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Investor News

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VEGF Trap-Eye (aflibercept solution for injection) Met Primary Endpoint in Two Phase 3 Trials for the Treatment of Diabetic Macular Edema

Leverkusen, Germany, August 6, 2013 – Bayer HealthCare and Regeneron Pharmaceuticals, Inc. today announced that in the Phase 3 VIVID-DME and VISTA-DME trials of VEGF Trap-Eye (aflibercept solution for injection) for the treatment of diabetic macular edema (DME), VEGF Trap-Eye 2 milligrams (mg) dosed monthly and VEGF Trap-Eye 2 mg dosed every two months (after 5 initial monthly injections), achieved the primary endpoint of significantly greater improvements in best-corrected visual acuity (BCVA) from baseline compared to laser photocoagulation at 52 weeks. Both VEGF Trap-Eye treatment arms demonstrated similar improvements in BCVA.

“DME is a leading cause of vision loss in adults under the age of 50 suffering from diabetes,” said Kemal Malik, M.D., Member of the Bayer HealthCare Executive Committee and Head of Global Development. “We look forward to being able to offer medical benefit to patients with this new treatment option for DME.”

The VIVID-DME and VISTA-DME trials are similarly designed, randomized, double-masked, active control trials to evaluate the safety and efficacy of VEGF Trap-Eye in patients with DME. Patients in both trials were randomized to receive either VEGF Trap-Eye 2 mg monthly, VEGF Trap-Eye 2 mg every two months (after 5 initial monthly injections), or the comparator treatment of laser photocoagulation.

In the VIVID-DME trial, after one year patients receiving VEGF Trap-Eye 2 mg monthly had a mean change from baseline in best-corrected visual acuity (BCVA) of 10.5 letters ($p<0.0001$ compared to laser), patients receiving VEGF Trap-Eye 2 mg every other month (after 5 initial monthly injections) had a mean change from baseline in BCVA of 10.7

letters (p<0.0001 compared to laser), compared to patients receiving laser photocoagulation who had a mean change from baseline in BCVA of 1.2 letters.

In the VISTA-DME trial, after one year patients receiving VEGF Trap-Eye 2 mg monthly had a mean change from baseline in best-corrected visual acuity (BCVA) of 12.5 letters (p<0.0001 compared to laser), patients receiving VEGF Trap-Eye 2 mg every other month (after 5 initial monthly injections) had a mean change from baseline in BCVA of 10.7 letters (p<0.0001 compared to laser), compared to patients receiving laser photocoagulation who had a mean change from baseline in BCVA of 0.2 letters.

In these trials, VEGF Trap-Eye was generally well tolerated with a similar overall incidence of adverse events (AEs), ocular serious AEs, and non-ocular serious AEs across the treatment groups and the laser control group. Arterial thromboembolic events as defined by the Anti-Platelet Trialists' Collaboration (non-fatal stroke, non-fatal myocardial infarction, and vascular death) also occurred at similar rates across the treatment groups and the laser control group. AEs were typical of those seen in other studies in patients with diabetes receiving intravitreal anti-VEGF therapy. The most frequent ocular treatment emergent AEs (TEAEs) observed in the VIVID-DME and VISTA-DME trials included conjunctival hemorrhage, eye pain, and vitreous floaters. The most frequent non-ocular TEAEs included hypertension and nasopharyngitis, which occurred with similar frequency in the treatment groups and the laser control group.

Full one-year data from the VIVID-DME and VISTA-DME trials will be presented at upcoming medical conferences. Bayer HealthCare plans to submit an application for marketing approval for the treatment of DME in Europe in 2013. Based on discussions with the U.S. Food and Drug Administration (FDA), Regeneron now expects to submit an application for U.S. marketing approval for the treatment of DME in 2013, approximately one year ahead of the previously announced timeline. Both trials are planned to continue up to 148 weeks.

VEGF Trap-Eye was approved under the brand name EYLEA® in the United States for the treatment of neovascular (wet) Age-related Macular Degeneration (AMD) in November 2011 and for Macular Edema following Central Retinal Vein Occlusion (CRVO) in September 2012. EYLEA has also been approved in Europe, Japan, Australia, and in several other countries for use in wet AMD and was recommended for approval by the European Committee for Medicinal Products for Human Use (CHMP) for the treatment of

visual impairment due to Macular Edema Secondary to Central Retinal Vein Occlusion (CRVO) in July 2013.

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 share equally the profits from sales of EYLEA, except for Japan where Regeneron receives a royalty on net sales.

About the Phase 3 DME Program

The Phase 3 DME program consists of three double-masked trials: VIVID-DME, VISTA-DME, and VIVID-EAST-DME, and one open label single arm safety trial in Japanese patients (VIVID-Japan). All three double masked studies have three treatment arms, where patients are randomized to receive either VEGF Trap-Eye 2 mg monthly, VEGF Trap-Eye 2 mg every two months (after 5 initial monthly injections), or the comparator treatment of laser photocoagulation. The primary endpoint of all three studies is the mean change in best-corrected visual acuity from baseline, as measured on the Early Treatment Diabetic Retinopathy Scale (ETDRS) eye chart, a standard chart used in research to measure visual acuity. The VIVID-DME, VISTA-DME, VIVID-EAST-DME, and VIVID-Japan studies are ongoing.

About Diabetic Macular Edema (DME)

DME is a common complication of Diabetic Retinopathy (DR), a disease affecting the blood vessels of the retina. 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 at about 6.2 million people. 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 and VEGF Trap-Eye (aflibercept solution for injection)
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. Scarring and loss of fine-resolution central vision often results.

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 their cognate VEGF receptors.

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, oncology, rheumatoid arthritis, allergic asthma, and atopic dermatitis. 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 18.6 billion (2012), 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 55,300 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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Bayer Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

Regeneron Forward-Looking Statements
This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's products, product candidates, and research and clinical programs now underway or planned; including without limitation EYLEA®(aflibercept) Injection for DME; unforeseen safety issues resulting from the administration of products and product candidates in patients; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, to be cancelled or terminated without any further product success; and risks associated with third party intellectual property and pending or future litigation relating thereto. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission, including its Form 10-K for the year ended December 31, 2012 and Form 10-Q for the quarter ended June 30, 2013. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise, unless required by law.