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Investor News

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Bayer and Regeneron Initiate Phase III Trial of VEGF Trap-Eye (Aflibercept) for the Treatment of Diabetic Macular Edema in Asia and Russia

Leverkusen, Germany, February 19, 2013 – Bayer HealthCare and Regeneron Pharmaceuticals, Inc. today announced that they have initiated a new Phase III trial to evaluate the efficacy and safety of VEGF Trap-Eye (aflibercept ophthalmic solution) in the treatment of Diabetic Macular Edema (DME) in Russia, China, and other Asian countries. The companies are extending their global development program for VEGF Trap-Eye in DME after promising results in the global Phase II DME program.

“DME is a leading cause of vision loss in adults under the age of 50 suffering from diabetes and represents a significant unmet medical need, especially in China, where currently the only therapy for DME is macular laser photocoagulation,” said Kemal Malik, M.D., Member of the Bayer HealthCare Executive Committee and Head of Global Development. “With this new trial, we look forward to potentially bringing another treatment option to patients with DME in Asia and Russia.”

A further Phase III trial is currently underway with VEGF Trap-Eye in the treatment of myopic choroidal neovascularization (mCNV).

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 Central Retinal Vein Occlusion (CRVO) in September 2012. In Japan EYLEA was approved for the use in wet AMD in September 2012. EYLEA has also been approved in Europe, Australia, and in several other countries for the treatment of wet AMD last year.

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 the Phase III DME Program VIVID EAST

The VIVID EAST-DME study (**V**EGF Trap-Eye **I**n **V**ision **I**mpairment **D**ue to **DME**) has three treatment arms. In the first arm, patients will be treated every month with 2 milligrams (mg) of VEGF Trap-Eye. In the second arm, patients will be treated with 2 mg of VEGF Trap-Eye every two months after an initial phase of five monthly injections. In the third arm, the comparator arm, patients will be treated with macular laser photocoagulation. The primary endpoint is the mean change in visual acuity from baseline to week 52 as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart, a standard chart used in clinical research to measure visual acuity. All patients will be followed for a maximum of one year.

The first Phase III trial of VEGF Trap-Eye in DME, named VIVID-DME, is being conducted in Europe and Japan by Bayer HealthCare and is already fully enrolled. A second study led by Regeneron, named VISTA-DME is being conducted in the United States and is fully enrolled as well.

About Diabetic Macular Edema (DME)

DME is the most prevalent cause of moderate vision loss in patients with diabetes. DME is a common complication of Diabetic Retinopathy (DR), a disease affecting the blood vessels of the retina. Clinically significant DME is a leading cause of blindness in younger adults (under 50). Clinically significant 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.

DME is the most frequent cause of blindness in young and mid-aged adults. The treatable population for DME globally is estimated about 6.2 million. According to the American Diabetes Association, over 18 million Americans currently suffer from diabetes, and many more are at risk for developing diabetes. The incidence of diabetes is steadily climbing and it is projected that up to seven percent of all patients with diabetes will develop DME during their lifetime.

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 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 markets 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, rheumatoid arthritis, and asthma. 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 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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