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Regeneron and Bayer Start Phase 3 Trial to Extend Ophthalmology Research & Development Program for VEGF Trap-Eye in Asia

Collaboration with the Singapore Eye Research Institute to tackle a major eye disease common in Asia

TARRYTOWN, N.Y., BERLIN and SINGAPORE, Jan. 18, 2011 /PRNewswire/ -- Regeneron (Nasdaq: REGN) and Bayer HealthCare today announced initiation of a new Phase 3 clinical trial in collaboration with the Singapore Eye Research Institute (SERI) investigating the efficacy and safety of VEGF Trap-Eye (aflibercept ophthalmic solution) in patients with choroidal neovascularisation (CNV) of the retina as a result of pathologic myopia. The trial has started in Japan and other Asian countries, including China, Korea, Singapore, and Taiwan.

Myopia is one of the most common eye conditions and is highly prevalent in Asian populations, including Singapore where 40% of adults have myopia and nearly 10% have high myopia. Myopic CNV is a complication of high myopia where abnormal blood vessels grow and leak blood and fluid into the retina as a result of degenerative changes in the retinal lining of the eye and is a potentially blinding condition. Currently, there is no well-established treatment for myopic CNV. VEGF Trap-Eye has previously met its primary efficacy endpoint in a Phase 3 trial for neovascular (wet) age-related macular degeneration (AMD).

Collaboration with the Singapore Eye Research Institute (SERI)

SERI has been appointed as the Asian reading center partner for this study. The Singapore Advanced Imaging Laboratory for Ocular Research (SAILOR) will serve as the first reading center for VEGF Trap-Eye studies in the region. SAILOR brings together an inter-disciplinary group of clinician researchers and scientists to collaborate on cutting-edge computer image research. SAILOR is the first clinical translational research unit to be located in Fusionopolis, a research and development complex in Singapore, and serves as a hub of translational research programs in ocular imaging among clinicians, scientists, computer scientists, and other experts. One of the major programs SAILOR has developed is a "tele-ophthalmic ocular imaging platform" to allow transfer and data capture of ocular images for diagnosis and screening. SAILOR will read the images for this myopic CNV trial from the different Asian sites.

"Myopia is a common problem in Singapore and Asia. In particular, myopic CNV, which affects certain groups of people with higher degrees of myopia, may lead to vision loss. There remains uncertainty regarding the best methods of treatment for myopic CNV and this new trial will go towards addressing this clinical need," said Prof. Wong Tien Yin, Director of SERI and Co-Director of SAILOR.

About mCNV

Myopic choroidal neovascularization is a disease of the retina where new, abnormal blood vessels grow into the retina in persons who are severely myopic (typically more than minus six diopters) and have pathological changes in the back of the eye. In myopic patients, the eyeball is too long, which puts strain on the retina and leads to those pathological changes. Anti-VEGF treatment has been shown to be effective in wet age-related macular degeneration, which is also characterised by the growth of new, abnormal blood vessels in the retina. Severe myopia is particularly common in Asia, with some scientists believing that it may be generally more common in Asians than in people from European descent. Myopic CNV (mCNV) is associated with high degrees of myopia and leads to progressive loss of the patient's sight, ending in blindness. In East Asia, the prevalence of myopia is significantly higher than in the West Asia, and seems to have an earlier onset. In Japan, mCNV is the second most common cause of blindness.

About the mCNV Trial

The Phase 3 myopic CNV trial, named MYRROR, will enroll approximately 250 patients and has started in Japan. Other Asian countries, including Singapore, China, Korea, and Taiwan, will join this clinical study throughout the year. Three out of four patients in the trial will receive an injection of VEGF Trap-Eye into the affected eye (and repeated injections on a PRN, as needed, basis, if required). One out of four patients will receive a sham procedure. The clinical outcome of the two treatment groups after 24 weeks will be assessed by a different team of doctors who are unaware of what treatment the patients received. From week 24 onward, sham patients may receive active treatment. The primary outcome measure of the trial is the mean change in vision (best corrected visual acuity) after 24 weeks, compared to baseline. Secondary outcome measures include the percentage of patients who gain or lose certain amounts of letters in the visual test, changes in retinal thickness from baseline, changes in the total mCNV lesion size, and vessel leakage as seen on an angiogram of the affected eye. The study is scheduled to run until June 2013.

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), diabetic macular edema (DME), central retinal vein occlusion (CRVO), and other eye diseases and disorders.

In November 2010, Regeneron and Bayer HealthCare announced positive top-line results from two parallel Phase 3 studies in patients with wet AMD, VIEW 1 and VIEW 2. In these trials, all regimens of VEGF Trap-Eye, including VEGF Trap-Eye dosed every two months, successfully met the primary endpoint compared to the current standard of care, ranibizumab dosed every month. The primary endpoint was statistical non-inferiority in the proportion of patients who maintained (or improved) vision over 52 weeks compared to ranibizumab. 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. There were no notable differences in non-ocular adverse events among the study arms. Bayer HealthCare and Regeneron are planning to submit regulatory applications for marketing approval for the treatment of wet AMD in Europe and the U.S. in the first half of 2011.

Trials in other indications such as CRVO and DME are currently underway or in preparation.

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.

About Singapore Eye Research Institute (SERI)

SERI is the national research institute for ophthalmic and vision research in Singapore. Serving as the research institute of the Singapore National Eye Centre, and affiliated to the Yong Loo Lin School of Medicine, National University of Singapore, as well the Duke-NUS Graduate Medical School, SERI undertakes vision research in collaboration with local clinical ophthalmic centers and biomedical research institutions, as well as major eye centers and research institutes throughout the world. For further information, kindly visit www.seri.com.sg.

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 15,988 million (2009), 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 53.400 employees and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

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, Bayer HealthCare, and Astellas 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, 2009 and Form 10-Q for the quarter ended September 30, 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 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.

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