REGENERON

Enrollment Completed in Regeneron and Bayer HealthCare Phase 3 Studies of VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration (Wet AMD)

September 14, 2009

TARRYTOWN, N.Y., Sept 14, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced the completion of patient enrollment in two randomized, double-masked, Phase 3 clinical trials evaluating VEGF Trap-Eye in the treatment of the neovascular form of age-related macular degeneration (wet AMD). In each study of the VIEW (VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD) program, VEGF Trap-Eye is being evaluated for its effect on maintaining and improving vision when dosed as an intravitreal injection on a schedule of 0.5 milligram (mg) every four weeks, 2.0 mg every four weeks, or 2.0 mg every eight weeks (following three monthly doses), as compared with intravitreal ranibizumab (Lucentis((R)), a registered trademark of Genentech, Inc.) administered 0.5 mg every four weeks during the first year of the studies. As-needed (PRN) dosing with both agents is being evaluated during the second year of each study. These studies are part of the global development program for VEGF Trap-Eye being conducted by Regeneron and Bayer HealthCare AG. Each study has enrolled in excess of the targeted 1,200 patient goal. One-year primary endpoint data from both studies are expected in the fourth quarter of 2010.

VEGF Trap-Eye, an investigational drug, is being developed by Regeneron and Bayer HealthCare AG for the potential treatment of eye diseases, including wet AMD, diabetic macular edema (DME), and Central Retinal Vein Occlusion (CRVO). Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States. Bayer HealthCare has exclusive rights to market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye.

"Even with recent advances in the treatment of wet AMD, vision is not improved or stabilized in all patients despite monthly office visits and examinations that are inconvenient for these often elderly patients," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "This Phase 3 program is exploring various doses and dosing schedules with our novel anti-VEGF investigational agent to evaluate whether further improvements in vision and/or longer dosing intervals than monthly administration are possible."

About the VIEW Program

The VIEW 1 study is being conducted in the United States and Canada by Regeneron and the VIEW 2 study is being conducted in Europe, Asia Pacific, Japan, and Latin America by Bayer HealthCare. In the first year of the studies, the safety and efficacy of VEGF Trap-Eye at doses of 0.5 mg and 2.0 mg administered at four-week intervals and 2.0 mg at an eight-week dosing interval following one additional 2.0 mg dose at week four are being evaluated. Patients randomized to the ranibizumab arm of the trial will receive a 0.5 mg dose every four weeks. After the first year of treatment, patients will continue to be followed and treated for another year on a flexible, criteria-based extended PRN regimen with a dose administered at least every 12 weeks, but not more often than every four weeks until the end of the study.

The primary endpoint of these non-inferiority studies is the proportion of patients treated with VEGF Trap-Eye who maintain vision at the end of one year, compared to ranibizumab patients. Visual acuity is defined as the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, a standard chart used in research to measure visual acuity. Maintenance of vision is defined as losing fewer than three lines (equivalent to 15 letters) on the ETDRS chart. Key secondary endpoints include the mean change from baseline in visual acuity as measured by ETDRS and the proportion of patients who gained at least 15 letters of vision at week 52.

About VEGF Trap-Eye

Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body whose normal role is to trigger the 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, which lead to the development of wet AMD. 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 (PIGF). Investigational VEGF Trap-Eye is a specific blocker of VEGF-A and PIGF that has been demonstrated in preclinical models to bind these growth factors with greater affinity than their natural receptors. Blockade of VEGF can prevent abnormal blood vessel formation as well as vascular leak and has proven beneficial in the treatment of wet AMD.

VEGF Trap-Eye is also in Phase 3 development for the treatment of Central Retinal Vein Occlusion (CRVO), another cause of blindness. The COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study is being led by Regeneron and the GALILEO (General Assessment Limiting InfiLtration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. Patients in both studies will receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients will be dosed on a PRN (as needed) basis for another six months. All patients will be eligible for rescue laser treatment. Initial data from the program are anticipated in early 2011.

VEGF Trap-Eye is also in Phase 2 development for the treatment of Diabetic Macular Edema (DME). VEGF Trap-Eye dosed at 0.5 mg or 2 mg monthly, 2 mg every eight weeks after three monthly loading doses, or 2 mg on an as-needed (PRN) basis after three monthly loading doses is being compared to focal laser treatment, the current standard of care in DME. The primary efficacy endpoint evaluation is mean improvement in visual acuity at six months. Patient enrollment has been completed with initial data expected in the first half of 2010.

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.

About Regeneron

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST((R))(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.

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 VEGF Trap-Eye, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize VEGF Trap-Eye, competing drugs that may be superior to VEGF Trap-Eye, uncertainty of market acceptance of VEGF Trap-Eye, 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 and Form 10-Q for the quarter ending June 30, 2009. 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.

Contact Information:
Peter Dworkin
Investor Relations
914.345.7640
peter.dworkin@regeneron.com
Laura Lindsay
Media Relations
914.345.7800
laura.lindsay@regeneron.com

SOURCE Regeneron Pharmaceuticals, Inc.

http://www.regeneron.com