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Investor News

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Bayer Receives EU Approval for EYLEA® in Diabetic Macular Edema

Leverkusen, Germany, August 11, 2014 – Bayer HealthCare announced today that EYLEA® (aflibercept solution for injection into the eye) has been approved by the European Commission for the treatment of visual impairment due to diabetic macular edema (DME). Bayer plans for an immediate roll-out with Germany being one of the first launch countries in Europe.

“The approval of EYLEA in Europe in this important indication is great news for the increasing number of patients suffering from visual impairment due to DME,” said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “This is an important step that further demonstrates our commitment in ophthalmology to bring new treatment options to patients suffering from serious ophthalmologic conditions.”

“The results of two phase 3 studies were very encouraging with the majority of patients with visual impairment due to diabetic macular edema experiencing a significant two-line improvement in visual acuity with aflibercept solution for injection,” said Prof. Jean-Francois Korobelnik, Principal Investigator of the VIVID-DME trial and Chief of Ophthalmology, CHU Bordeaux. “Early diagnosis of DME is critical, and if not treated rigorously, there is a high risk of DME leading to blindness.”

EYLEA has been approved in many countries for the treatment of neovascular age-related macular degeneration (wet AMD) and for the treatment of visual impairment due to macular edema secondary to central retinal vein occlusion (CRVO). Regulatory submissions have been made in Asia Pacific including Japan and Latin America for the treatment of DME. In Japan, EYLEA has been additionally submitted for approval to regulators for the treatment of choroidal neovascularization secondary to pathologic myopia (mCNV). Furthermore a regulatory submission has been made in Europe and the

U.S. for EYLEA for the treatment of visual impairment due to macular edema following branch retinal vein occlusion.

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, except for Japan where 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 3-4% of people with diabetes 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 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 commercializes 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, 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 18.9 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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