



## **EYLEA™ (aflibercept injection) Submitted in Japan for Marketing Authorization for the Treatment of Wet Age-Related Macular Degeneration**

June 29, 2011

TARRYTOWN, N.Y. and BERLIN, June 28, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Bayer HealthCare today announced that Bayer Yakuin, Ltd., Osaka, Japan, has submitted an application to the Ministry of Health, Labor and Welfare (MHLW) in Japan for marketing authorization for EYLEA™, also known as VEGF Trap-Eye, for the treatment of the neovascular form of age-related macular degeneration (wet AMD). Regeneron and Bayer HealthCare are collaborating on the global development of EYLEA for the treatment of wet AMD, central retinal vein occlusion (CRVO), diabetic macular edema (DME), and myopic choroidal neovascularization (mCNV).

"The submission of EYLEA for marketing authorization in Japan so soon after our European submission confirms Bayer's and our commitment to bringing this potentially important new therapy to wet AMD patients across the globe," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron.

The submission to MHLW is based on the positive results from two Phase 3 trials, the VIEW 1 study conducted in North America and the VIEW 2 study conducted in Japan, Europe, and other countries. In these trials, all regimens of EYLEA, including 2 milligrams (mg) dosed every two months (following three initial monthly doses), successfully met the primary endpoint of statistical non-inferiority compared to the current standard of care, ranibizumab 0.5 mg dosed every month, in the proportion of patients who maintained (or improved) vision over 52 weeks. 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, which were balanced across all treatment groups in both studies. There were no notable differences in non-ocular adverse events among the study arms.

EYLEA was submitted for marketing approval for the treatment of wet AMD in the U.S. in February 2011 by Regeneron and in Europe in June 2011 by Bayer HealthCare.

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 the VIEW Program**

The VIEW (VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD) program consists of two randomized, double-masked, Phase 3 clinical trials evaluating EYLEA™ in the treatment of the neovascular form of age-related macular degeneration (wet AMD). The VIEW 1 study, which randomized 1,217 patients, is being conducted in the United States and Canada by Regeneron under a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration. The VIEW 2 study, which randomized 1,240 patients, is being conducted in Europe, Asia Pacific, Japan, and Latin America by Bayer HealthCare. The study designs are essentially identical. The primary endpoint evaluation was conducted at 52 weeks.

In each of the studies, EYLEA was evaluated for its effect on maintaining and improving vision when dosed as an intravitreal injection on a schedule of 0.5 mg monthly, 2 mg monthly, or 2 mg every two months (following three monthly loading doses), as compared with intravitreal ranibizumab administered 0.5 mg every month during the first year of the studies. As-needed (PRN) dosing with both agents, with a dose administered at least every three months (but not more often than monthly), is being evaluated during the second year of each study.

### **About EYLEA**

EYLEA 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 with Phase 3 programs for the treatment of the neovascular form of age-related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), diabetic macular edema (DME), myopic choroidal neovascularization (mCNV).

Regeneron submitted a Biologics License Application (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. Bayer HealthCare submitted an application for marketing authorization in Europe in June 2011.

### **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).

### **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 more than EUR 16.913 billion (2010), 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 55,700 employees and is represented in more than 100 countries. Find more information at [www.bayerhealthcare.com](http://www.bayerhealthcare.com).

#### **About Bayer Yakuhin, Ltd.**

Bayer Yakuhin Ltd., headquartered in Osaka, Japan, is a healthcare company which combines business activities of pharmaceuticals, dermatology, Consumer Care (OTC product) and Animal Health (companion and food animal products). The Pharmaceuticals business is focused on the following areas: Diagnostic Imaging, General Medicine, Oncology, Specialty Medicine and Women's Healthcare. Bayer Yakuhin aims to be one of the leading pharmaceutical companies, which responds to Japanese patients' unmet medical needs, with the spirit of Bayer's corporate slogan, "Science For A Better Life." Bayer Yakuhin homepage: <http://www.bayer.co.jp/byl>

#### **Regeneron 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 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 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.*

#### **Bayer Forward-Looking Statements**

*This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at [www.bayer.com](http://www.bayer.com). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.*

#### Your Contact at Bayer:

**Doreen Schroeder, Tel. +49 30 468-11399**

E-Mail: [doreen.schroeder@bayer.com](mailto:doreen.schroeder@bayer.com)

#### Your Investor Relations Contact at Regeneron:

**Michael Aberman, M.D., Tel. +1 (914) 345-7799**

E-Mail: [michael.aberman@regeneron.com](mailto:michael.aberman@regeneron.com)

#### Your Media Contact at Regeneron:

**Peter Dworkin, Tel. +1 (914) 345-7640**

E-Mail: [peter.dworkin@regeneron.com](mailto:peter.dworkin@regeneron.com)

SOURCE Regeneron Pharmaceuticals, Inc.

News Provided by Acquire Media