February 18, 2010

VEGF Trap-Eye Shows Positive Results in a Phase 2 Study in Patients With Diabetic Macular Edema

- Statistically significant improvement in vision achieved over 24 weeks - Results to be presented at Angiogenesis 2010: Clinical Trials meeting in Miami, Florida on February 20, 2010

TARRYTOWN, N.Y. and LEVERKUSEN, Germany, Feb 18, 2010 /PRNewswire via COMTEX News Network/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) and Bayer HealthCare AG today announced that VEGF Trap-Eye showed positive results in a Phase 2 study in patients with diabetic macular edema (DME). The primary endpoint of the study, a statistically significant improvement in visual acuity over 24 weeks compared to the standard of care in DME, macular laser therapy, was met. Visual acuity improvement was measured by the mean number of letters gained over the initial 24 weeks of the study.

"The ability of VEGF Trap-Eye to significantly improve vision in patients with DME in this initial Phase 2 study is encouraging," said Dr. Kemal Malik, member of the Bayer HealthCare Executive Committee responsible for global development. "Bayer and Regeneron will discuss the next steps in further developing VEGF Trap-Eye in this indication."

"The magnitude of the gain in visual acuity achieved with VEGF Trap-Eye in this Phase 2 study demonstrates the biologic activity of VEGF Trap-Eye in treating diabetic macular edema, a disease in which high levels of vascular endothelial growth factor (VEGF) are present," said Diana Do, MD, the Principal Investigator for the study and Assistant Professor of Ophthalmology at the Wilmer Eye Institute, The Johns Hopkins University School of Medicine in Baltimore, Maryland.

Patients in each of the four dosing groups receiving VEGF Trap-Eye achieved statistically significantly greater mean improvements in visual acuity (8.5 to 11.4 letters of vision gained) compared to patients receiving macular laser therapy (2.5 letters gained) at week 24 ($p < 0.01$ for each VEGF Trap-Eye group versus laser). VEGF Trap-Eye was generally well tolerated, and there were no drug-related serious adverse events.

The results of the Phase 2 study will be presented at the Angiogenesis 2010: Clinical Trials meeting on February 20, 2010 in Miami, Florida. Slides summarizing the data presented will be made available at that time on the Regeneron website (www.regeneron.com on the Presentations Page, under the Investor Relations section).

About the Phase 2 Study Results

In this double-masked, prospective, randomized, multi-center Phase 2 trial, entitled **DA VINCI** (**D**ME **A**nd **V**EGF Trap-Eye: **IN**vestigation of **C**linical Impact), 219 patients with clinically significant DME with central macular involvement were randomized to five groups. The control group received macular laser therapy at week one, and patients were eligible for repeat laser treatments, but no more frequently than at 16 week intervals. Two groups received monthly doses of 0.5 or 2.0 milligrams (mg) of VEGF Trap-Eye throughout the 6-month dosing period. Two groups received three initial monthly doses of 2.0 mg of VEGF Trap-Eye (at baseline and weeks 4 and 8), followed through week 24 by either every 8-week dosing or as-needed (PRN) dosing with specific repeat dosing criteria. The following summarizes the mean gain in visual acuity at week 24 by dosing arm and the mean number of treatments received by patients over the first six monthly visits:

- Standard-of-care macular laser therapy (n=44; 1.7 treatments): +2.5 letters gained
- VEGF Trap Eye 0.5 mg monthly (n=44; 5.6 injections): +8.6 letters gained
- VEGF Trap-Eye 2 mg monthly (n=44; 5.5 injections): +11.4 letters gained
- VEGF Trap-Eye 2 mg every other month, following 3 monthly injections (n=42: 3.8 injections): +8.5 letters gained
- VEGF Trap-Eye 2 mg as-needed, following 3 monthly injections (n=45; 4.4 injections): +10.3 letters gained

The study was not designed to evaluate statistical differences among the results achieved in each of the VEGF Trap-Eye groups, and no significant differences were observed. Over 90 percent of the VEGF Trap-Eye patients and the laser patients remained in the study at the 6-month primary endpoint evaluation.

VEGF Trap-Eye was generally well-tolerated, and there were no ocular or non-ocular drug-related serious adverse events reported in the study. The adverse events reported were those typically associated with intravitreal injections or the underlying disease. The most frequent adverse events reported among patients receiving VEGF Trap-Eye included conjunctival hemorrhage, eye pain, floaters (myodesopsia), ocular redness (hyperemia), and increased intraocular pressure. There were three deaths among the 175 patients treated with VEGF Trap-Eye and none in the 44 patients treated with laser over 6 months. All three patients had underlying risk factors for their cause of death, and the cases were not reported to be drug-

related.

Following the initial 24 weeks of treatment, patients continue to be treated for another 24 weeks on the same dosing regimens. Initial one-year results will be available later this year. Regeneron and Bayer HealthCare are sponsors of the DA VINCI study.

About Diabetic Macular Edema (DME)

Diabetic macular edema (DME) is the most prevalent cause of moderate vision loss in patients with diabetes. DME is a common complication of Diabetic Retinopathy (DR), a disease affecting the blood vessels of the retina. Clinically significant DME is a leading cause of blindness in younger adults (under 50). Clinically significant DME occurs when fluid leaks into the center of the macula, the light-sensitive part of the retina responsible for sharp, direct vision. Fluid in the macula can cause severe vision loss or blindness.

Approximately 370,000 Americans currently suffer from clinically significant DME, with 95,000 new cases arising each year. According to the American Diabetes Association, more than 18 million Americans currently suffer from diabetes, and many other people are at risk for developing diabetes. With the incidence of diabetes steadily climbing, it is projected that up to 10 percent of all patients with diabetes will develop DME during their lifetime.

About VEGF Trap-Eye

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.

VEGF Trap-Eye is currently in Phase 3 development in wet (age-related) macular degeneration (AMD). The **VIEW 1** (**V**EGF Trap-Eye: **I**nvestigation of **E**fficacy and Safety in **W**et AMD) study is being conducted in the United States and Canada by Regeneron and the **VIEW 2** study is being conducted in Europe, Asia Pacific, Japan, and Latin America by Bayer HealthCare. The primary endpoint of these non-inferiority studies is the proportion of patients treated with VEGF Trap-Eye who maintain vision at the end of one year, compared to ranibizumab patients. Patient enrollment has been completed in both studies with initial year-one primary endpoint data expected in the second half of 2010.

VEGF Trap-Eye is also in Phase 3 development for the treatment of central retinal vein occlusion (CRVO), another major cause of blindness. The **COPERNICUS** (**CO**ntrolled **P**hase 3 **E**valuation of **R**epeated i**N**travitreal administration of VEGF Trap-Eye **I**n **C**entral retinal vein occlusion: **U**tility and **S**afety) study is being led by Regeneron, and the **GALILEO** (**G**eneral **A**ssessment **L**imiting **I**nfi**L**tration of **E**xudates in central retinal vein **O**cclusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. Initial data from the CRVO program are anticipated in early 2011.

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(R) (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, age-related macular degeneration, and certain cancers. Additional therapeutic candidates are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

Forward Looking Statement - Regeneron

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, 2008 and Form 10-Q for the quarter ending September 30, 2009. 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.

About Bayer HealthCare Pharmaceuticals

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, Bayer Schering Pharma, Consumer Care and Medical Care divisions. 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 Statements - Bayer HealthCare AG

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup 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 Bayer's public reports which are available on the Bayer website at www.bayer.com. 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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