



Regeneron Announces EYLEA™ (afibercept ophthalmic solution) Receives Unanimous Recommendation for Approval for Treatment of Wet AMD from FDA Advisory Committee

June 17, 2011

TARRYTOWN, N.Y., June 17, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced that the Dermatologic and Ophthalmic Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) has voted unanimously to recommend that the FDA approve EYLEA™, also known as VEGF Trap-Eye, for the treatment of the neovascular form of age-related macular degeneration (wet AMD) at a dose of 2 milligrams (mg) every eight weeks, following three initial doses given every four weeks.

The committee's recommendation will be considered by the FDA in its review of the Biologics License Application (BLA) for EYLEA, but the committee's recommendation is not binding on the FDA. Regeneron submitted a BLA 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 EYLEA BLA is August 20, 2011.

"The positive recommendation by the advisory committee is an important step toward providing wet AMD patients with a new treatment option that could potentially reduce the burden that exists with current therapies," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "We look forward to continuing to work with the FDA as it completes its evaluation of the EYLEA BLA."

About EYLEA

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.

EYLEA (afibercept ophthalmic solution), also known as 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). EYLEA is a specific and highly potent blocker of these growth factors. EYLEA 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 EYLEA 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 submitted an application for marketing authorization in Europe in wet AMD in June 2011.

The EYLEA wet AMD regulatory submissions are based on the positive results from two Phase 3 trials, the VIEW 1 study and the VIEW 2 study. In these trials, all regimens of EYLEA, including 2 milligrams (mg) of EYLEA dosed every two months (following three loading doses), successfully met the primary endpoint of non-inferiority compared to the current standard of care, ranibizumab 0.5 mg dosed every month. The primary endpoint analysis 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 EYLEA and ranibizumab. The most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters.

Bayer HealthCare will market EYLEA™ outside the United States, where the companies will share equally the profits from any future sales of EYLEA. Regeneron maintains exclusive rights to EYLEA 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 www.regeneron.com.

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 Sanofi 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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