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Investor News

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Bayer Submits Aflibercept Solution for Intravitreal Injection for the Treatment of Myopic Choroidal Neovascularization in the EU

Leverkusen, Germany, March 11, 2015 – Bayer HealthCare has submitted an application for marketing authorization of aflibercept solution for intravitreal injection for the treatment of myopic choroidal neovascularization (myopic CNV) to the European Medicines Agency (EMA).

“Myopic CNV is a severe eye condition which can affect any age group and if left untreated can progress to legal blindness in a majority of patients,” said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “Treatment options that could not only prevent permanent vision loss but could also improve visual acuity have great benefits for patients with myopic choroidal neovascularization.”

Pathologic myopia and the associated myopic CNV is a common cause of blindness globally in people under the age of 40 associated with severe myopia (short sightedness) and more prevalent in Asian countries than in European countries. 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.

The application is based on positive data from the Phase 3 MYRROR study in 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 2 letters ($p<0.0001$), as measured on the Early Treatment Diabetic Retinopathy Scale (ETDRS) eye chart, a standard chart used in research to measure visual acuity.

Aflibercept solution for intravitreal injection has been approved already under the brand name EYLEA® in Japan for the treatment of myopic CNV in September 2014. In addition, EYLEA has been approved in more than 80 countries for the treatment of patients with neovascular age-related macular degeneration (wet AMD), in around 30 countries for the treatment of visual impairment due to macular edema secondary to retinal vein occlusion (RVO) and over 40 countries for the treatment of visual impairment due to macular edema secondary to central retinal vein occlusion (CRVO). EYLEA is also approved for the treatment of diabetic macular edema (DME) in more than 40 countries. Over three million doses of EYLEA have been administered since launch worldwide. For the treatment of macular edema secondary to branch retinal vein occlusion (BRVO), an application for marketing authorization has been submitted in Japan.

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 multi-center, double-masked, sham-controlled trial that randomized 122 patients to receive either aflibercept solution 2 mg or sham. The trial was designed to assess the safety and efficacy of aflibercept solution, with three quarters of patients receiving an injection of aflibercept solution and one quarter receiving a sham injection. 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. Patients in the active treatment arm received one initial 2 mg dose of aflibercept solution. 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 aflibercept solution 2 mg and were eligible to receive additional treatment in case of CNV persistence or recurrence through week 44.

In the MYRROR study, patients receiving aflibercept solution had a mean improvement in best-corrected visual acuity (BCVA) at week 24 of 12.1 letters from baseline, compared to a loss of 2 letters in patients receiving sham injections ($p<0.0001$).

The efficacy gains seen at week 24 were maintained and even extended further in the EYLEA arm until week 48. Patients received in the first quarter of the study, i.e. from baseline to week 12, a median of 2 injections. In each of the following three quarters, the median of injections was 0.

About Myopic Choroidal Neovascularization (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 incite the development of choroidal neovascularization. Anti-VEGF treatment has been shown to be effective in wet age related macular degeneration, which is also characterized by an acute growth of new, abnormal blood vessels in the retina.

About VEGF and Aflibercept Solution for Intravitreal Injection
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 intravitreal 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.

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 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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