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Investor News

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Bayer and Regeneron Initiate Phase III Clinical Trial for the Treatment of Wet Age-Related Macular Degeneration in China

Leverkusen, November 28, 2011 – Bayer HealthCare and Regeneron Pharmaceuticals, Inc. today announced that they have initiated a Phase III clinical trial evaluating the efficacy and safety of VEGF Trap-Eye (aflibercept) in the neovascular form of age-related macular degeneration (wet AMD) in China.

The new trial, named SIGHT, will include approximately 300 patients and will be the largest retinal trial conducted in China. SIGHT is being led by Bayer.

“Currently, only photodynamic therapy with verteporfin is approved as a treatment for wet AMD in China, and it is only approved for the subpopulation of patients with predominantly classic wet AMD,” said Kemal Malik, M.D., Head of Global Development and member of the Bayer HealthCare Executive Committee. “After reporting positive data from our large VIEW program in wet AMD, we look forward to potentially bringing this new treatment to patients with wet AMD in China."

About the SIGHT Trial

The SIGHT (VEGF Trap-Eye: Investigation of Efficacy and Safety in Chinese patients with wet AMD) trial consists of a randomized, double-masked, Phase III clinical trial evaluating VEGF Trap-Eye in the treatment of the neovascular form of age-related macular degeneration (wet AMD).

VEGF Trap-Eye will be evaluated for its effect on improving and maintaining vision when dosed as an intravitreal injection on a schedule of 2 milligrams (mg) every two months (following three initial monthly doses), as compared with Photodynamic Therapy (PDT) with verteporfin. After assessment of the primary endpoint at week 28, all patients, including those on PDT, will receive VEGF Trap-Eye treatment until the end of the study at week 52.

About Wet AMD

Age-related Macular Degeneration (AMD) is a leading cause of acquired blindness. Macular degeneration is diagnosed as either dry (non-exudative) or wet (exudative). In wet AMD, new blood vessels grow beneath the retina and leak blood and fluid. This leakage causes disruption and dysfunction of the retina creating blind spots in central vision, and it can account for blindness in wet AMD patients. Wet AMD is the leading cause of blindness for people over the age of 65 in the U.S. and Europe. In China, there were an estimated 540,000 newly diagnosed wet AMD patients over the age of 50 in 2010.

About VEGF Trap-Eye (aflibercept)

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. However, in certain diseases, such as wet age-related macular degeneration, 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) with higher affinity than their natural receptors, and thereby can inhibit the binding and activation of these cognate VEGF receptors.

Regeneron and Bayer HealthCare are collaborating on the global development of VEGF Trap-Eye for the treatment of neovascular age-related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), diabetic macular edema (DME), and other eye diseases and disorders. Recently Regeneron has received approval from the U.S. Food and Drug Administration (FDA) for EYLEA™ Intravitreal Injection, known as VEGF Trap-Eye, for the treatment of patients with wet age-related macular degeneration (wet AMD). Bayer submitted an application for marketing authorization in Europe and Japan in wet AMD in the first half of 2011.

Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally the profits from any future sales of VEGF Trap-Eye. Regeneron maintains exclusive rights to EYLEA in the United States.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets two products, ARCALYST® (rilonacept) Injection for Subcutaneous Use and EYLEA™ (aflibercept) Injection. Regeneron also has completed several Phase III studies and is conducting an additional Phase III clinical trial for the product candidate ZALTRAP® (aflibercept) Concentrate for Intravenous Infusion. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on the Regeneron web site at www.regeneron.com.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 16.9 billion (2010), 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 and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2010) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

To learn more about wet Age-related Macular Degeneration (AMD), please visit www.bayerpharma.com/en/AMD

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Regeneron Forward Looking Statement
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 EYLEA and Regeneron's product candidates and research and clinical programs now underway or planned, 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 EYLEA and other products and drug candidates, competing drugs that may be superior to EYLEA and Regeneron's products and drug candidates, uncertainty of market acceptance of EYLEA and Regeneron's products and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, to be canceled or terminated without any 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, 2010 and Form 10-Q for the quarter ended September 30, 2011. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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.