

# REGENERON

## Regeneron and Bayer HealthCare Announce VEGF Trap-Eye Achieved Durable Improvement in Vision over 52 Weeks in a Phase 2 Study in Patients with Age-related Macular Degeneration

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Regeneron and Bayer HealthCare Announce VEGF Trap-Eye Achieved Durable Improvement in Vision over 52 Weeks in a Phase 2 Study in Patients with Age-related Macular Degeneration **Tarrytown, NY and Leverkusen, Germany (August 19, 2008)** – Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) and Bayer HealthCare AG today announced that patients with wet age-related macular degeneration (AMD) receiving VEGF Trap-Eye in a Phase 2 extension study on a PRN (as needed) dosing schedule continued to show highly significant improvements at 52 weeks in the primary and key secondary endpoints of retinal thickness (an anatomic measure of treatment effect) and vision gain. The 12-week primary endpoint results from the fixed-dosing period of the study were presented at the 2007 Retina Society conference in September 2007. The 32-week results of the Phase 2 study were presented at the 2008 Association for Research in Vision and Ophthalmology (ARVO) meeting in Fort Lauderdale, Florida in April 2008. A full analysis of the 52-week results of the Phase 2 study will be presented at the 2008 meeting of the Retina Society on September 26-28, 2008 in Scottsdale, Arizona.

In this double-masked, prospective, randomized, multi-center Phase 2 trial, 157 patients were randomized to five dose groups and treated with VEGF Trap-Eye in one eye. Two groups initially received monthly doses of 0.5 or 2.0 milligrams (mg) of VEGF Trap-Eye (at weeks 0, 4, 8, and 12) and three groups received quarterly doses of 0.5, 2.0, or 4.0 mg of VEGF Trap-Eye (at baseline and week 12). Following the initial 12-week fixed-dosing phase of the trial, patients continued to receive therapy at the same dose on a PRN dosing schedule based upon the physician assessment of the need for re-treatment in accordance with pre-specified criteria. Patients were monitored for safety, retinal thickness, and visual acuity. These data represent the final one-year analysis from the 52-week study.

Patients receiving four monthly doses of VEGF Trap-Eye, either 2.0 or 0.5 mg, for 12 weeks followed by PRN dosing thereafter, achieved mean improvements in visual acuity versus baseline of 9.0 letters ( $p < 0.0001$ ) and 5.4 letters ( $p = 0.085$ ), respectively, and mean decreases in retinal thickness versus baseline of 143 microns ( $p < 0.0001$ ) and 125 microns ( $p < 0.0001$ ) at week 52, respectively. During the subsequent PRN dosing phase, patients initially dosed on a 2.0 mg monthly schedule received, on average, only 1.6 additional injections and those initially dosed on a 0.5 mg monthly schedule received, on average, 2.5 injections.

For all dose cohorts combined, there was a 5.3 mean letter gain in visual acuity versus baseline at the week 52 evaluation visit ( $p < 0.0001$ ). The mean decrease in retinal thickness for all dose groups combined at week 52 was 130 microns versus baseline ( $p < 0.0001$ ). During the week 12 to week 52 PRN dosing period, patients from all dose groups combined received, on average, only two additional injections.

VEGF Trap-Eye was generally well tolerated and there were no drug-related serious adverse events. There was one reported case of culture-negative endophthalmitis/uveitis in the study eye and one arterial thrombotic event, neither of which was deemed to be drug-related. The most common adverse events were those typically associated with intravitreal injections.

"Based upon retinal physicians' feedback, there remains a significant unmet medical need for a treatment for wet AMD that can reliably improve visual acuity over time without the need for monthly intravitreal injections," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "We are excited about these study findings and the potential for VEGF Trap-Eye to fulfill this need pending the results of our ongoing Phase 3 clinical studies."

"The 52-week results underline that VEGF Trap-Eye has the potential to significantly reduce retinal thickness and improve vision," said Dr. Kemal Malik, member of the Bayer HealthCare Executive Committee responsible for product development. "The further development of this compound is important for millions of people worldwide who suffer from this devastating ocular disease."

### About the Phase 3 Program in Wet AMD

Regeneron and Bayer HealthCare initiated a Phase 3 global development program for VEGF Trap-Eye in wet AMD in August 2007. In two Phase 3 trials, VIEW 1 and VIEW 2 (VEGF Trap-Eye: Investigation of Efficacy and Safety in **W**et Age-related Macular Degeneration), the companies are evaluating VEGF Trap-Eye dosed 0.5 mg every 4 weeks, 2 mg every 4 weeks, or 2 mg every 8 weeks (following three monthly doses) in direct comparison with ranibizumab (Lucentis®, a registered trademark of Genentech, Inc.) administered 0.5 mg every four weeks according to its U.S. label during the first year of the studies. PRN dosing will be evaluated during the second year of each study. The VIEW1 study ([http://www.regeneron.com/vegfrap\\_eye.html](http://www.regeneron.com/vegfrap_eye.html)) is currently enrolling patients in the United States and Canada and the VIEW2 study ([www.view2study.com](http://www.view2study.com)) is currently enrolling patients in Europe, Asia Pacific, Japan, and Latin America. The companies are collaborating on the global development of VEGF Trap-Eye for the treatment of wet AMD, diabetic eye diseases, 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 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). 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.

Mylan Exhibit 1089

### **About Wet AMD**

Age-related Macular Degeneration (AMD) is a leading cause of acquired blindness. 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 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 Pharmaceuticals, Inc.**

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](http://www.regeneron.com).

### **Forward Looking Statement**

*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, 2007 and Form 10-Q for the quarter ending June 30, 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.*

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