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Investor News

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VEGF Trap-Eye in myopic choroidal neovascularization:

Bayer and Regeneron start clinical Phase III 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

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Leverkusen, January 18, 2011 – Bayer HealthCare and Regeneron Pharmaceuticals today announced initiation of a new Phase III 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, named MYRROR, has started in Japan and will start in other Asian countries, including China, Korea Singapore and Taiwan.

Myopia is one of the most common eye conditions and is highly prevalent in Asian countries such as Singapore and Japan, where around 40% of adults have myopia and nearly 10% of these 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 III trial for neovascular (wet) age-related macular degeneration (AMD).

”With this study, we hope to show the efficacy of VEGF Trap-Eye in combating yet another important cause of vision loss, myopic choroidal neovascularization (CNV). This particular unmet medical need is of importance in Asia and this study further demonstrates Bayer’s commitment to ophthalmology and to this region,” said Rupert

Sandbrink, Vice President, Global Clinical Development in the therapeutic area of ophthalmology at Bayer.

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, 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.

According to the World Health Organization, Asia has the biggest burden of world blindness (53%) mostly affecting the elderly and children, yet, three-quarters of all blindness can be prevented or treated.

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 dioptres) 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 (wet AMD), which is also characterised by the growth of new, abnormal blood vessels in the retina.

Severe myopia is particularly common in Asia. Myopic CNV 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

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), and 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

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, 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.

Recent results from two large Phase III trials with VEGF Trap-Eye in wet age related macular degeneration (wet AMD) have been very encouraging. Injections of VEGF Trap-Eye every other month were demonstrated to be non-inferior to monthly injections with the standard of care, ranibizumab. Bayer and Regeneron plan to file regulatory submissions for marketing approval in this indication in the first half of 2011. Trials in

other indications such as central retinal vein occlusion (CRVO) and diabetic macular oedema (DME) are currently underway or in preparation.

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 centres 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 III 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.

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

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