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Bayer initiates Phase III trial of Aflibercept to prevent blindness in premature infants

Leverkusen, Germany, June 21, 2019 – Bayer has initiated a Phase III trial of its anti-VEGF treatment aflibercept for intravitreal injection in retinopathy of prematurity (ROP), an eye condition in premature infants which can lead to irreversible blindness.

ROP occurs in premature infants as a result of incomplete or abnormal development of blood vessels serving the retina, potentially causing scarring and retinal detachment leading to visual impairment and irreversible blindness. Even with the currently available treatments it is believed to account for 6-18% of childhood blindness in developed countries. Taking into account its prevalence and severity, childhood blindness, including ROP, is a priority for VISION 2020: The Right to Sight, a joint global initiative between the World Health Organization and the International Agency for the Prevention of Blindness.

“To suffer severe irreversible vision loss beginning in infancy is devastating for both affected children and their families, and preventing it must always be an absolute priority,” said Professor Stahl from the University Eye Hospital in Greifswald, Germany. “In its severest form, retinopathy of prematurity can cause total blindness; however, it is also a condition that, for many, can be managed if detected and treated appropriately at the right time. Since many mechanisms of the disease are not yet sufficiently known and the condition remains an ongoing threat around the globe, it is important to continue to further research into retinopathy of prematurity.”

“Childhood visual impairment and blindness can have far-reaching consequences, affecting all aspects of a child’s development. We have initiated this Phase III study to evaluate the potential of providing physicians with an additional treatment for premature infants with ROP,” said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development. “This trial is an

important step forward in our commitment to addressing the most significant unmet needs in ophthalmology.”

This Phase III, multi-center, randomized trial is designed to assess efficacy, safety and tolerability of intravitreal aflibercept for the treatment of ROP. Approximately 100 infants will be enrolled in 34 countries and will be randomized to receive intravitreal aflibercept or laser photocoagulation.

Aflibercept is a proven treatment option for patients with visual impairment due to several retinal conditions and has consistently delivered excellent outcomes in reducing preventable vision loss, both in randomised clinical studies as well as in real world clinical settings.

Aflibercept has been approved under the brand name EYLEA® in approximately 100 countries for five indications to treat patients with wAMD and patients with visual impairment due to: macula edema following retinal vein occlusion (RVO; branch RVO or central RVO) and diabetic macular edema (DME). Aflibercept has also been approved for the treatment of myopic choroidal neovascularization. Around 25 million vials of Eylea have been sold since launch worldwide resulting in approximately 3.6 million patient years of experience.

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.

About VEGF and aflibercept solution for injection into the eye
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.

About Bayer

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