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# VEGF Trap-Eye Shows Positive Results in Phase II Study in Patients with Diabetic Macular Edema

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

Leverkusen, Germany and Tarrytown, NY, USA, February 18, 2010 - Bayer HealthCare AG and Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced that VEGF Trap-Eye showed positive results in a Phase II 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 treatment, 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 II study is encouraging," said Kemal Malik, MD, Head of Global Development and member of the Bayer HealthCare Executive Committee. "Bayer and Regeneron will discuss the next steps in further developing VEGF Trap-Eye in this indication."

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"The magnitude of the gain in visual acuity achieved with VEGF Trap-Eye in this Phase II 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 and Assistant Head of the Retina Fellowship Training Program 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 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.

A full analysis of the primary endpoint results of the Phase II study will be presented at the Angiogenesis 2010 - Clinical Trials meeting on February 20, 2010 in Miami, Florida. Slides presented will be made available at that time on the Regeneron website ([www.regeneron.com](http://www.regeneron.com) on the Presentations Page, under the Investor Relations section).

#### About the Phase II study

In this double-masked, prospective, randomized, multi-center Phase II trial, entitled DA VINCI (DME And VEGF Trap-Eye: INvestigation of Clinical Impact), 219 patients with clinically significant DME with central macular involvement were randomized to five groups. The control group received macular laser treatment 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

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the first six monthly visits:

- Standard-of-care macular laser treatment (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 control 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 the 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

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## DA VINCI study.

### About Diabetic Macular Edema (DME)

Diabetic Macular Edema is the most prevalent cause of moderate vision loss in patients with diabetes. DME is a common complication of Diabetic Retinopathy, 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 III development in wet (age-related) macular degeneration (AMD). The VIEW 1 (VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet 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 III development for the treatment of Central Retinal Vein Occlusion (CRVO), another major cause of blindness. The

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COPERNICUS (COntrolled Phase III Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study is being led by Regeneron and the GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion 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® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase III clinical trials for the potential treatment of cancer, eye diseases, and gout. 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](http://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, 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](http://www.bayerhealthcare.com).

#### About Bayer Schering Pharma

Bayer Schering Pharma is a worldwide leading specialty pharmaceutical company. Its research and business activities are focused on the following areas: Diagnostic Imaging, General Medicine, Specialty Medicine and Women's Healthcare. With innovative products, Bayer Schering Pharma aims for leading

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