

# FDA Schedules Advisory Committee Meeting to Discuss BLA for VEGF Trap-Eye for the Treatment of Wet Age-Related Macular Degeneration

May 23, 2011

TARRYTOWN, N.Y. May 23, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced that the U.S. Food and Drug Administration (FDA) has informed the company that it has scheduled a Dermatologic and Ophthalmic Drugs Advisory Committee Meeting to be held on June 17, 2011 to discuss 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). Under Section 505 of the Federal Food, Drug, and Cosmetic Act, absent special circumstances, all new chemical entities, such as VEGF Trap-Eye, are referred to an advisory committee for review.

Regeneron submitted a Biologics License Application for marketing approval in wet AMD in the U.S. in February 2011 and received a Priority Review designation. Under priority review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011.

Further information on the advisory committee meeting can be found in the Federal Register at

http://www.accessdata.fda.gov/scripts/oc/ohrms/advdisplay.cfm

### **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 age-related macular degeneration, 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 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 (PIGF). 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 global development of VEGF Trap-Eye for the treatment of the neovascular form of age related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), diabetic macular edema (DME), and other eye diseases and disorders. Bayer plans to file regulatory submissions in Europe in the second quarter 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 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, 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 <a href="https://www.regeneron.com">www.regeneron.com</a>.

## **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 its 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 and Form 10-Q for the quarter ended March 31, 2011. 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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