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News Release

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Aflibercept 8 mg met primary endpoint in phase III study and demonstrates vision gains with extended treatment intervals in retinal vein occlusion

- Approximately 90% of aflibercept 8 mg patients were extended to every 8-week dosing and maintained their interval through 36 weeks
- Aflibercept 8 mg demonstrated rapid and robust reduction of fluid in the retina, as measured by changes in central subfield thickness
- Aflibercept 8 mg was well tolerated, with a safety profile consistent with previous clinical trials
- Detailed results will be submitted to regulatory authorities worldwide and presented at upcoming scientific meetings

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Berlin, December 17, 2024 – Bayer announced today positive topline results from the global phase III QUASAR study evaluating the efficacy and safety of aflibercept 8 mg in patients with macular edema following retinal vein occlusion (RVO), including central, branch and hemiretinal vein occlusion. The study met its primary endpoint at week 36, demonstrating that patients receiving aflibercept 8 mg every 8 weeks (after initial monthly doses) achieved non-inferior visual acuity gains compared to those receiving the current standard therapy Eylea™ 2 mg (aflibercept 2 mg) every 4 weeks.

Aflibercept 8 mg was well tolerated, and its safety profile was consistent with previous clinical trials.

“These encouraging data demonstrate that aflibercept 8 mg has the potential to become a new standard of care in the treatment of exudative retinal diseases including patients living with retinal vein occlusion, which is known to have a high VEGF load,” said Professor Richard Gale, Clinical Director at York Teaching Hospital, UK.

“The successful outcome of the study establishes the capacity of aflibercept 8 mg to provide sustained disease control,” said Christian Rommel, Member of the Executive Committee of Bayer’s Pharmaceuticals Division and Head of Research and Development. “Aflibercept 8 mg delivers rapid and resilient fluid control and allows long treatment intervals with vision gains and tolerability comparable to Eylea 2 mg.”

In QUASAR the vast majority of aflibercept 8 mg patients (approximately 90%) were extended to every 8-week dosing and maintained their interval through 36 weeks. Almost 70% were assigned every 12-week dosing at the week 32 visit, potentially further alleviating the burden associated with frequent injections. Aflibercept 8 mg also demonstrated rapid and robust reduction of fluid in the retina similar to Eylea 2 mg, as measured by changes in central subfield thickness (CST) from baseline through week 36. Reduction of fluid in the retina and reducing CST are associated with disease control. The mean number of injections through week 36 was reduced to 6.1 or 6.9 injections with aflibercept 8 mg dosed every 8 weeks (following 3 or 5 initial monthly doses) versus 8.8 injections with Eylea 2 mg dosed every 4 weeks. Despite fewer injections, aflibercept 8 mg every 8 weeks achieved similar efficacy and safety to Eylea 2 mg every 4 weeks at week 36.

Detailed results will be submitted to regulatory authorities worldwide and presented at upcoming medical meetings.

Aflibercept 8 mg is approved in more than 50 countries for the indications neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular edema (DME) under the brand name Eylea™ 8 mg. Eylea 8 mg became the first anti-VEGF treatment approved in major markets such as the EU and UK for treatment intervals of up to 5 months in DME and nAMD. In the EU and further countries. Eylea 8 mg is available in a vial and a pre-filled syringe that simplifies the accurate delivery of the recommended dose.

Eylea 8 mg (aflibercept 8 mg; in the United States and Canada: 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 QUASAR

The QUASAR trial is a global randomized, double-masked, active-controlled phase III study evaluating the efficacy and safety of Eylea 8 mg used with extended dosing intervals in treatment-naïve patients with macular edema secondary to retinal vein occlusion including central retinal vein occlusion (CRVO), branch retinal vein occlusion (BRVO) and hemiretinal vein occlusion (HRVO). The primary endpoint of this study is to document change in best corrected visual acuity (BCVA), as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) letter score, from the date of randomization through 36 weeks of treatment. The study compares BCVA changes between patients who received Eylea 8 mg every 8 weeks following either 3 or 5 initial monthly doses compared to Eylea 2 mg every 4 weeks. Treatment intervals could be further adjusted based on treatment response continuously evaluated under clinically relevant dose regimen modification (DRM) criteria. Treatment intervals could be shortened by 4 weeks at any dosing visit if patients met DRM criteria. Treatment intervals could be extended based on DRM criteria from week 32 (for the study arms with aflibercept 2 mg and aflibercept 8 mg following 3 initial monthly doses) or week 40 (for the study arm with aflibercept 8 mg following 5 initial monthly doses). Patients will be treated up to week 60 followed by a monitoring period until week 64. The trial has enrolled more than 800 patients from 27 countries.

About RVO

Retinal vein occlusion (RVO) is a chronic condition that currently affects 28 million adults globally and can lead to sudden, rapid vision loss. There are two main types of RVO – central retinal vein occlusion (CRVO) and branch retinal vein occlusion (BRVO). CRVO occurs when there is a blockage in the main vein of the retina at the optic nerve. BRVO occurs when the smaller, branch retinal veins are obstructed, and is up to six times more common than CRVO. RVO leads to a reduced oxygen supply to the retina, increasing the production of vascular endothelial growth factor (VEGF) and placental growth factor (PlGF). The blocked vein can cause fluid and blood to leak into the retina resulting in a swelling and bleeding of the macula, the center of the retina responsible for fine vision. This swelling is called macular edema, and VEGF plays a major role in driving this pathology.

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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