FDA Grants Priority Review for VEGF Trap-Eye for the Treatment of Wet Age-Related Macular Degeneration

April 18, 2011

TARRYTOWN, N.Y., April 18, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's Biologics License Application (BLA) for VEGF Trap-Eye for the treatment of the neovascular form of age-related macular degeneration (wet AMD). The FDA also granted the Company's request for priority review of its BLA. A Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. Under priority review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011.

"We are very pleased that the FDA has chosen to grant priority review to VEGF Trap-Eye. We look forward to working closely with the FDA to achieve our goal of bringing a new treatment option that offers a major advance to patients with age-related macular degeneration," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron.

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, which exhibit vascular permeability and lead to edema. VEGF Trap-Eye is a fusion protein consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1. VEGF Trap-Eye 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.

Regeneron and Bayer HealthCare are collaborating on the development of VEGF Trap-Eye for the treatment of wet AMD, central retinal vein occlusion, diabetic macular edema, myopic choroidal neovascularisation, and other eye diseases and disorders. Bayer HealthCare intends to submit a regulatory application outside of the United States in the first half of 2011. If approved by regulatory authorities, 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 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.

Forward Looking Statements

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 our product candidates and research and clinical programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our product and drug candidates, competing drugs that may be superior to our product and drug candidates, uncertainty of market acceptance of our 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 our 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, 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.

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