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Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

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Myopic Choroidal Neovascularization:

Bayer Submits VEGF Trap-Eye (aflibercept solution for injection) for the Treatment of Myopic Choroidal Neovascularization in Japan

Leverkusen, Germany, November 28, 2013 – Bayer HealthCare has submitted VEGF Trap-Eye (aflibercept solution for injection) for the treatment of myopic choroidal neovascularization (myopic CNV) for regulatory approval in Japan. In Japan, pathologic myopia and the associated myopic CNV is one of the most common causes of blindness.

“Pathologic myopia, which develops various lesions affecting the back of the eye such as myopic CNV, impacts a significant number of patients in Japan,” said Professor Tatsuro Ishibashi, M.D., Department of Ophthalmology, Faculty of Medicine, Kyushu University and Coordinating Investigator of the Phase 3 MYRROR study. “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.”

“Unfortunately, mCNV has a poor prognosis and there are more treatment options needed to address this urgent medical need for these patients, many of whom are of working age,” said Kemal Malik, M.D., Member of the Bayer HealthCare Executive Committee and Head of Global Development. “We hope to be able to bring VEGF Trap-Eye to patients and the ophthalmology community in Japan soon to improve the prognosis of this vision-threatening condition.”

The regulatory submission is based on positive data from the Phase 3 MYRROR study in mCNV. The topline results were announced earlier this year with more detailed data presented at the recent American Academy of Ophthalmology Congress in New Orleans.

VEGF Trap-Eye has been approved under the brand name EYLEA® in Europe, the United States, Japan, Australia, and in many other countries for the treatment of patients with neovascular age-related macular degeneration (wet AMD). EYLEA has also been approved in Europe for the treatment of visual impairment due to macular edema secondary to CRVO as well as in the U.S., Japan and in several countries in Asia and Latin America for the treatment of macular edema following CRVO.

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 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 (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 VEGF Trap-Eye (aflibercept solution for 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. However, in certain diseases, it is associated with the growth of abnormal new blood vessels in the

eye, which exhibit abnormal increased permeability that leads to edema in certain diseases of the retina.

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. EYLEA 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.

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 54,900 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

Bayer AG, Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Jürgen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Fabian Klingen (+49-214-30-35426)
Judith Nestmann (+49-214-30-66836)
Constance Spitzer (+49-214-30-33021)
Dr. Olaf Weber (+49-214-30-33567)

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