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Investor News

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Bayer Submits VEGF Trap-Eye (aflibercept solution for injection) for Treatment of Diabetic Macular Edema in the EU

Leverkusen, Germany, November 7, 2013 – Bayer HealthCare has submitted an application for marketing authorization of VEGF Trap-Eye (aflibercept solution for injection) for the treatment of patients with diabetic macular edema (DME) to the European Medicines Agency (EMA). Regeneron has submitted a supplemental BLA ('Biologics License Application') for VEGF Trap-Eye in this indication to the Food and Drug Administration (FDA).

VEGF Trap-Eye 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. and in selected countries in Asia and Latin America for the treatment of macular edema following CRVO.

"The number of patients suffering from diabetes on a worldwide basis continues to increase, and with it the need for new treatment options. DME affects many patients, including those under the age of 50. Whatever a person`s age, vision impairment impacts everyday tasks and has a detrimental effect on quality of life", said Kemal Malik, M.D., Member of the Bayer HealthCare Executive Committee and Head of Global Development. "With this filing, Bayer and Regeneron hope to make a significant contribution towards alleviating the impact of this disease in the future."

The submission of EYLEA for DME is based on data from the positive Phase 3 VISTA-DME and VIVID-DME studies. One-year data from the VIVID-DME and VISTA-DME trials

were already presented at medical congresses in the U.S. and Europe. Both trials are planned to continue up to 148 weeks.

Bayer HealthCare and Regeneron Pharmaceuticals, Inc. 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 these 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. 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.

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 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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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.