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Regeneron and Bayer HealthCare Initiate Phase 3 Global Development Program For VEGF Trap-Eye In Wet Age-Related Macular Degeneration (AMD)

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Regeneron and Bayer HealthCare Initiate Phase 3 Global Development Program For VEGF Trap-Eye In Wet Age-Related Macular Degeneration (AMD)TARRYTOWN, N.Y. & LEVERKUSEN, Germany--(BUSINESS WIRE)--Aug. 2, 2007--Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) and Bayer HealthCare AG (NYSE:BAY) announced today that the companies have initiated a Phase 3 study of the VEGF Trap-Eye in the neovascular form of age-related macular degeneration (wet AMD). The study will be a non-inferiority comparison of the VEGF Trap-Eye and ranibizumab (Lucentis®, a registered trademark of Genentech, Inc.), an anti-angiogenic agent approved for use in wet AMD. The study will be conducted pursuant to a Special Protocol Assessment from the U.S. Food and Drug Administration (FDA). This trial, known as VIEW 1 (VEGF Trap: Investigation of Efficacy and safety in Wet age-related macular degeneration), is the first study in the companies' Phase 3 global development program in wet AMD, which is planned to be carried out in the U.S., Europe, and other parts of the world.

"Age-related macular degeneration continues to be one of the leading causes of blindness in adults, and new therapies are essential to providing optimal patient care," stated Jeffrey Heier, M.D., a clinical ophthalmologist at Ophthalmic Consultants of Boston and chair of the steering committee for the trial. "The results of early phase studies of VEGF Trap-Eye suggest it has the potential to be a highly efficacious treatment with less frequent administration. If these results are confirmed in Phase 3 trials, it would be important for both patients and physicians and would be a significant advance in the treatment of these patients."

"The initiation of this Phase 3 trial represents a major milestone in the development of the VEGF Trap-Eye to treat wet AMD," said Avner Ingerman, M.D., vice president and ophthalmology team leader for Regeneron. "While this trial enables us to continue in our effort to improve the lives of patients suffering from wet AMD, it also signals the beginning of a larger, more global development program investigating the potential of VEGF Trap-Eye for the treatment of diabetic eye diseases and other eye diseases and disorders."

The randomized, double-masked Phase 3 study is expected to enroll approximately 1,200 patients in more than 200 centers throughout the United States and Canada. The study will evaluate the safety and efficacy of the VEGF Trap-Eye at doses of 0.5 milligrams (mg) and 2.0 mg administered at four-week dosing intervals and 2.0 mg at an eight-week dosing interval, compared to 0.5 mg of ranibizumab administered every four weeks, consistent with its labeled dosing schedule.

The primary endpoint of the study is the proportion of patients treated with the VEGF Trap-Eye who maintain or improve 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. Maintenance of vision is defined as losing fewer than three lines (equivalent to 15 letters) on the ETDRS chart. After the first year of treatment, patients will continue to be treated and followed for another year.

In an analysis of interim data from the ongoing Phase 2 trial in wet AMD, where patients were treated with the VEGF Trap-Eye either monthly or quarterly, combined data for all patients demonstrated a statistically significant reduction in retinal thickness and improvement in visual acuity after 12 weeks, compared to baseline. There were no drug-related serious adverse events, and treatment with the VEGF Trap-Eye was generally well-tolerated. The most common adverse events were those typically associated with intravitreal injections. The interim results of this Phase 2 trial were presented at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO) this past May. The companies expect to report final primary endpoint results of the trial at a scientific meeting later this quarter.

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

About the 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, which lead to the development of wet AMD. The 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). The VEGF Trap-Eye is a specific and highly potent blocker of these growth factors. Blockade of VEGF, which can prevent abnormal blood vessel formation and vascular leak, has proven beneficial in the treatment of wet AMD. Blocking VEGF has been shown to be effective in patients with wet AMD; and a VEGF inhibitor, ranibizumab, has been approved for treatment of patients with this condition.

About AMD

Age-related macular degeneration (AMD) is a leading cause of acquired blindness. Patients with this condition can experience a loss of vision due to the development of abnormal, fragile blood vessels in the back of the eye. A particular type of AMD, called wet AMD, accounts for approximately 90 percent of AMD-related blindness. Wet AMD is the leading cause of blindness for people over the age of 65 in the U.S. and Europe.

Macular degeneration is diagnosed as either dry (nonexudative) 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 lead to blindness in wet AMD patients.

About Regeneron Pharmaceuticals

Regeneron is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic medicines for the treatment of serious medical conditions. Regeneron has therapeutic candidates 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 worldwide 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 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.

Forward Looking Statement - Regeneron

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of our drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our drug candidates, competing drugs that are superior to our product candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our 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 June 30, 2007. 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.

Forward-Looking Statements - Bayer HealthCare

This news release contains forward-looking statements based on current assumptions and forecasts made by Bayer Group 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 our annual and interim reports to the Frankfurt Stock Exchange and in our reports filed with the U.S. Securities and Exchange Commission (including our Form 20-F). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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