Regeneron and Bayer Announce Approval of EYLEA® (aflibercept) Injection for the Treatment of Wet Age-Related Macular Degeneration in Australia

March 8, 2012

TARRYTOWN, N.Y. and BERLIN, March 8, 2012 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) and Bayer HealthCare today announced that Bayer HealthCare has received approval from the Australian Therapeutic Goods Administration (TGA) for EYLEA® (aflibercept) Injection for the treatment of patients with neovascular (wet) age-related macular degeneration (wet AMD) at a recommended dose of 2 milligrams (mg) via intravitreal injection per month for three consecutive months, followed by 2 milligrams via intravitreal injection every two months. Bayer Healthcare plans to launch EYLEA in Australia in the second half 2012.

"The approval of EYLEA represents an important new option for wet AMD patients in Australia," said George D Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "EYLEA allows for clinical efficacy that is non-inferior to monthly ranibizumab, but with fewer injections and less frequent office visits. We believe that this may help reduce treatment challenges for wet AMD patients and their physicians in Australia."

The TGA approval of EYLEA is based upon the results of two positive Phase 3 clinical studies (VIEW 1 and VIEW 2) which demonstrated that EYLEA dosed every other month, following 3 initial monthly injections, was non-inferior to Lucentis® (ranibizumab injection) dosed every four weeks, as measured by the primary endpoint of maintenance of visual acuity (less than 15 letters of vision loss on an eye chart) over 52 weeks. The most common adverse reactions (frequency of 5% or more) reported in patients receiving EYLEA were conjunctival hemorrhage, cataract, eye pain, vitreous detachment, vitreous floaters, and increased intraocular pressure.

EYLEA is currently in a Phase 3 clinical study for wet AMD in China. Beyond the wet AMD indication, EYLEA is in Phase 3 clinical studies for the treatment of diabetic macular edema (DME), myopic choroidal neovascularization (mCNV), branch retinal vein occlusion (BRVO). Bayer HealthCare has submitted applications for marketing authorization in Europe, Japan, and other countries for EYLEA for the treatment of wet AMD in 2011. Regeneron has filed an sBLA for EYLEA in central retinal vein occlusion (CRVO) in the United States, and has been granted a Prescription Drug User Fee Act (PDUFA) date of September 23, 2012.

Bayer HealthCare and Regeneron Pharmaceuticals, Inc. are collaborating on the global development of EYLEA®. EYLEA was approved in the United States for the treatment of wet AMD in November 2011. Regeneron maintains exclusive rights to EYLEA in the United States. Bayer HealthCare owns the exclusive marketing rights outside the United States, where the companies will share equally the profits from any future sales of EYLEA.

About EYLEA® (aflibercept) Injection For Intravitreal Injection
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 wet age-related macular degeneration, it is also associated with the growth of abnormal new blood vessels in the eye, which exhibit abnormal increased permeability that leads to edema. Scarring and loss of fine-resolution central vision often results.

EYLEA (aflibercept) Injection, known in the scientific literature as VEGF Trap-Eye, is a recombinant fusion protein, consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 and formulated as an iso-osmotic solution for intravitreal administration. EYLEA acts as a soluble decoy receptor that binds VEGF-A and placental growth factor (PlGF) and thereby can inhibit the binding and activation of these cognate VEGF receptors.

IMPORTANT PRESCRIBING INFORMATION
In the United States, EYLEA is indicated for the treatment of patients with neovascular age-related macular degeneration (wet AMD).

The recommended dose for EYLEA is 2 mg administered by intravitreal injection every four weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg once every eight weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every four weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every four weeks compared to every eight weeks.

IMPORTANT SAFETY INFORMATION
EYLEA is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately.

Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

There is a potential risk of arterial thromboembolic events (ATEs) following use of intravitreal VEGF inhibitors, including EYLEA, defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of ATEs with EYLEA® in clinical trials was 1.8% during the first year.

The most common adverse reactions (greater than or equal to 5%) reported in patients receiving EYLEA (aflibercept) Injection were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure.

Serious adverse reactions related to the injection procedure have occurred in less than 0.1% of intravitreal injections with EYLEA including endophthalmitis, traumatic cataract, and increased intraocular pressure.

Please see the full Prescribing Information for EYLEA, available online at www.regeneron.com/EYLEA-fpi.pdf.

About Wet AMD
Age-related Macular Degeneration (AMD) is a leading cause of acquired blindness. Macular degeneration is diagnosed as either dry (non-exudative) or wet (exudative). In wet AMD, new blood vessels grow beneath the retina and leak blood and fluid. This leakage causes disruption and dysfunction of the retina creating blind spots in central vision, and it can account for blindness in wet AMD patients. Wet AMD is the leading cause of blindness for people over the age of 65 in the U.S. and Europe.

About Regeneron Pharmaceuticals
Regeneron is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets two products in the United States, one for the treatment of neovascular (wet) age-related macular degeneration and another for the treatment of a rare inflammatory condition. Additionally, Regeneron has three regulatory applications pending before the U.S. Food and Drug Administration (FDA) and 10 drug candidates in clinical development. More information and recent news releases are available on the Regeneron web site at 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 EUR 17.2 billion (2011), 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, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2011) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

To learn more about age-related macular degeneration (AMD), please visit:
www.bayerpharma.de/en/AMD

Regeneron Forward-Looking Statement
This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future 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 EYLEA and Regeneron's product candidates, potential new indications for EYLEA, 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 and new indications for marketed products, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize EYLEA and other product and drug candidates and possible new indications for marketed products, competing drugs that may be superior to EYLEA and Regeneron's product and drug candidates and possible new indications for marketed products, uncertainty of market acceptance of EYLEA and Regeneron's product and drug candidates and possible new indications for marketed products, unforeseen safety issues resulting from the administration of products and product candidates in patients, 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, 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 Statement
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. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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