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News Release

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Bayer Submits Aflibercept for regulatory approval in the EU and Japan for Retinopathy of Prematurity in premature babies

Berlin, November 10, 2021 – Bayer has filed applications for a new therapeutic indication for aflibercept (solution for injection) in premature babies with treatment-requiring retinopathy of prematurity (ROP) in the EU and Japan.

“Our clinical development program for premature babies with ROP addresses an important medical need in this vulnerable pediatric patient population facing severe vision impairment. The regulatory submissions in the EU and in Japan form another step forward in our commitment to addressing patient-relevant needs in eye care,” said Dr. Christian Rommel, Member of the Executive Committee of Bayer AG’s Pharmaceutical Division and Head of Research and Development.

Retinopathy of Prematurity requiring treatment is one of the most serious eye diseases that can lead to significant vision impairment and blindness secondary to retinal detachment. It is estimated that worldwide each year approximately 50,000 babies born prematurely who survive the neonatal period develop vision-threatening ROP.

Bayer’s regulatory submissions are based on final results from the 6-month Phase 3 FIREFLEYE study of aflibercept 0.4mg versus laser surgery which were presented at the 21st Congress of the European Society of Retina Specialists (EURETINA) in September 2021, as well as on interim data from the ongoing long-term follow-up Phase 3b FIREFLEYE NEXT study

“Results of the FIREFLEYE study show that treatment success was numerically higher with aflibercept than with laser,” said Professor Dr. Andreas Stahl, Head of the University Department of Ophthalmology, University Medical Center, Greifswald, Germany, “and

achieved with mostly single injections per eligible eye, less frequent need for rescue treatment and reduced requirement for general anesthesia compared to laser.”

Aflibercept showed a positive benefit-risk profile in patients with ROP treated in 27 countries worldwide in the FIREFLEYE study, the first randomized prospective clinical trial comparing aflibercept to laser in premature babies with ROP requiring treatment. Although the FIREFLEYE Phase 3 study missed statistical significance for the primary endpoint of demonstrating non-inferiority of aflibercept 0.4 mg to laser (90% CI* for treatment difference: -8.0% to +16.2%), the treatment success with aflibercept 0.4mg (85.5%) is considered clinically relevant. In the control group (laser surgery) a response rate of 82.1% was observed. In this study, aflibercept has demonstrated to be efficacious, safe and well-tolerated.

About Retinopathy of Prematurity (ROP)

Retinopathy of prematurity (ROP) is a vascular disease of the immature retina of preterm babies, characterized by incomplete vessel growth which triggers elevated intraocular levels of vascular growth factor (VEGF) and abnormal vessel growth. Key risk factors include low age and weight at birth. Mild ROP usually resolves spontaneously, while severe forms of ROP require timely treatment. Laser surgery, the standard of care for ROP, destroys retinal tissue and can be associated with significant complications such as high myopia (nearsightedness) and peripheral visual field deficits. The VEGF inhibitor aflibercept injected into the eye targets those elevated intraocular levels of VEGF.

About VEGF and aflibercept solution for injection into the eye

Aflibercept solution for injection into the eye, also known under its brand name Eylea®, has been approved in over 100 countries for five indications for adults, which includes the treatment of neovascular wet AMD and the treatment of visual impairment due to: macular edema following retinal vein occlusion (RVO; branch RVO or central RVO), diabetic macular edema (DME) and myopic choroidal neovascularization (myopic CNV). Over 47 million vials/pre-filled syringes of Eylea have been sold since its launch worldwide, with 6.8 million patient-years of experience and a well-established ocular and systemic safety profile.

Bayer and Regeneron Pharmaceuticals, Inc. are collaborating on the global development of aflibercept. Regeneron maintains exclusive rights to Eylea 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, except for Japan where Regeneron receives a percentage of net sales.

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 human VEGF receptors 1 and 2 extracellular domains 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.

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