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Investor News

Not intended for U.S. and UK media

VEGF Trap-Eye Submitted for Marketing Authorization for the Treatment of Wet Age-Related Macular Degeneration in Japan

Leverkusen, June 29, 2011 – Bayer HealthCare and Regeneron Pharmaceuticals, Inc. today announced that Bayer Yakuhin, Ltd., Osaka, Japan, has submitted an application to the Ministry of Health, Labour and Welfare (MHLW) in Japan for marketing authorization for VEGF Trap-Eye (aflibercept ophthalmic solution) for the treatment of the neovascular form of age-related macular degeneration (wet AMD). Bayer HealthCare and Regeneron 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 myopic choroidal neovascularization (mCNV).

“It is our pleasure that we were able to file VEGF Trap-Eye in wet AMD in Japan almost simultaneously to the European submission. We hope to allow Japanese patients to benefit from VEGF Trap-Eye as a new treatment option with the potential of fewer injections and reduced overall burden,” said Erik Louvel, M.D., Operating Officer and Head of Product Development Department at Bayer Yakuhin.

In Japan, age-related macular degeneration (AMD) is the 4th most common cause of acquired blindness and the number of patients is increasing. The research conducted in 2007 targeting residents in Hisayama, Fukuoka, shows that 1.2% of residents over the age of 50 had wet AMD in at least one eye. Extrapolating from this study, the number of patients in Japan estimated to have wet AMD eligible for treatment with anti-VEGF therapy is approximately 700,000.

The submission to MHLW is based on the positive results from two Phase III trials, the VIEW 1 study conducted in North America and the VIEW 2 study conducted in Japan, Europe and other countries. In these trials, all regimens of VEGF Trap-Eye, including 2 milligrams (mg) dosed every two months (following three initial monthly doses), successfully met the primary endpoint of statistical non-inferiority compared to the current

standard of care, ranibizumab 0.5 mg dosed every month, in the proportion of patients who maintained (or improved) vision over 52 weeks. A generally favorable safety profile was observed for both VEGF Trap-Eye and ranibizumab. Ocular adverse events were balanced across all treatment groups in both studies. There were no notable differences in non-ocular adverse events between the study arms.

VEGF Trap-Eye was submitted for marketing approval for the treatment of wet AMD in the U.S. in February 2011 by Regeneron and in Europe in June 2011 by Bayer HealthCare.

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 the VIEW Program

The VIEW (VEGF Trap-Eye: 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 1,217 patients, is being conducted in the United States and Canada by Regeneron under a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration. The VIEW 2 study, which randomized 1,240 patients, is being 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.

In each of the studies, VEGF Trap-Eye was evaluated for its effect on maintaining and improving vision when dosed as an intravitreal injection on a schedule of 0.5 mg monthly, 2 mg monthly, or 2 mg every two months (following three monthly loading doses), as compared with intravitreal ranibizumab administered 0.5 mg every month during the first year of the studies. As-needed (PRN) dosing with both agents, with a dose administered at least every three months (but not more often than monthly) is being evaluated during the second year of each study.

About VEGF Trap-Eye

VEGF Trap-Eye is a fully human fusion protein, consisting of portions of 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.

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 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.

About Bayer Yakuhin, Ltd.

Bayer Yakuhin Ltd., headquartered in Osaka, is a healthcare company which combines business activities of pharmaceuticals, dermatology, Consumer Care (OTC product) and Animal Health (companion and food animal products). Pharmaceuticals business is focused on the following areas: Diagnostic Imaging, General Medicine, Oncology, Specialty Medicine and Women's Healthcare. Bayer Yakuhin aims to be one of leading pharmaceutical companies, which responds to Japanese patients' unmet medical needs, with the spirit of Bayer's corporate slogan "Science For A Better Life".
Bayer Yakuhin homepage: http://www.bayer.co.jp/byl

Find more information at www.bayerpharma.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.