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News Release

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Eylea™ 8 mg pre-filled syringe approved in the EU

- Germany will be one of the first markets to launch the new pre-filled syringe
- The pre-filled syringe provides an easy and accurate way to administer Eylea 8 mg

Berlin, September 9, 2024 – The European Medicines Agency (EMA) has approved the pre-filled syringe for the administration of Eylea™ 8 mg (114.3 mg/ml solution for injection) in the European Union. The new pre-filled syringe OcuClick™ will provide ophthalmologists with an efficient and simple way to accurately deliver the 70-microliter dose of Eylea 8 mg for the approved indications of neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME). Germany will be one of the first markets where the pre-filled syringe is launched.

“We are thrilled about the introduction of the pre-filled syringe for Eylea 8 mg, as it represents a significant advancement in administering an eye injection. This simple, easy, and accurate application method will greatly benefit ophthalmologists and patients, allowing for fast and precise treatment,” said University Professor Dr. med Oliver Zeitz, Senior Consultant and Site Manager of the Department of Ophthalmology at the Charité Campus Benjamin Franklin, Berlin, Germany.

“As a leader in ophthalmology we relentlessly strive for customer-oriented solutions,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization, and Member of the Pharmaceuticals Leadership Team at Bayer. “OcuClick offers the doctor excellent control, precision, and simplicity for the administration of Eylea 8 mg. This innovative ophthalmic syringe, combined with the Eylea 8 mg solution approved for extended treatment intervals of up to five months in appropriate patients, shows how our innovation can directly benefit patients.”

Eylea 8 mg has been developed to reduce the disease burden and to extend treatment intervals with comparable efficacy and safety to standard of care Eylea 2 mg. The successful pivotal clinical trials PULSAR and PHOTON led to the approval in nAMD and DME in the European Union with the unprecedented labelling that allows for extended treatment intervals of up to five months in appropriate patients. Eylea 8 mg met its primary endpoint in PULSAR and PHOTON demonstrating non-inferior best-corrected visual acuity at extended intervals of 12- and 16 weeks compared to Eylea 2 mg at a fixed 8-week interval.

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 following any regulatory approvals.

About Eylea 8 mg and VEGF
Eylea 8 mg (aflibercept 8 mg, 114.3 mg/ml solution for injection) has been approved to date in more than 40 markets for the treatment of neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME). Further regulatory applications for Eylea 8 mg in additional markets are ongoing.

Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body. Its normal role in a healthy organism is to trigger formation of new blood vessels (angiogenesis) supporting the growth of the body's tissues and organs. It is also associated with the growth of abnormal new blood vessels in the eye, which exhibit abnormal increased permeability that leads to edema.

Aflibercept solution for injection is a recombinant fusion protein, consisting of portions of extracellular domains of human VEGF receptors 1 and 2, fused to the Fc portion of human IgG1 and formulated as an iso-osmotic solution for intravitreal administration. Aflibercept acts as a soluble decoy receptor that binds VEGF-A and Placental Growth Factor (PGF) and thereby can inhibit the binding and activation of their cognate VEGF receptors.

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
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