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Investor News

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Bayer and Regeneron Report Positive Results for VEGF Trap-Eye in Second Phase 3 Study in Central Retinal Vein Occlusion

Phase 3 GALILEO study confirms results of previously announced Phase 3 COPERNICUS study

Leverkusen, April 27, 2011 – Bayer HealthCare and Regeneron Pharmaceuticals, Inc. today announced positive top-line results for VEGF Trap-Eye (aflibercept ophthalmic solution) in the Phase 3 GALILEO study in patients with macular edema due to central retinal vein occlusion (CRVO). The positive results from the GALILEO study confirm the results of the similarly designed Phase 3 COPERNICUS study that were announced in December 2010.

In GALILEO, the primary endpoint at week 24 was achieved: 60.2 percent of patients receiving monthly VEGF Trap-Eye 2 milligrams (mg) gained at least 15 letters of vision from baseline, compared to 22.1 percent of patients receiving sham injections ($p<0.0001$). The key secondary endpoint of the study was also met: patients receiving VEGF Trap-Eye 2mg monthly gained, on average, 18 letters of vision compared to a mean gain of 3.3 letters with sham injections ($p<0.0001$).

“After reporting positive results from the VIEW 1 and VIEW 2 Phase 3 studies for the treatment of the neovascular form of age-related macular degeneration, or wet AMD, we are very pleased to now also have two positive Phase 3 trials with VEGF Trap-Eye in central retinal vein occlusion,” said Kemal Malik, M.D., Head of Global Development and member of the Bayer HealthCare Executive Committee.

“With two Phase 3 trials showing impressive improvement in vision relative to control, VEGF Trap-Eye has the potential to provide patients and physicians a new treatment option for central retinal vein occlusion,” said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories.

As in the COPERNICUS trial, VEGF Trap-Eye was generally well tolerated in the GALILEO study and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. The incidence of ocular serious adverse events was higher in the sham group compared to the active treatment arm (8.8% vs. 2.9%).

Regeneron intends to submit a regulatory application for marketing approval in CRVO in the U.S. in the second half of 2011, and Bayer HealthCare is planning to submit regulatory applications in Europe in 2012.

Detailed results of the GALILEO study will be presented at the EURETINA Congress in London in May, 2011.

About the Phase 3 CRVO Program

Patients in the COPERNICUS (Controlled Phase 3 Evaluation of Repeated intravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) and the almost identical GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) studies received six monthly injections of either VEGF Trap-Eye at a dose of 2mg or sham injections.

Patients in both trials were randomized in a 3:2 ratio with 114 patients randomized to receive VEGF Trap-Eye and 73 randomized to the control arm in COPERNICUS and 104 patients randomized to receive VEGF Trap-Eye and 68 randomized to the control arm in GALILEO. At the end of the initial six months, all patients randomized to VEGF Trap-Eye are dosed on a PRN (as needed) basis for another six months. In the COPERNICUS trial, patients randomized to sham injections in the first six months were eligible to cross over to VEGF Trap-Eye PRN dosing in the second six months. During the second six months of the studies, all patients are eligible for rescue laser treatment. Visual acuity is measured as a score based on the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart, a standard chart used in research to measure visual acuity.

Phase 3 GALILEO Study Results

In the GALILEO study, 60.2 percent of patients receiving VEGF Trap-Eye 2mg monthly gained at least 15 letters of vision from baseline, compared to 22.1 percent of patients receiving sham injections ($p<0.0001$), the primary endpoint of the study. Patients

receiving VEGF Trap-Eye 2mg monthly gained, on average, 18 letters of vision compared to a mean gain of 3.3 letters with sham injections ($p<0.0001$), a secondary endpoint.

VEGF Trap-Eye was generally well tolerated and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the VEGF Trap-Eye group were 2.9 percent and were more frequent in the control group (8.8 percent). The most frequently reported adverse events overall in the VEGF Trap-Eye arm were eye pain, conjunctival hemorrhage and elevated intraocular pressure. The most frequently reported adverse events in the control group were macular edema, eye irritation and reduction of visual acuity. The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. The most frequent non-ocular adverse events were headache and nasopharyngitis. There were no deaths in the study.

About Central Retinal Vein Occlusion (CRVO)

Over 100,000 people in the United States and more than 66,000 people in key European countries are estimated to suffer from CRVO. CRVO is caused by obstruction of the central retinal vein that leads to a back up of blood and fluid in the retina. This causes retinal injury and loss of vision. The retina can also become "ischemic" (starved for oxygen), resulting in the growth of new, inappropriate blood vessels that can cause further vision loss and more serious complications. Release of vascular endothelial growth factor (VEGF) contributes to increased vascular permeability in the eye and inappropriate new vessel growth. It is believed that anti-VEGF treatment may help decrease vascular permeability and edema and prevent the inappropriate growth of new blood vessels in the retina in patients with CRVO.

About VEGF Trap-Eye

VEGF Trap-Eye is a fully human fusion protein, consisting of soluble VEGF receptors 1 and 2, 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 specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

Bayer HealthCare and Regeneron are collaborating on the global development of VEGF Trap-Eye for the treatment of the neovascular form of age related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), diabetic macular edema (DME), and other eye diseases and disorders.

Regeneron submitted a Biologics License Application (BLA) for marketing approval in wet AMD in the U.S. in February 2011 and received a Priority Review designation. Under Priority Review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011. Bayer plans to file regulatory submissions in Europe in the second quarter of 2011.

In April 2011, Bayer HealthCare and Regeneron announced the initiation of a Phase 3 program in DME.

Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally the profits from any future sales of VEGF Trap-Eye. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

About Regeneron Pharmaceuticals

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 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration, central retinal vein occlusion and diabetic macular edema), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at 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 subgroup of Bayer AG with annual sales of more than EUR 16.913 billion (2010), 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, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55.700 employees and is

represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

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Regeneron Forward Looking Statement
This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron, and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's product candidates and research and clinical programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's product and drug candidates, competing drugs that may be 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 license or collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property and pending or future litigation relating thereto. 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, including its Form 10-K for the year ended December 31, 2010. 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.

Bayer Forward-Looking Statement
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.