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Investor News

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Treatment of visual impairment due to macular edema secondary to branch retinal vein occlusion (BRVO):

Bayer Submits Aflibercept Solution for Injection Into the Eye for Fourth Indication in EU

Leverkusen, Germany, June 11, 2014 – Bayer HealthCare has applied for marketing authorization of aflibercept solution for injection for the treatment of patients with visual impairment due to macular edema secondary to branch retinal vein occlusion (BRVO) to the European Medicines Agency (EMA). Aflibercept solution for injection into the eye has already been approved under the brand name EYLEA® for the treatment of patients with neovascular age-related macular degeneration (wet AMD) and the treatment of visual impairment due to macular edema secondary to central retinal vein occlusion (CRVO). Bayer has already filed for marketing authorization for the treatment of diabetic macular edema (DME).

“BRVO is a common retinal vascular disorder with an estimated 14 million people affected worldwide, and it is a severe disease which is potentially blinding if not treated early and appropriately,” said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “The submission is an important milestone as it marks the fourth regulatory submission in the EU for aflibercept solution for injection into the eye in the past few years. Bayer is committed to improving outcomes for the millions of patients suffering from a broad range of vision-threatening retinal diseases.”

The EMA submission is based on the positive results from the Phase 3 VIBRANT trial, which was a double-masked, randomized, active-controlled study of patients with macular edema secondary to BRVO. In the VIBRANT study, 53% of patients who received aflibercept solution for injection 2 milligram (mg) monthly gained at least 15 letters (equivalent to three lines) in best corrected visual acuity (BCVA) from baseline at week 24, the primary endpoint of the study, compared to 27% of patients who received laser,

the current standard of care (p<0.001). In addition, aflibercept solution for injection met a key secondary endpoint, achieving a 17.0 letter mean improvement over baseline in BCVA compared to a 6.9 letter mean improvement in patients who received laser (p<0.0001). Aflibercept solution for injection into the eye was generally well tolerated. Through week 24, the most common ocular adverse events in patients treated with aflibercept solution for injection were conjunctival hemorrhage and eye pain. The incidence of serious adverse events (SAE) was 9.9% in the aflibercept solution for injection group and 9.8% in the laser group. Up to week 24, one death and one Anti-Platelet Trialists' Collaboration (APTC) defined event (non-fatal stroke) occurred during the trial, both events occurred in patients in the laser group. There were no cases of intraocular inflammation. There was one ocular SAE in a patient in the aflibercept solution for injection group, which was a traumatic cataract.

About the Phase 3 VIBRANT Study

VIBRANT was a Phase 3, randomized, double-masked, active-controlled 52-week study, comparing aflibercept solution for injection 2 mg monthly with laser photocoagulation in subjects with macular edema secondary to BRVO. The primary endpoint was the proportion of subjects who gained at least 15 letters in BCVA from baseline at week 24, as measured on the Early Treatment Diabetic Retinopathy Scale (ETDRS) eye chart, a standard chart used in research to measure visual acuity. At week 24, patients initially randomized to aflibercept solution for injection 2 mg monthly continued with dosing every two months, while those initially randomized to receive laser continued as is unless they qualified for rescue therapy (aflibercept solution for injection 2 mg monthly for 3 months, followed by dosing every other month through week 52). The 52 week VIBRANT results will be presented later this year.

About Branch Retinal Vein Occlusion (BRVO)

BRVO is a common retinal vascular disorder affecting 13.9 million people worldwide and is a significant cause of visual impairment. Of the two main types of retinal vein occlusion (RVO) – CRVO and BRVO – the latter is more common with prevalence four times higher than that of CRVO. In BRVO, one or more branches of the main blood vessel draining the retina are blocked, resulting in the release of vascular endothelial growth factor and consequent retinal edema.

About VEGF and aflibercept solution for injection into the eye
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.

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. Aflibercept 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.

Aflibercept solution for injection into the eye has been approved under the brand name EYLEA® in over 70 countries for the treatment of patients with neovascular age-related macular degeneration (wet AMD) and nearly 60 countries for the treatment of visual impairment due to macular edema secondary to central retinal vein occlusion (CRVO). Over 1.5 million doses of EYLEA have been administered since launch. Regulatory submissions have been made in Europe, Japan, Asia Pacific, Latin America and the United States (U.S.) for the treatment of diabetic macular edema (DME) and for BRVO in the U.S. In Japan and Asia Pacific, EYLEA has also been submitted for approval to regulators for the treatment of choroidal neovascularization secondary to pathologic myopia (myopic CNV).

Bayer HealthCare and Regeneron Pharmaceuticals, Inc. are collaborating on the global development of EYLEA. Regeneron maintains exclusive rights to EYLEA in the U.S. Bayer HealthCare licensed the exclusive marketing rights outside the U.S., where the companies share equally the profits from sales of EYLEA, except for Japan where Regeneron receives a percentage of net sales.

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, 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 18.9 billion (2013), 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 56,000 employees (Dec 31, 2013) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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Regeneron's late-stage product candidates and new indications for marketed products, such as the application of EYLEA® (aflibercept) Injection in the treatment of Macular Edema Secondary to Branch Retinal Vein Occlusion and in the treatment of Diabetic Macular Edema; 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 LLC, 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, 2013 and its Form 10-Q for the quarter ended March 31, 2014. 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.