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Investor News

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Treatment of visual impairment due to macular edema secondary to retinal vein occlusion (branch RVO or central RVO):

Bayer Receives EU Approval for EYLEA for the Treatment of Retinal Vein Occlusion

Leverkusen, Germany, February 26, 2015 – Bayer HealthCare announced today that EYLEA® (aflibercept solution for injection into the eye) has been approved by the European Commission for the treatment of patients with visual impairment due to macular edema secondary to retinal vein occlusion (RVO). This new indication includes macular edema following branch retinal vein occlusion (BRVO) in addition to the previously-approved indication of macular edema secondary to central retinal vein occlusion in adults (CRVO). The recommended treatment approach is to initiate therapy with one injection per month until maximum visual acuity is achieved and/or there are no signs of disease activity. Treatment may then be continued with a “treat and extend” regimen with gradually increased treatment intervals to maintain stable visual and/or anatomic outcomes.

“RVO is a chronic disease that requires early and ongoing management to obtain the best possible vision, which is critical as many patients are still of working-age,” said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “This new therapeutic approach allows physicians to individualize therapy for each patient, maximizing time between treatments. This reduces the treatment burden on patients, physicians and their clinics.”

The approval is based on positive results from the double-masked, randomized, active-controlled phase 3 VIBRANT study in patients with visual impairment due to macular edema secondary to BRVO. The primary endpoint was the proportion of subjects who gained at least 15 letters in best corrected visual acuity (BCVA) from baseline at week 24, as measured on the Early Treatment Diabetic Retinopathy Scale (ETDRS) eye chart, a

standard chart used in research to measure visual acuity. More than half of the patients who were treated with aflibercept solution for injection gained at least three lines of vision.

About Retinal Vein Occlusion

Retinal vein occlusion (RVO) includes branch retinal vein occlusion (BRVO) and central retinal vein occlusion (CRVO). RVO is a chronic eye condition that can lead to sudden vision loss and is second only to diabetic retinopathy as the most frequent cause of visual loss from diseases affecting the blood vessels of the retina. While each patient experiences RVO differently, all patients are at risk for vision loss which can impact their ability to participate in everyday activities and may cause significant financial burden to patients, their families as well as broader society. RVO has a significant global impact with an estimated 16.4 million people affected worldwide, including around 13.9 million with BRVO and 2.5 million with CRVO.

RVO is the result of a blockage in a blood vessel of the retina, the light sensitive part of the eye. In CRVO, the blockage occurs in the main retinal vein at the optic nerve. In BRVO, the blockage occurs in one of the branch retinal veins. If a blockage in any of the retinal veins (central or branch) is not resolved, it can result in a number of complications. The most common reason for vision impairment in patients with RVO is macular edema, swelling of the macula, which is the central portion of the retina responsible for seeing fine details.

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.

Aflibercept solution for 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 receptors.

Aflibercept solution for injection into the eye has been approved under the brand name EYLEA® in more than 80 countries for the treatment of patients with neovascular age-

related macular degeneration (wet AMD) and around 40 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 diabetic macular edema (DME) in over 40 countries. Over three million doses of EYLEA have been administered since launch worldwide. In Japan, EYLEA has been additionally approved for the treatment of myopic choroidal neovascularization and an application for marketing authorization has also been submitted for the treatment of macular edema secondary to BRVO. In the U.S., EYLEA is already approved for the treatment of RVO.

Bayer HealthCare and Regeneron Pharmaceuticals, Inc. are collaborating on the global development of EYLEA. Regeneron maintains exclusive rights to EYLEA in the U.S. Bayer HealthCare licensed the exclusive marketing rights outside the U.S., where the companies share equally the profits from sales of EYLEA, except for Japan where Regeneron receives a percentage of net sales.

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 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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