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Investor News

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Bayer Receives Approval for EYLEA® for the Treatment of Myopic Choroidal Neovascularization in Japan

Leverkusen, Germany, September 22, 2014 – Bayer HealthCare has received approval from the Ministry of Health, Labour and Welfare (MHLW) in Japan for EYLEA® (aflibercept solution for injection) for the treatment of myopic choroidal neovascularization (myopic CNV). In Japan, pathologic myopia and the associated myopic CNV is the second most common cause of blindness.

“Myopic CNV has a poor prognosis and more treatment options are needed to address the urgent medical need for these patients, many of whom are of working age. This additional approval for EYLEA is great news for patients in Japan suffering from this potentially sight-threatening eye condition,” 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 could also improve visual acuity would have great benefits for patients with pathologic myopia.”

The approval is based on positive data from the Phase 3 MYRROR study in myopic CNV. The topline results, where patients receiving EYLEA had a mean improvement in best-corrected visual acuity (BCVA) from baseline at week 24 of 12.1 letters, compared to a loss of 2 letters in patients receiving sham injections ($p<0.0001$), were announced at the American Academy of Ophthalmology Congress in New Orleans.

EYLEA® has been approved in almost 80 countries for the treatment of patients with neovascular age-related macular degeneration (wet AMD) and around 60 countries for the treatment of visual impairment due to macular edema secondary to central retinal vein occlusion (CRVO). The eye drug is also approved for the treatment of diabetic macular edema (DME) in over 30 countries. Over two million doses of the eye drug have been administered since launch. For the treatment of macular edema secondary to branch

retinal vein occlusion (BRVO), application for marketing authorization have also been submitted in Europe, Japan, and the U.S.

Bayer HealthCare and Regeneron Pharmaceuticals, Inc. are collaborating on the global development of EYLEA. Regeneron maintains exclusive rights to EYLEA in the United States. Bayer HealthCare 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 royalty on net sales.

About Phase 3 MYRROR Program

MYRROR was a double-masked, sham-controlled trial that randomized 122 patients to receive either EYLEA 2 mg or sham. Patients in the active treatment arm received one initial 2 mg dose of EYLEA. Patients were evaluated every 4 weeks and were eligible to receive additional intravitreal injections if the myopic CNV persisted or recurred through week 44. Patients on the sham arm received monthly sham injections through week 20. Starting at week 24, they could receive a single injection of EYLEA 2 mg and were eligible to receive additional treatment in case of CNV persistence or recurrence through week 44. The primary endpoint of the study was the mean change at week 24 from baseline in best-corrected visual acuity (BCVA) as measured on the Early Treatment Diabetic Retinopathy Scale (ETDRS) eye chart, a standard chart used in research to measure visual acuity.

About mCNV

"Myopic choroidal neovascularization" is a disease of the retina where new, abnormal blood vessels grow into the retina in persons who are severely myopic (typically more than 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 treatment has been shown to be effective in wet age related macular degeneration (wet AMD), which is also characterised by an acute growth of new, abnormal blood vessels in the retina.

Severe myopia is particularly common in Asia. Myopic CNV is associated with high degrees of myopia and leads to progressive vision loss. Myopic CNV has a poor prognosis and, if left untreated, can, within approximately 10 years, progress to legal blindness in a majority of patients. In East Asia, the prevalence of myopia is significantly

higher than in West Asia, and appears to have an earlier onset. In Japan, pathologic myopia is the second most common cause of blindness.

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.

EYLEA® 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.

About Bayer HealthCare
The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 18.9 billion (2013), 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 56,000 employees (Dec 31, 2013) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com

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