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Investor News

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Bayer and Regeneron Announce Start of Phase 3 Clinical Program in Diabetic Macular Edema

Extends ophthalmology research & development program for VEGF Trap-Eye

Leverkusen, April 8, 2011 – Bayer HealthCare and Regeneron Pharmaceuticals, Inc. today announced that they have initiated the first of two Phase 3 clinical trials evaluating the efficacy and safety of VEGF Trap-Eye (aflibercept ophthalmic solution), an investigational new agent for the treatment of certain eye diseases, in the treatment of Diabetic Macular Edema (DME). The companies are extending their development program for VEGF Trap-Eye in DME after promising results in the global Phase 2 DME program.

The first Phase 3 trial in DME, named VIVID-DME, is being led by Bayer HealthCare and has started in Australia. The trial will also be conducted in Europe and Japan. A second study led by Regeneron, named VISTA-DME, is expected to begin later in 2011 in the United States, Canada, and other countries.

“Clinically significant DME is a leading cause of vision loss in adults under the age of 50 suffering from diabetes,” said Dr. Kemal Malik, Head of Global Development and member of the Bayer HealthCare Executive Committee. “After reporting positive results from our global Phase 3 program (VIEW 1 and VIEW 2 studies) for the treatment of the neovascular form of age-related macular degeneration (wet AMD), we are pleased to start a Phase 3 program with VEGF Trap-Eye in DME which may help to address this significant unmet medical need.”

The Phase 3 program in DME expands the companies’ global development collaboration for VEGF Trap-Eye. The companies announced positive data for two Phase 3 studies in patients with wet AMD in November 2010 and for the first of two Phase 3 studies in patients with Central Retinal Vein Occlusion (CRVO) in December 2010.

About the Phase 3 DME Program
The VIVID-DME study (**V**EGF Trap-Eye **I**n **V**ision **I**mpairment **D**ue to **DME**) has three study arms. In the first arm, patients will be treated every month with 2 milligrams (mg) of VEGF Trap-Eye. In the second arm, patients will be treated with 2mg of VEGF Trap-Eye every two months after a loading phase of monthly injections. In the third arm, the comparator arm, patients will be treated with macular laser photocoagulation. The primary endpoint is mean change in visual acuity from baseline as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart, a standard chart used in research to measure visual acuity. All patients will be followed for three years.
The VISTA-DME study (**V**EGF Trap-Eye: **I**nvestigation of **S**afety, **T**reatment effect, and **A**natomic outcomes in **DME**) is expected to begin later in 2011.

About Diabetic Macular Edema (DME)
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.

According to figures from the World Health Organization, DME is the second leading cause of blindness in Western industrialized countries. In Europe, about 8% of the population is affected by DME. This figure in Germany is around 4%, with a rising tendency, and is thus the most common cause of blindness in people of working age, ie: between the ages of 30 to 60. In Germany, about 40,000 diabetic patients go blind each year, whereby the risk of blindness in diabetics is 25 times higher than in non-diabetics. Approximately 370,000 Americans currently suffer from clinically significant DME, with 95,000 new cases arising each year. According to the American Diabetes Association, over 18 million Americans currently suffer from diabetes, and many more are at risk for developing diabetes. The incidence of diabetes is steadily climbing and it is projected that up to 10 percent of all patients with diabetes will develop DME during their lifetime.

About VEGF Trap-Eye
Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body. Its normal role in a healthy organism is to trigger formation of new blood vessels (angiogenesis) supporting the growth of the body's tissues and organs. However, in

certain diseases, such as diabetes, it is also associated with the growth of abnormal new blood vessels in the eye exhibiting vascular permeability and leading to edema. VEGF Trap-Eye is a fully human, soluble VEGF receptor fusion protein that binds all forms of VEGF-A along with another vascular growth factor, the Placental Growth Factor (PlGF). VEGF Trap-Eye is a specific and highly potent blocker of VEGF-A and PlGF that has been demonstrated in preclinical models to bind these growth factors with greater affinity than their natural receptors. Regeneron and Bayer HealthCare are collaborating on the global development of VEGF Trap-Eye. 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.

Regeneron submitted a Biologics License Application for marketing approval in wet age-related macular degeneration (wet AMD) in the US in February 2011, and Bayer plans to submit a regulatory application outside the US in the first half of 2011. Phase 3 studies in central retinal vein occlusion (CRVO) and in patients with choroidal neovascularisation (CNV) of the retina as a result of pathologic myopia - a major eye disease common in Asia - are currently underway.

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 and central retinal vein occlusion), 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 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 (Dec 31, 2010) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

To learn more about Age-related macular degeneration (AMD), please visit: www.bayerpharma.com/en/AMD

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Regeneron Forward Looking Statement
This news release includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties. These include, among others, risks and timing 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 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. 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, 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.

Forward-Looking Statements
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.