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April 28, 2008

Regeneron and Bayer HealthCare Announce Encouraging 32-Week Follow-Up Results from a Phase 2 Study of VEGF Trap-Eye in Age-Related Macular Degeneration

Gains in visual acuity achieved in initial 12-week fixed dosing phase of study maintained in PRN (as-needed) dosing phase

TARRYTOWN, N.Y. & LEVERKUSEN, Germany--(BUSINESS WIRE)--April 28, 2008--Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) and Bayer HealthCare AG today announced that VEGF Trap-Eye dosed on a PRN (as-needed) dosing schedule maintained the statistically significant gain in visual acuity achieved after an initial, 12-week, fixed-dosing phase of a Phase 2 study in the neovascular form of Age-related Macular Degeneration (wet AMD). A full analysis of the 32-week results of the Phase 2 study will be presented today at the 2008 Association for Research in Vision and Ophthalmology (ARVO) meeting in Fort Lauderdale, Florida. The data being reported at the meeting are available on the Regeneron website (www.regeneron.com on the Investor Relations page, under the Presentations heading).

Study results showed that across all dose groups in the study population, the 6.6 mean letter gain in visual acuity achieved versus baseline at the week 16 evaluation visit, following 12 weeks of fixed dosing, was maintained out to week 32 (a 6.7 mean letter gain versus baseline; p less than 0.0001) using a PRN dosing schedule (where dosing frequency was determined by the physician's assessment of pre-specified criteria). The decrease in retinal thickness, an anatomical measure of treatment effect achieved with a fixed-dose schedule was also maintained for all dose groups combined at week 32 (a 137 micron mean decrease versus baseline, p less than0.0001).

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 for 12 weeks 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-dose 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 week 32 analysis from the 52-week study, which is continuing to follow patients.

Patients receiving monthly doses of VEGF Trap-Eye, either 0.5 or 2.0 mg, for 12 weeks followed by PRN dosing thereafter achieved mean improvements in visual acuity of 8.0 (p less than0.01 versus baseline) and 10.1 letters (p less than0.0001 versus baseline), respectively, and mean decreases in retinal thickness of 141 (p less than0.0001 versus baseline) and 162 microns (p less than0.0001 versus baseline) at week 32, respectively. While PRN dosing also maintained the improvements in retinal thickness and visual acuity achieved versus baseline following a fixed dosing regimen utilizing quarterly dosing at baseline and week 12, the results achieved with a quarterly fixed dosing regimen were generally not as robust as obtained with initial fixed monthly dosing.

VEGF Trap-Eye was generally safe and 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, which was deemed not to be drug-related. The most common adverse events were those typically associated with intravitreal injections.

After the last fixed-dose administration at week 12, patients from all dose groups combined required, on average, only one additional injection over the following 20 weeks to maintain the visual acuity gain established during the fixed-dosing period. Notably, 55 percent of the patients who received 2.0 mg monthly for 12 weeks did not require any additional treatment throughout the next 20-week PRN dosing period. Moreover, 97 percent of the patients who received 2.0 mg monthly for 12 weeks did not require re-dosing at the week 16 evaluation visit, indicating that an 8-week dosing schedule may be feasible.

"Due to its high affinity for all isoforms of VEGF-A and PlGF, potent mediators of blood vessel overgrowth in wet AMD, as well as its long residence time in the eye, it is anticipated that VEGF Trap-Eye may be able to be dosed at a frequency less than once monthly, especially on a chronic basis, without compromising visual acuity," stated Quan Dong Nguyen, M.D., M.Sc.,* Assistant Professor of Ophthalmology, Wilmer Ophthalmological Institute, the Johns Hopkins University School of Medicine, Baltimore, MD and a primary investigator in the Phase 2 study. "These emerging Phase 2 clinical data seem to support the concept of durability of VEGF Trap-Eye."

In this study, treatment with VEGF Trap-Eye was associated with a reduction in the size of the choroidal neovascular membrane (CNV), the lesion that is the underlying cause of vision loss due to wet AMD. Patients initially treated with a 0.5 mg or 2.0 mg monthly fixed dose for 12 weeks, followed by PRN dosing thereafter, experienced 1.55 mm(2) and 2.52 mm(2) reductions in

mean CNV size at 24 weeks (the most recently available analysis from the independent reading center) versus baseline, respectively. Patients treated initially with fixed quarterly dosing also experienced an overall reduction in CNV size.

"Regression in CNV size is generally not seen when treating wet AMD patients. The reduction in CNV size achieved thus far with VEGF Trap-Eye treatment highlights the potential clinical utility of this investigational treatment in patients suffering from this devastating condition," stated Jason Slakter, M.D., Clinical Professor of Ophthalmology, New York University School of Medicine, New York.

"These study results further increase our confidence in the design of our Phase 3 clinical program for VEGF Trap-Eye in wet AMD," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "These studies are evaluating the clinical efficacy and safety of VEGF Trap-Eye, using a monthly loading dose of 0.5 mg or 2.0 mg for 12 weeks, followed by a nine-month fixed-dosing regimen of 0.5 mg monthly, 2.0 mg monthly, or 2.0 mg every eight weeks. In the second year of the studies, all patients will be dosed on a PRN basis."

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, the companies are evaluating VEGF Trap-Eye using four- and eight-week dosing intervals in direct comparison with ranibizumab (Lucentis®, a registered trademark of Genentech, Inc.) administered every four weeks according to its label during the first year of the studies. PRN dosing will be evaluated during the second year of each study. The VIEW1 study is currently enrolling patients in the United States and Canada. The VIEW2 study has recently been initiated and will enroll patients in up to 200 centers 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 and a VEGF inhibitor, ranibizumab, has been approved for treatment of patients with this condition.

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.

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. 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.

* The assessment made by Dr. Nguyen does not necessarily imply endorsement by the Johns Hopkins University, the Johns Hopkins Hospital, or the Johns Hopkins Medical Institutions.

CONTACT: Regeneron Pharmaceuticals, Inc.
Investor Relations, 914-345-7640
invest@regeneron.com
or
Corporate Communications
Laura Lindsay, 914-345-7800
laura.lindsay@regeneron.com
or
Media Relations
Kimberly Chen, 212-845-5634
kchen@biosector2.com

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