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Investor News

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Bayer Receives Approval for EYLEA® in Diabetic Macular Edema in Japan

Leverkusen, Germany, November 18, 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 patients with diabetic macular edema (DME).

“Clinically significant DME is a leading cause of vision loss in the working age population suffering from diabetes. In Japan, the retirement age tends to be rising due to declining birthrates and aging population. The loss of even a single line of letters on ETDRS eye chart may impact a patient’s ability to work, and could mean they leave the workforce early.” said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “The approval of EYLEA in Japan in this important indication is great news for the increasing number of patients suffering from DME.”

The approval of EYLEA for DME in Japan is based on positive data from the VIVID-DME and VISTA-DME studies and one open label single arm safety trial in Japanese patients (VIVID-Japan). In the Phase III VIVID-DME and VISTA-DME trials, aflibercept solution for injection 2 milligrams (mg) dosed monthly and aflibercept solution for injection 2 mg dosed every two months (after 5 initial monthly injections), achieved the primary endpoint of significantly greater improvements in best-corrected visual acuity (BCVA) from baseline compared to laser photocoagulation at 52 weeks. Further, patients treated with aflibercept solution for injection every two months on average gained more than two lines of vision at one year vs laser, as measured on the Early Treatment Diabetic Retinopathy Scale (ETDRS) eye chart, a standard chart used in research to measure visual acuity.

EYLEA® has been approved in more than 80 countries for the treatment of patients with neovascular age-related macular degeneration and more than 60 countries for the treatment of visual impairment due to macular edema secondary to central retinal vein

occlusion. EYLEA is also approved for the treatment of DME in over 30 countries. In Japan, EYLEA has been additionally approved for the treatment of myopic choroidal neovascularization. Applications for marketing authorization have also been submitted in Europe and Japan based on the data from Phase III in patients with branch retinal vein occlusion. Over two million doses of EYLEA have been administered since launch worldwide.

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 has licensed the exclusive marketing rights outside the United States, where the companies share equally the profits from sales of EYLEA. In Japan Regeneron receives a percentage of net sales.

About Diabetic Macular Edema (DME)
Diabetic macular edema (DME) and diabetic retinopathy (DR) are common microvascular complications in people with diabetes. Diabetic retinopathy is a disease affecting the blood vessels of the retina. DME occurs when fluid leaks into the center of the macula, the light-sensitive part of the retina responsible for sharp, direct vision. Fluid in the macula can cause severe vision loss or blindness.

Visual impairment due to DME is estimated to affect around 3% of people with diabetes around the world and is therefore the most frequent cause of blindness in young and mid-aged adults in most developed countries. As the incidence of diabetes has been steadily climbing, it is projected that the number of people impacted by DME will also grow.

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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