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Investor News

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VEGF Trap-Eye in myopic choroidal neovascularization:

Positive Phase 3 Results for VEGF Trap-Eye (Intravitreal Aflibercept) in Myopic Choroidal Neovascularization (mCNV)

Leverkusen, Germany, June 6, 2013 – Bayer HealthCare announced today positive top-line results for VEGF Trap-Eye (aflibercept ophthalmic solution) from the Phase 3 MYRROR study in myopic choroidal neovascularization (mCNV). In this trial, patients receiving VEGF Trap-Eye at a dose of 2 milligrams (mg) 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 ($p<0.0001$). VEGF Trap-Eye treatment was started with a single injection; additional injections were given only in case of newly occurring or persisting mCNV.

“Effective treatment options are urgently needed for patients with myopic choroidal neovascularization (mCNV),” said Kemal Malik, MD, member of the Bayer HealthCare Executive Committee and Head of Global Development. “We are pleased that the results of this study demonstrate that VEGF Trap-Eye provides a treatment option for these patients.”

Data from this study will be presented at an upcoming medical conference. Bayer HealthCare expects to submit the first application for regulatory approval for this indication in Asia in the second half of 2013.

VEGF Trap-Eye was generally well tolerated. The most common adverse events observed in the MYRROR trial that occurred with a frequency of 2% or more were conjunctival hemorrhage, dry eye, eye pain, headache and nasopharyngitis.

VEGF Trap-Eye was approved under the brand name EYLEA® in the United States for the treatment of neovascular (wet) Age-related Macular Degeneration (AMD) in November 2011 and for Macular Edema following Central Retinal Vein Occlusion (CRVO) in September 2012. Outside of the U.S. EYLEA has been approved for use in wet AMD in Japan, Australia, Europe, and several other countries.

Bayer HealthCare and Regeneron 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 will share equally the profits from any future sales of EYLEA, except for Japan where Regeneron will receive 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 VEGF Trap-Eye 2 mg or sham. Patients in the active treatment arm received one initial 2 mg dose of VEGF Trap-Eye. Patients were evaluated every 4 weeks and were eligible to receive additional VEGF Trap-Eye 2 mg intravitreal injections on an as-needed (PRN) basis, determined by visual and anatomic criteria, through 20 weeks. Patients on the sham arm received monthly sham injections through week 20. Starting at week 24, patients in both arms were eligible to receive VEGF Trap-Eye 2 mg on a PRN basis 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 an acute 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 (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 Trap-Eye (aflibercept solution for injection)

VEGF Trap-Eye 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. VEGF Trap-Eye acts as a soluble decoy receptor that binds VEGF-A and placental growth factor (PlGF) and thereby can inhibit the binding and activation of these cognate VEGF receptors. VEGF Trap-Eye is specially purified form of aflibercept and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

About Regeneron Pharmaceuticals

Regeneron is a leading science-based biopharmaceutical company based in Tarrytown, New York that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets medicines for eye diseases, colorectal cancer, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, oncology, rheumatoid arthritis, allergic asthma, and atopic dermatitis. For additional information about the company, please visit www.regeneron.com.

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 18.6 billion (2012), 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 55,300 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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