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Investor News

Not intended for U.S. and UK media

Bayer receives approval for EYLEA® in Europe for the Treatment of Wet Age-Related Macular Degeneration

New treatment allows dosing every other month following three initial monthly injections in wet AMD patients

Leverkusen, Germany, November 27, 2012 – Bayer HealthCare announced today that EYLEA® (aflibercept solution for injection), also known in the scientific literature as VEGF Trap-Eye, has been approved by the European Commission for the treatment of patients with neovascular (wet) age-related macular degeneration (wet AMD) at a recommended dose of 2 milligrams (mg). EYLEA treatment is initiated with one injection per month for three consecutive doses, followed by one injection every two months. There is no requirement for monitoring between injections. After the first 12 months of treatment with EYLEA, the treatment interval may be extended based on visual and anatomic outcomes. In this case the schedule for monitoring should be determined by the treating physician and may be more frequent than the schedule of injections.

“The approval of EYLEA in Europe is great news for the increasing number of patients suffering from wet AMD, a sight threatening eye condition,” said Dr Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “Furthermore we are very pleased to announce already that we will launch EYLEA in one of our biggest markets – Japan – very soon. We are looking forward to providing this new treatment which allows dosing every other month following three initial monthly injections in wet AMD patients in Europe very soon as well.”

Beyond wet AMD, Phase III trials with VEGF Trap-Eye have been completed for the treatment of Macular Edema following central retinal vein occlusion (CRVO) and are currently under way in the treatment of diabetic macular edema (DME) and myopic choroidal neovascularization (mCNV). Bayer plans to submit VEGF Trap-Eye for marketing authorization in Macular Edema following CRVO in Europe by the end of 2012.

EYLEA is already approved in the United States in wet AMD and in Macular Edema following CRVO. Bayer has already received approval for EYLEA for the treatment of wet AMD in several markets, including Japan, Australia, and some countries in Latin America earlier this year. Submissions have been filed in this indication for marketing authorization in additional countries worldwide.

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 solution for injection)
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. EYLEA, also known in the scientific literature as VEGF Trap-Eye, 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. EYLEA is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

About Wet AMD
Age-related macular degeneration (AMD) is a leading cause of acquired blindness, if left untreated. 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.

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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