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Investor News

Bayer and Regeneron start additional Phase 3 Study for VEGF Trap-Eye in Wet Age-related Macular Degeneration

International study to evaluate efficacy and safety in treating a leading cause of blindness

Leverkusen, May 8, 2008 - Bayer HealthCare AG and development partner Regeneron Pharmaceuticals, Inc. (NASDAQ:REGN) today announced that the first patient has been dosed in the new VIEW 2 trial, a second Phase 3 clinical study in a development program evaluating VEGF Trap-Eye for the treatment of the neovascular form of age-related macular degeneration (wet AMD), a leading cause of blindness in adults.

VIEW 2 (VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD) will enroll approximately 1,200 patients in up to 200 centers in Europe, Asia Pacific, Japan and Latin America. The first Phase 3 trial, VIEW 1, began enrolling patients in August 2007 in the United States and Canada. Both VIEW 1 and VIEW 2 are designed to evaluate the efficacy and safety of VEGF Trap-Eye administered by intravitreal injection, at dosing intervals of 4 and 8 weeks. The development program will include visual acuity endpoints and anatomical endpoints, including retinal thickness, a measure of disease activity. The trial is intended to establish non-inferiority of VEGF Trap-Eye with Lucentis® (ranibizumab) an antiangiogenic agent approved for use in wet AMD in major markets globally.

Wet AMD accounts for about 90 percent of all severe AMD-related vision loss. It occurs when abnormal blood vessels in the eye leak fluid and blood into the macula, the area of the retina that allows for vision of fine details. This can lead to a rapid loss of central vision with continued progression.

“Results from the Phase 2 study have shown that VEGF Trap-Eye has the potential to significantly reduce retinal thickness and improve vision,” said Kemal Malik, MD, Head of Global Development and member of the Bayer HealthCare Executive Committee. “Dosing

of the first patient in this confirmatory Phase 3 trial is an important milestone for this compound intended to treat a devastating ocular disease that impacts millions of people worldwide."

"New therapies are still needed to provide optimal care to those patients with wet AMD," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "This global Phase 3 clinical program will provide additional data to further evaluate the efficacy and safety of VEGF Trap-Eye using different dosing regimens."

Bayer HealthCare and Regeneron are collaborating on the global development of VEGF Trap-Eye for treatment of wet AMD, diabetic eye diseases, and other ocular diseases and disorders. Once approved, Bayer HealthCare will market VEGF Trap-Eye outside the U.S., where the parties will share equally in profits from any future sales of VEGF Trap-Eye. Regeneron maintains exclusive rights to VEGF Trap-Eye in the U.S. VIEW 2 primary analysis results are anticipated in 2011.

About VIEW 2

In the first year, the VIEW 2 study will evaluate the safety and efficacy of VEGF Trap-Eye at doses of 0.5 milligrams (mg) and 2.0 mg administered at 4-week intervals and 2.0 mg at an 8-week dosing interval, including one additional 2.0 mg dose at week four. Patients randomized to the ranibizumab arm of the trial will receive a 0.5 mg dose every 4 weeks. After the first year of treatment, patients will continue to be followed and treated for another year on a flexible, criteria-based extended regimen with a dose administered at least every 12 weeks, but not more often than every 4 weeks until the end of the study.

The primary endpoint of the study 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.

In a Phase 2 trial in 157 patients, announced in October 2007 at the Retina Society Conference in Boston, VEGF Trap-Eye met both primary and secondary key endpoints: a statistically significant reduction in retinal thickness (a measure of disease activity) after 12 weeks of treatment compared with baseline and a statistically significant improvement from baseline in visual acuity (ability to read letters on an eye chart).

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) and VEGF-B. VEGF Trap-Eye is a specific and highly potent blocker of these growth factors. Blockade of VEGF can prevent abnormal blood vessel formation as well as vascular leak and has proven beneficial in the treatment of wet AMD.

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 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 subsidiary of Bayer AG, 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, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma AG. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Find more information at www.bayerhealthcare.com.

research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Specialty Medicine and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading positions in specialized markets worldwide. Using new ideas, Bayer Schering Pharma aims to make a contribution to medical progress and strives to improve the quality of life. Find more information at www.bayerscheringpharma.de.

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™ (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, and inflammatory diseases, 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.

(Note: Lucentis® is a registered trademark of Genentech, Inc.)

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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-Q for the quarter ended March 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.