Bayer AG
Communications
51368 Leverkusen
Germany
Tel. +49 214 30-1
media.bayer.com

News Release

Not intended for U.S. and UK Media

Bayer announces Phase III trials with new aflibercept 8mg formulation

Berlin, February 10, 2020 – Bayer and Regeneron Pharmaceuticals, Inc., today announced two planned phase III studies, PHOTON and PULSAR, evaluating extended treatment intervals with a new aflibercept 8mg formulation for intravitreal injection in adults with visual impairment due to diabetic macular edema (DME) and wet age-related macular degeneration (wet AMD), respectively. Aflibercept 2mg is already approved under the brand name Eylea® in more than 100 countries for five indications. Both trials are planned to start in 2020.

The rationale of the PHOTON and PULSAR trials was presented at the Angiogenesis, Exudation, and Degeneration 2020 Conference in Miami, Florida. The multi-center, randomized, double-masked trials will assess the efficacy and safety of aflibercept 8mg in treatment regimes of 12 weeks (3 months) and greater.

“We have already seen that certain patients are able to achieve excellent visual outcomes on extended dosing intervals up to 16 weeks (4 months) with Eylea 2mg, particularly using a treat and extend protocol as reflected in the label in Europe and several other regions. The PHOTON and PULSAR trials will evaluate if even more patients can benefit from longer treatment intervals on aflibercept 8mg,” said Dr. Joerg Moeller, Member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Research and Development.

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 Eylea (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.

Aflibercept has been approved under the brand name Eylea in more than 100 countries for five indications for adults, which in addition to the treatment of visual impairment due to DME and neovascular (wet) age-related macular degeneration, includes the treatment of visual impairment due to: macular edema following retinal vein occlusion (RVO; branch RVO or central RVO) and myopic choroidal neovascularization (myopic CNV). Around 30 million vials of Eylea have been sold since its launch worldwide, resulting in over four million patient years of experience.

About Bayer
Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to benefit people by supporting efforts to overcome the major challenges presented by a growing and aging global population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2018, the Group employed around 117,000 people and had sales of 39.6 billion euros. Capital expenditures amounted to 2.6 billion euros, R&D expenses to 5.2 billion euros. For more information, go to www.bayer.com.

Contact:
Doreen Schroeder, phone +49 30 468-11399
Email: doreen.schroeder@bayer.com

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Forward-Looking Statements
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