



## **Regeneron Announces Review of Biologics License Application for EYLEA™ (afibercept injection) Extended by Three Months by FDA**

August 16, 2011

TARRYTOWN, N.Y., Aug. 16, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced that it has received notification from the U.S. Food and Drug Administration (FDA) that the agency has extended its target date to complete the priority review of the EYLEA Biologics License Application (BLA) for the treatment of neovascular age-related macular degeneration (wet AMD) to November 18, 2011, which is a three month extension from the original Prescription Drug User Fee Act (PDUFA) action date.

The extension is a result of the agency classifying recent responses to questions regarding the chemistry, manufacturing, and controls (CMC) section of the BLA as a major amendment to the BLA. The new action date will give the agency additional time to review the information submitted.

### **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 injection) for intravitreal use, 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 neovascular 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.

Bayer HealthCare will market EYLEA™ (afibercept injection) 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.

### **Conference Call Information**

Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron, and other members of senior management will host a conference call to discuss the extension of the review period for EYLEA BLA for the treatment of patients with wet AMD, as well as other corporate matters. The interactive call will be held on August 17, 2011 at 8:30 a.m. Eastern Time and can be accessed live through the Regeneron website at [www.regeneron.com](http://www.regeneron.com) on the Investor Relations page. The call, including the question and answer session, can also be accessed by dialing:

Domestic Dial-in Number: (888) 660-6127

International Dial-in Number: (973) 890-8355

Participant Passcode: 92316573

An archived version of the conference call will be available for 30 days on the company's website at [www.regeneron.com](http://www.regeneron.com) on the Investor Relations page.

### **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](http://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 June 30, 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.

**Contact Information:**

Michael Aberman, M.D.	Peter Dworkin
Investor Relations	Corporate Communications
914.345.7799	914.345.7640
<a href="mailto:michael.aberman@regeneron.com">michael.aberman@regeneron.com</a>	<a href="mailto:peter.dworkin@regeneron.com">peter.dworkin@regeneron.com</a>

SOURCE Regeneron Pharmaceuticals, Inc.

News Provided by Acquire Media