47.6 billion euros. R&D expenses before special items amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements
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