Bayer’s aflibercept 8 mg recommended for approval in EU

- Recommendation by Committee for Medicinal Products for Human Use (CHMP) based on positive results from PULSAR clinical trial in neovascular (wet) age-related macular degeneration (nAMD) and PHOTON trial in diabetic macular edema (DME)
- If approved by European Commission, aflibercept 8 mg will be the only drug providing extended treatment intervals of up to 5 months for patients with nAMD and DME
- Extended treatment intervals with aflibercept 8 mg achieved with comparable efficacy and safety to standard of care drug Eylea™ (aflibercept 2 mg)
- European Commission decision anticipated within coming months

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**Berlin, November 10, 2023** – The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has adopted a positive opinion recommending aflibercept 8 mg with extended treatment intervals in two major retinal eye diseases, neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME) for approval. This includes injections with aflibercept 8 mg at extended treatment intervals of up to every 4 months, after 3 initial monthly doses. In patients with stable visual outcomes, treatment intervals of up to 5 months may be considered. Once approved, aflibercept 8 mg will be the only approved drug providing extended treatment intervals of up to 5 months, based on results in clinical trials, for patients with nAMD and DME.

The CHMP recommendation 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 Eylea (aflibercept 2 mg) with a fixed 8-week treatment interval at week 48.
“The clinical trials with aflibercept 8 mg have demonstrated sustained vision gains with extended treatment intervals, rapid and resilient fluid control, and a comparable safety profile to Eylea 2 mg. This concept of sustained disease control has been eagerly anticipated, because greater and longer lasting control of disease activity is needed to alleviate disease burden for patients and capacity constraints at eye clinics and ophthalmologists’ offices,” said Prof. Paolo Lanzetta, Chairman of the Department of Ophthalmology at the University of Udine, Italy, and a member of the steering committee of the clinical trials. “This can contribute to improved patient adherence and persistence, and support physicians to free up resources to help more patients.”

“Eylea has already transformed the standard of care for millions of people in the EU living with neovascular age-related macular degeneration and diabetic macular edema. This positive CHMP opinion underscores the potential of aflibercept 8 mg to set a new benchmark for the treatment of these progressive blinding diseases,” said Dr. Christian Rommel, Member of the Executive Committee of Bayer’s Pharmaceuticals Division and Head of Research and Development.

The final decision from the European Commission is expected in the coming months. Bayer has applied for the brand name of aflibercept 8 mg to be ‘Eylea 114.3 mg/ml solution for injection’ (Eylea™ 8mg).

Aflibercept 8 mg was approved for use by the FDA on August 18, 2023. Bayer has submitted regulatory applications for aflibercept 8 mg in additional key markets.

Aflibercept 8 mg is being jointly developed by Bayer and Regeneron. Regeneron maintains exclusive rights to Eylea (aflibercept 2 mg) and aflibercept 8 mg 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 (aflibercept 2 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
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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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