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Investor News

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Bayer Submits VEGF Trap-Eye (aflibercept) for Treatment of Macular Edema Following Central Retinal Vein Occlusion in Japan

Leverkusen, January 7, 2013 – Bayer HealthCare today announced that Bayer Yakuhin, Ltd., Osaka, Japan, has submitted an application for marketing authorization for VEGF Trap-Eye (aflibercept solution for injection) for the treatment of macular edema following Central Retinal Vein Occlusion (CRVO) to the Ministry of Health, Labour and Welfare (MHLW) in Japan.

The submission of VEGF Trap-Eye for macular edema following CRVO is based on data from the Phase III COPERNICUS and GALILEO studies. In both studies, the primary efficacy endpoint was the proportion of patients who gained at least 15 letters – measured on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart – of Best Corrected Visual Acuity (BCVA) at 24 weeks compared to baseline on the ETDRS visual acuity charts. The VEGF Trap-Eye 2 milligrams monthly group was significantly superior to the sham control group for the primary endpoint. The effects were largely maintained in the follow-up phase until week 52.

The 52-week results of the GALILEO and COPERNICUS studies demonstrated a favorable safety profile for VEGF Trap-Eye.

VEGF Trap-Eye was approved under the brand name EYLEA® in the United States for the treatment of wet AMD in November 2011 and for macular edema following CRVO in September 2012. In Japan EYLEA was approved for use in wet AMD in September 2012. EYLEA has also been approved in Europe, Australia, and in several other countries for use in wet AMD last year.

Phase III trials are currently under way with VEGF Trap-Eye in the treatment of diabetic macular edema (DME) and myopic choroidal neovascularization (mCNV).

Bayer HealthCare and Regeneron are collaborating on the global development of VEGF Trap-Eye. Regeneron maintains exclusive rights to VEGF Trap-Eye 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 VEGF Trap-Eye, except for Japan where Regeneron will receive a royalty on net sales.

About Central Retinal Vein Occlusion (CRVO)

Over 100,000 people in the United States and more than 66,000 people in major European countries are estimated to suffer from CRVO. CRVO is caused by obstruction of the central retinal vein that leads to a back up of blood and fluid in the retina. The fluid can result in retinal injury and loss of vision. VEGF levels are elevated in response to this retinal injury contributing to macular edema. It is believed that anti-VEGF treatment may help decrease vascular permeability and edema.

About VEGF Trap-Eye (aflibercept solution for injection)

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. 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 these cognate VEGF receptors. VEGF Trap-Eye is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

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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