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Investor News

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Aflibercept solution for injection into the eye:

Bayer's Eye Drug Recommended for EU Approval in Fifth Indication

Leverkusen, Germany, September 25, 2015 – The European Committee for Medicinal Products for Human Use (CHMP) has recommended aflibercept solution for injection into the eye for the treatment of visual impairment due to myopic choroidal neovascularization (myopic CNV) for approval in the EU. Myopic CNV is a disease of the retina associated with high degrees of myopia (near-sightedness) and frequently affects people of working age. It is a common cause of blindness in near-sighted subjects worldwide.

"If left untreated, myopic CNV has an extremely poor prognosis resulting in blindness in the affected eye within a few years," said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. "A treatment option that could not only prevent permanent vision loss, but also improve visual acuity would have great benefits for patients with myopic CNV."

The CHMP's positive recommendation is based on the results of the Phase 3 MYRROR study in patients with myopic CNV. Patients receiving aflibercept solution for injection had a mean improvement in best-corrected visual acuity (BCVA) from baseline at week 24 of 12.1 letters, while patients receiving sham injections lost two letters ($p<0.0001$), as measured on the Early Treatment Diabetic Retinopathy Scale (ETDRS) eye chart, a standard instrument used in medical research to measure visual acuity. The efficacy gains seen at week 24 were maintained and even extended further in the aflibercept arm until week 48.

About Myopic Choroidal Neovascularization
Myopic choroidal neovascularization (mCNV) is a disease of the retina in persons who are severely myopic (typically at least minus six diopters) and have pathological changes

in the back of the eye. The disease is characterized by an abnormally elongated eye with a physical stretching of the sclera, choroid and retina, resulting in degenerative and progressive changes. These degenerative changes can induce the development of choroidal neovascularization. Anti-VEGF therapy has already been shown to be effective in the treatment of wet age-related macular degeneration (wet AMD), which is also characterized by an acute growth of new, abnormal blood vessels in the retina.

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 (PlGF) and thereby can inhibit the binding and activation of their cognate VEGF receptors.

Aflibercept solution for injection into the eye has been approved under the brand name EYLEA® for the treatment of patients with wet age-related macular degeneration, for the treatment of visual impairment due to diabetic macular edema, and for the treatment of visual impairment due to macular edema secondary to retinal vein occlusion (branch RVO or central RVO). Over five million doses of EYLEA have been administered worldwide since its launch. EYLEA has already been approved for the treatment of myopic choroidal neovascularization in Japan.

Bayer HealthCare and Regeneron Pharmaceuticals, Inc. are collaborating closely on the global development of EYLEA. Regeneron has exclusive marketing rights for EYLEA in the USA. Bayer HealthCare has licensed the exclusive marketing rights outside the USA, where the companies share equally the profits from sales of EYLEA, except for Japan where Regeneron receives a royalty on net sales.

About Bayer HealthCare
The Bayer Group is a global enterprise with core competencies in the fields of health care and agriculture. Bayer HealthCare, a subgroup of Bayer AG with annual sales of around

EUR 20.0 billion (2014), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 60,700 employees (Dec 31, 2014) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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