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# Investor News

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## EYLEA® (aflibercept) Injection Approved for the Treatment of Wet Age-Related Macular Degeneration in Japan

**Leverkusen, Germany, September 28, 2012** – Bayer HealthCare has received approval from the Ministry of Health, Labour and Welfare (MHLW) in Japan for EYLEA® (aflibercept) Injection for the treatment of patients with neovascular (wet) age-related macular degeneration (wet AMD) at a recommended dose of 2 milligram (mg) intravitreal injection per month for three consecutive months (treatment initiation). Thereafter, in the maintenance phase, the recommended treatment is usually one intravitreal injection every two months. The dosing interval may be adjusted according to patient response.

“The approval of EYLEA in Japan for the treatment of wet AMD is great news for increasing numbers of patients in Japan suffering from this potentially sight threatening eye condition,” said Kemal Malik, M.D., Member of the Bayer HealthCare Executive Committee and Head of Global Development. “We are looking forward to providing this new treatment which allows dosing every other month following three initial monthly doses.”

The MHLW approval is based upon the results of two Phase III clinical studies (VIEW 1 and VIEW 2), which demonstrated that EYLEA dosed every other month, following three initial monthly doses, was non-inferior to Lucentis® (ranibizumab injection) dosed every four weeks, as measured by the primary endpoint of the proportion of patients who maintained visual acuity (less than 15 letters of vision lost on an eye chart) over 52 weeks. The most common adverse reactions (frequency of 5.0% or more) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, vitreous detachment, cataract, vitreous floaters, and increased intraocular pressure.

Beyond the wet AMD indication, Phase III trials are currently underway with VEGF Trap-Eye in the treatment of diabetic macular edema (DME) and myopic choroidal neovascularization (mCNV). Myopia is one of the most common eye conditions and is

highly prevalent in Asian countries such as Singapore and Japan, where around 40% of adults have myopia and nearly 10% of these have high myopia.

EYLEA was already approved in the United States in Macular Edema following Central Retinal Vein Occlusion (CRVO) and in wet AMD. Bayer received approval in Australia earlier this year for the treatment of wet AMD and received the recommendation for approval of VEGF Trap-Eye by the European Committee for Medicinal Products for Human Use (CHMP). Bayer plans to submit for marketing authorization in CRVO in Europe at the end of 2012.

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 EYLEA® (aflibercept) Injection for Intravitreal Injection**
EYLEA, also known as 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 Wet AMD**
Age-related macular degeneration (AMD) is a leading cause of acquired blindness. Macular degeneration is diagnosed as either dry (non-exudative) or wet (exudative). In wet AMD, new blood vessels grow beneath the retina and leak blood and fluid. This leakage causes disruption and dysfunction of the retina creating blind spots in central vision, and it can account for blindness in wet AMD patients. Wet AMD is the leading cause of blindness for people over the age of 65 in the U.S. and Europe. In Japan, AMD is the fourth most common cause of acquired blindness and the number of patients is increasing. Research conducted in 2007 targeting residents in Hisayama, Fukuoka, shows that 1.2% of residents over the age of 50 had wet AMD in at least one eye. Extrapolating from this study, the number of patients in Japan estimated to have wet AMD eligible for treatment with anti-VEGF therapy is approximately 700,000.

**About Regeneron Pharmaceuticals**

Regeneron is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets three products in the United States, EYLEA® (aflibercept) Injection, ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion, and ARCALYST® (rilonacept) Injection for Subcutaneous Use; ZALTRAP is co-commercialized with Sanofi. Phase 3 studies are in progress with EYLEA in two additional indications and with product candidates sarilumab and REGN727. Regeneron has active research and development programs in many disease areas, including ophthalmology, inflammation, cancer, and hypercholesterolemia. Additional information and recent news releases are available on the Regeneron web site at 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 17.2 billion (2011), 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 55,700 employees (Dec 31, 2011) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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