May 8, 2012

Regeneron and Bayer Announce Co-Promotion Agreement With Santen For EYLEA® (aflibercept) Injection in Japan

Collaboration agreement between Regeneron and Bayer amended to a royalty arrangement in Japan

TARRYTOWN, N.Y., May 8, 2012 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) and Bayer HealthCare today announced that Bayer's Japanese subsidiary, Bayer Yakuhin, Ltd. ("Bayer Yakuhin"), and Santen Pharmaceutical Co., Ltd.（"Santen"） entered into a co-promotion agreement for EYLEA® (aflibercept) Injection in Japan. As previously announced, Bayer Yakuhin has submitted an application for marketing authorization to the Ministry of Health, Labor and Welfare (MHLW) for EYLEA for the treatment of neovascular age-related macular degeneration (wet AMD).

"With this agreement and upon marketing authorization, a newly formed Bayer Yakuhin ophthalmology field force and Santen, the leading ophthalmology company in Japan, will promote EYLEA," said Sebastian Guth, President & CEO of Bayer Yakuhin, Ltd. "We expect that the combined resources of the two companies will allow EYLEA to achieve a broader and faster reach into the Japanese ophthalmology community and potentially benefit a greater number of patients."

Bayer and Regeneron have also amended their existing global license and collaboration agreement for EYLEA to convert the 50/50 profit share for Japan into a royalty arrangement that approximates the economics of the profit split. In certain specified circumstances, the royalty may revert to a profit share arrangement.

EYLEA is approved for sale in the United States for the treatment of wet AMD and marketing approval has also been granted in Australia. Bayer HealthCare has submitted applications in Europe and other countries and has initiated 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), and branch retinal vein occlusion (BRVO). 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, except for Japan where Regeneron will receive a royalty on net sales.

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, ARCALYST® (rilonacept) Injection For Subcutaneous Use and EYLEA® (aflibercept) Injection, and has filed regulatory applications with the U.S. Food and Drug Administration (FDA) for second indications for each of these products. A regulatory application has also been submitted to the FDA for the product candidate ZALTRAP® (aflibercept) Concentrate for Intravenous Infusion. Phase 3 studies are in progress with EYLEA® in a third indication, and with product candidate sarilumab. Earlier-stage clinical programs are underway with nine additional monoclonal antibodies. Regeneron has active research and development programs in many disease areas, including ophthalmology, inflammation, cancer, and hypercholesterolemia. Additional information and recent news releases are available on the Regeneron web site at www.regeneron.com.

About Santen
Founded in 1890, Santen is a global company headquartered in Osaka, Japan. Santen researches, develops and markets ophthalmic products for physicians worldwide. Among prescription ophthalmic pharmaceuticals, Santen holds the top share within the Japanese market and is one of the leading ophthalmic companies worldwide. For more information, visit www.santen.com.

About Bayer Yakuhin, Ltd.
Bayer Yakuhin Ltd., headquartered in Osaka, is a healthcare company which combines business activities of Pharmaceuticals, Radiology & Interventional and Animal Health (companion and food animal products). Pharmaceuticals business is focused on the following areas: Cardiovascular & Neurology, Oncology & Hematology, Women's Health & Dermatology and Ophthalmology. Bayer Yakuhin aims to be one of 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

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 Statements

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 in Japan and other countries 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 EYLEA in Japan, 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, the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi or Bayer HealthCare, to be cancelled or terminated, 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, 2011 and Form 10-Q for the quarter ended March 31, 2012. 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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