

# REGENERON

## Positive Interim Phase 2 Data Reported for VEGF Trap-Eye in Age-Related Macular Degeneration

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Positive Interim Phase 2 Data Reported for VEGF Trap-Eye in Age-Related Macular Degeneration TARRYTOWN, N.Y. & LEVERKUSEN, Germany, Mar 27, 2007 (BUSINESS WIRE) -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) and Bayer HealthCare AG (NYSE: BAY) today announced positive preliminary data from a pre-planned interim analysis of a Phase 2 randomized study of their VEGF Trap-Eye in patients with the neovascular form of age-related macular degeneration (wet AMD). The VEGF Trap-Eye met its primary endpoint of a statistically significant reduction in retinal thickness after 12 weeks compared with baseline (all groups combined, decrease of 135 microns,  $p < 0.0001$ ). Mean change from baseline in visual acuity, a key secondary endpoint of the study, also demonstrated statistically significant improvement (all groups combined, increase of 5.9 letters,  $p < 0.0001$ ). Moreover, patients in the dose groups that received only a single dose, on average, demonstrated a decrease in excess retinal thickness ( $p < 0.0001$ ) and an increase in visual acuity ( $p = 0.012$ ) at 12 weeks. 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. Detailed data from this interim analysis will be presented at an upcoming scientific conference.

"These data support our efforts to develop the VEGF Trap as a potent blocker of VEGF in various diseases," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "Importantly, the VEGF Trap-Eye may offer the potential to improve vision in patients with wet AMD with dosing less frequently than every four weeks. Our Phase 3 program is being designed to test this possibility and further evaluate the safety and efficacy of various doses and dosing intervals of the VEGF Trap-Eye."

"We are very pleased with the outcome of this interim analysis and the findings support the potential of the VEGF Trap-Eye to improve the lives of patients suffering from wet AMD, which accounts for 90% of AMD related blindness," said Kemal Malik, M.D., member of the Bayer HealthCare Executive Committee, responsible for Global Development. "These results encourage us in our plans to foster next steps in development and to further study the VEGF Trap-Eye in additional eye diseases."

Based on these results, Regeneron and Bayer HealthCare AG plan to initiate the VEGF Trap-Eye Phase 3 program in the second half of 2007. The companies 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 AG and Regeneron will jointly commercialize the VEGF Trap-Eye outside the United States, and Regeneron maintains exclusive rights in the United States.

The Phase 2 study is a 12-week, multi-center trial involving 150 patients who are randomized to 5 groups and treated with the VEGF Trap-Eye in one eye. Two groups received either 0.5 or 2.0 mg of VEGF Trap-Eye administered every four weeks, and three groups received a single dose of 0.5, 2.0, or 4.0 mg of VEGF Trap-Eye. Patients are monitored for safety, retinal thickness, and visual acuity over 12 weeks. Retinal thickness is determined by optical coherence tomography (OCT) scans read at an independent reading center. Visual acuity is defined as the total number of letters read correctly on the Early Diabetic Retinopathy Study (ETDRS) chart. Maintenance of vision is defined as losing fewer than 3 lines (equivalent to 15 letters) on the ETDRS chart.

The interim analysis was conducted on the first 78 patients who completed 12 weeks of study. As summarized above, overall, patients had a statistically significant improvement in retinal thickness and visual acuity. All but one patient maintained or improved vision at 12 weeks. Although the improvement in visual acuity was numerically larger in patients receiving injections every 4 weeks, there were no statistically significant differences across the five dose groups in either retinal thickness or visual acuity at 12 weeks.

### 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.

### About AMD

Age-related macular degeneration (AMD) is a leading cause of acquired blindness. Patients with 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% 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 can account for 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.

#### About Bayer HealthCare

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.

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-K for the year ended December 31, 2006. 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.

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 public reports filed with the Frankfurt Stock Exchange and 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.

Additional information about Regeneron and recent news releases are available on Regeneron's worldwide web site at [www.regeneron.com](http://www.regeneron.com)

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