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Investor News

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Two-Year Results From Phase III Trial of VEGF Trap-Eye (aflibercept solution for injection) for the Treatment of Diabetic Macular Edema Show Sustained Improvement in Vision

Leverkusen, Germany, February 10, 2014 – Bayer HealthCare and Regeneron Pharmaceuticals, Inc. today announced positive two-year results from the Phase III VISTA-DME trial with VEGF Trap-Eye (aflibercept solution for injection) for the treatment of diabetic macular edema (DME). The results demonstrated a sustained improvement with VEGF Trap-Eye in best-corrected visual acuity (BCVA) in two different dosing regimens, compared to laser photocoagulation.

Patients in the VISTA-DME trial were randomized to receive either VEGF Trap-Eye 2 milligrams (mg) monthly (n=155), VEGF Trap-Eye 2 mg every two months (after 5 initial monthly injections) (n=152), or the comparator treatment of laser photocoagulation (n=154).

“DME is a leading cause of vision loss in adults under the age of 50,” said Dr. Jörg Möller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “The two-year data confirm the safety and efficacy of VEGF Trap-Eye in treating DME, and we look forward to hopefully offer this new treatment option for DME-patients soon.”

Trial results show that after 100 weeks, patients receiving VEGF Trap-Eye 2 mg dosed monthly had a mean change from baseline in BCVA of 11.5 letters (12.5 letters at 52 weeks). Patients receiving VEGF Trap-Eye 2 mg dosed every two months (after 5 initial monthly injections) had a mean change from baseline in BCVA of 11.1 letters (10.7 letters at 52 weeks). Patients in the laser photocoagulation treatment group had a mean change from baseline in BCVA of 0.9 letters (0.2 letters at 52 weeks).

In the VISTA-DME trial, 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 VEGF Trap-Eye 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 AEs observed in the VISTA-DME trials included conjunctival hemorrhage, eye pain, and vitreous floaters. The most frequent non-ocular AEs included hypertension, anemia, and urinary tract infection. Arterial thromboembolic events as defined by the Anti-Platelet Trialists' Collaboration (non-fatal stroke, non-fatal myocardial infarction, and vascular death) were similar across the treatment groups and the laser control group with events occurring in 13 out of 155 patients in the group dosed with VEGF Trap-Eye 2 mg monthly, 11 out of 152 patients in the group dosed with VEGF Trap-Eye 2 mg every 2 months (after 5 initial monthly injections), and 9 events out of 154 patients in the laser group. Eight out of 155 patients died in the group dosed with VEGF Trap-Eye 2 mg monthly, four out of 152 patients in the group dosed with VEGF Trap-Eye 2 mg every 2 months (after 5 initial monthly injections), and three out of 154 patients in the laser treatment group.

The 52-week results (primary analyses) from this study have been previously reported. Full two-year data from the VISTA-DME trial will be presented at upcoming medical conferences. Two-year results for the similarly designed VIVID-DME trial will become available later in 2014. Both the VISTA-DME and VIVID-DME trials will continue as planned up to 148 weeks.

VEGF Trap-Eye (aflibercept solution for injection) has been approved under the brand name EYLEA® in Europe, the United States, Japan, Australia, and in many other countries for the treatment of patients with neovascular age-related macular degeneration (wet AMD). EYLEA has also been approved in Europe for the treatment of visual impairment due to macular edema secondary to CRVO as well as in the U.S., Japan and in selected countries in Asia and Latin America for the treatment of macular edema following CRVO. Regulatory submissions have also been made in the U.S., the EU, and other countries, for EYLEA for the treatment of Diabetic Macular Edema, and in Japan for the treatment of choroidal neovascularization secondary to pathologic myopia (mCNV).

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 percentage on net sales.

About the Phase III DME Program

The global Phase III 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. Based on protocol specified criteria, patients were eligible to receive rescue treatment from week 24 onwards. Rescue treatment in the VEGF Trap-Eye groups was adjunct laser treatment, and in the laser control group, it was VEGF Trap-Eye 2mg. 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, and VIVID-EAST-DME 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.

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.

VEGF Trap-Eye (aflibercept solution for injection) 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 54,900 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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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. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. 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; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products, such as the application of EYLEA® (aflibercept) Injection in the treatment of Diabetic Macular Edema and choroidal neovascularization secondary to pathologic myopia; ongoing regulatory obligations and oversight impacting Regeneron's research and clinical programs and business; including those relating to patient privacy; 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 and commercial success 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 its Form 10-Q for the quarterly period ended September 30, 2013. The reader is cautioned not to rely on any forward-looking statements made by Regeneron. 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.