Bayer and Regeneron Extend Development Program for VEGF Trap-Eye to Include Central Retinal Vein Occlusion

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BERLIN and TARRYTOWN, N.Y., April 30 /PRNewswire-FirstCall/ -- Bayer HealthCare AG and Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced that the companies are extending their global development program for VEGF Trap-Eye, an investigational agent for the treatment of certain eye diseases, to include Central Retinal Vein Occlusion (CRVO). The companies plan to initiate a Phase 3 program evaluating the efficacy and safety of VEGF Trap-Eye in the treatment of CRVO in the second half of this year. CRVO is caused by obstruction of the central retinal vein that that leads to a back up of blood and fluid in the retina, resulting in retinal injury and loss of vision. The retina can also become "ischemic" (starved for oxygen), resulting in the growth of abnormal new blood vessels that can cause further vision loss and more serious complications.

The Phase 3 program in CRVO will consist of two, multinational, one-year clinical studies which have been reviewed with regulatory authorities. These studies will expand the companies' global development collaboration for VEGF Trap-Eye, which already includes two ongoing Phase 3 studies in patients with the neovascular form of Age-related Macular Degeneration (wet AMD) and a Phase 2 study in patients with Diabetic Macular Edema (DME). Enrollment in the wet AMD and DME studies is expected to be completed later this year.

"Although CRVO is a leading cause of blindness, there is currently no treatment available that can be universally considered to be the standard of care, and there is no approved treatment to prevent the loss of vision or improve vision once it is lost," said Dr. Kemal Malik, Head of Global Development and member of the Bayer HealthCare Executive Committee. "Since the underlying biology of CRVO is related to edema and the growth of abnormal new blood vessels that are mediated by vascular endothelial growth factor (VEGF), we are hopeful that VEGF Trap-Eye may help address this significant unmet medical need."

About CRVO

Over 100,000 people in the United States are estimated to suffer from CRVO. CRVO is caused by obstruction of the central retinal vein that leads to a back up of blood and fluid in the retina, resulting in retinal injury and loss of vision. The retina can also become "ischemic" (starved for oxygen), resulting in the growth of new abnormal blood vessels that can cause further vision loss and more serious complications. Release of VEGF contributes to increased vascular permeability in the eye and abnormal new vessel growth. It is believed that anti-VEGF treatment may help decrease vascular permeability and edema and prevent the growth of abnormal new blood vessels in the retina in patients with CRVO.

About the Phase 3 CRVO Program

In the Phase 3 CRVO program for VEGF Trap-Eye, Regeneron and Bayer HealthCare will conduct two identical multinational clinical studies: COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) will be led by Regeneron and GALILEO (General Assessment Limiting InfiLtration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) will be led by Bayer HealthCare. Enrollment will be initiated later in 2009.

Patients in both studies will receive 6 monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 milligrams (mg) or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after 6 months of treatment. At the end of the initial 6 months, all patients will be dosed on a PRN (as needed) basis for another 6 months. All patients will be eligible for rescue laser treatment.

About VEGF Trap-Eye

Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body whose normal role is to trigger formation of new blood vessels (angiogenesis) to support the growth of the body's tissues and organs. It has also been associated with the abnormal growth and fragility of new blood vessels in the eye and vascular permeability and edema. VEGF Trap-Eye is a fully human, soluble VEGF receptor fusion protein that binds all forms of VEGF-A along with the related Placental Growth Factor (PlGF). Investigational VEGF Trap-Eye is a specific blocker of VEGF-A and PlGF that has been demonstrated in preclinical models to bind these growth factors with greater affinity than their natural receptors.

Regeneron and Bayer HealthCare are collaborating on the global development of VEGF Trap-Eye for the treatment of wet AMD, DME, CRVO, and other eye diseases and disorders. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, inflammatory diseases, and pain and has preclinical programs in other diseases and disorders. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

About Bayer HealthCare Pharmaceuticals

Bayer HealthCare Pharmaceuticals Inc. is the U.S.-based pharmaceuticals operation of Bayer HealthCare, an affiliate of Bayer AG. One of the world's

leading, innovative companies in the healthcare and medical products industry, Bayer HealthCare combines the global activities of the Animal Health, Consumer Care, Diabetes Care, and Pharmaceuticals divisions. In the United States, Bayer HealthCare Pharmaceuticals comprises the following business units: Women's Healthcare, Diagnostic Imaging, General Medicine, Hematology/Neurology, and Oncology. The company's aim is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

Forward-Looking Statements - Bayer HealthCare AG

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.

Forward Looking Statement -- Regeneron Pharmaceuticals, Inc.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. 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 (SEC), including its Form 10-K for the year ended December 31, 2008. 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.

SOURCE Regeneron Pharmaceuticals, Inc.; Bayer HealthCare AG

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