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News Release

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Eylea™ 8 mg approved in China for wet age-related macular degeneration

- Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) approved Eylea™ 8 mg (aflibercept 8 mg) for the treatment of patients with neovascular (wet) age-related macular degeneration (nAMD)
- Approval is based on the global Phase III PULSAR study
- In PULSAR at week 48, Eylea 8 mg (aflibercept 8 mg) demonstrated comparable efficacy and safety with treatment intervals of 3 or 4 months (12 or 16 weeks) compared to standard of care Eylea™ 2 mg (aflibercept 2 mg) with a fixed bi-monthly interval

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Berlin, May 22, 2025 – The Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) has approved Eylea™ 8 mg (aflibercept 8 mg) for the treatment of neovascular (wet) age-related macular degeneration (nAMD) in China. The approval is based on positive results from the Phase III PULSAR trial at week 48, which demonstrated comparable efficacy and safety of Eylea 8 mg with treatment intervals of 3 or 4 months (12 or 16 weeks) compared to standard of care Eylea™ 2 mg (aflibercept 2 mg) with a fixed bi-monthly (every 8 weeks) interval.

"The approval of Eylea 8 mg in China marks a significant advancement in addressing the need for more durable treatment options for patients, caregivers and ophthalmologists," said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization, and Member of the Pharmaceuticals Leadership Team at Bayer. "Building on the high therapeutic standard of Eylea 2 mg, patients with wet age-related macular degeneration now have the option to benefit from Eylea 8 mg with long treatment intervals and still experience lasting vision gains, rapid and resilient fluid control, and comparable safety to Eylea 2 mg."

In the PULSAR clinical trial Eylea 8 mg met its primary endpoint of non-inferior best corrected visual acuity (BCVA) changes with 3- or 4-monthly dosing regimens compared to Eylea 2 mg (aflibercept 2 mg) with a fixed bi-monthly treatment interval at week 48, following initial monthly doses. The safety profile of Eylea 8 mg was consistent with the well-established safety profile of Eylea 2 mg.

Eylea 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 for both, neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (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 PULSAR

PULSAR is a double-masked, active-controlled pivotal Phase III trial, conducted in multiple centers globally. PULSAR evaluated the efficacy and safety of aflibercept 8 mg in nAMD 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. Patients were randomized at baseline and assigned to the three different arms. In PULSAR, 1,009 patients were treated. 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. Patients on aflibercept 8 mg arms were assessed at multiple time points for DRM criteria and may have had their dosing interval shortened to 8 or 12 weeks to secure appropriate disease control through week 48.

About nAMD

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.

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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