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Investor News

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Two year results of Phase III Studies with VEGF Trap-Eye in Wet Age-related Macular Degeneration Show Sustained Improvement in Visual Acuity

- Patients receiving VEGF Trap-Eye 2mg every other month achieved visual acuity gains similar to ranibizumab with, on average, five fewer injections over two years
- Patients who required the most intense therapy, on average, received 1.4 fewer injections in the VEGF Trap-Eye 2mg every other month group compared to the ranibizumab group in the second year

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Leverkusen, December 5, 2011 – Bayer HealthCare and Regeneron Pharmaceuticals, Inc. today announced that in an integrated analysis of two parallel Phase III studies (VIEW 1 and VIEW 2) in patients with the neovascular form of age-related macular degeneration (wet AMD), patients treated with VEGF Trap-Eye showed a sustained improvement in visual acuity at 96 weeks versus baseline. The 52 week results (primary analyses) from these studies have previously been reported. The VEGF Trap-Eye 2mg every eight weeks regimen was recently approved by the U.S. Food and Drug Administration (FDA).

During the first year of the VIEW 1 and VIEW 2 studies, patients were treated with three different dosing regimens of VEGF Trap-Eye, 0.5 milligram (mg) every four weeks, 2mg every four weeks, and 2mg every other month (following three initial monthly injections), compared to ranibizumab 0.5mg every four weeks. In the second year of the studies, patients were treated with the same dose per injection as in the first year and were evaluated monthly to determine need for retreatment. Patients were treated at least every 12 weeks. All year two analyses were considered exploratory.

In an integrated analysis of the VIEW 1 and VIEW 2 studies, the visual acuity gain from baseline in the VEGF Trap-Eye 2mg every other month group at week 96 was 7.6 letters compared to 8.4 letters at week 52, with an average of 11.2 injections over two years and

4.2 injections during the second year. The visual acuity gain from baseline in the monthly ranibizumab group at week 96 was 7.9 letters compared to 8.7 letters at week 52, with an average of 16.5 injections over two years and 4.7 injections during the second year. The results of each of the VIEW 1 and VIEW 2 studies were consistent with the integrated analysis.

The overall fewer average number of injections in the second year in the VEGF Trap-Eye 2mg every two months group compared to the ranibizumab group (4.2 versus 4.7) was driven by the fact that fewer patients needed more intense therapy in the VEGF Trap-Eye 2mg every two months group and those patients required fewer injections. The proportion of patients who required frequent injections (six or more) during the second year was lower in the VEGF Trap-Eye 2mg every two months group compared to the ranibizumab group (15.9% versus 26.5%). In the 25% of patients who required the most intense therapy (the greatest number of injections), patients in the VEGF Trap-Eye 2mg every two months group required an average of 1.4 fewer injections in the second year compared to the ranibizumab group (6.6 versus 8.0). In the 25% of patients in each group who had the fewest number of injections in the second year, the average number of injections was similar (approximately 3 for both groups, corresponding to the protocol-mandated minimum number of injections).

A generally favorable safety profile was observed for both VEGF Trap-Eye and ranibizumab. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies, with the most frequent events associated with the injection procedure, the underlying disease and/or the aging process. The most frequent ocular adverse events (greater 10% of patients for the overall study population) were conjunctival hemorrhage, eye pain, retinal hemorrhage, and visual acuity reduced. The most frequent serious non-ocular adverse events were typical of those reported in this elderly population who receive intravitreal treatment for wet AMD; the most frequently reported events (greater than 1% of patients for the overall study population) were falls, pneumonia, myocardial infarction and atrial fibrillation. There were no notable differences among the study arms. The incidence of arterial thrombotic events as defined by the “Anti-Platelet Trialists” group criteria was 3.2% for ranibizumab and 3.3% in the combined VEGF Trap-Eye groups.

“The VIEW 1 and VIEW 2 studies confirmed that the treatment effect seen with VEGF Trap-Eye at the end of one year is sustainable even with fewer injections in the second year”, said Dr Kemal Malik, Member of the Bayer HealthCare Executive Committee and

Chief Medical Officer. “Less frequent office visits, predictable every other month dosing in the first year and fewer injections in the second year may have the potential to significantly reduce the burden for patients.”

Further results from year two of the studies will be presented at upcoming medical conferences in 2012.

Regeneron and Bayer HealthCare are collaborating on the global development of VEGF Trap-Eye for the treatment of wet AMD, central retinal vein occlusion (CRVO), diabetic macular edema (DME), and other eye diseases and disorders. Bayer submitted an application for marketing authorization in Europe and Japan in wet AMD in the first half of 2011.

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 EYLEA in the United States.

About the VIEW Program

The VIEW (VEGF Trap: Investigation of Efficacy and Safety in Wet AMD) program consists of two randomized, double-masked, Phase III clinical trials evaluating VEGF Trap-Eye in the treatment of the neovascular form of age-related macular degeneration (wet AMD). The VIEW 1 study, which randomized 1217 patients, was conducted in the United States and Canada by Regeneron. The VIEW 2 study, which randomized 1240 patients, was conducted in Europe, Asia Pacific, Japan and Latin America by Bayer HealthCare. The study designs are essentially identical. The primary endpoint evaluation was conducted at 52 weeks.

About Wet AMD

Age-related Macular Degeneration (AMD) is a leading cause of acquired blindness. Macular degeneration is diagnosed as either dry (non-exudative) 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 VEGF Trap-Eye (aflibercept)

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 wet age-related macular degeneration, it is also associated with the growth of abnormal new blood vessels in the eye, which exhibit abnormal increased permeability that leads to edema. Scarring and loss of fine-resolution central vision often results.

VEGF Trap-Eye is a recombinant fusion protein consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 and formulated as an iso-osmotic solution for intravitreal administration. VEGF Trap-Eye acts as a soluble decoy receptor that binds VEGF-A and placental growth factor (PlGF), and thereby can inhibit the binding and activation of these cognate VEGF receptors.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets two products, ARCALYST® (rilonacept) Injection For Subcutaneous Use and EYLEA™ (aflibercept) Injection. Regeneron also has completed several Phase 3 studies and is conducting an additional Phase 3 clinical trial for the product candidate ZALTRAP® (aflibercept) Concentrate for Intravenous Infusion. 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 the Regeneron 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 16.9 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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Bayer Forward-Looking Statements
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