Regeneron Announces Submission of Application for EYLEA® (aflibercept) Injection in Japan for Macular Edema Following Branch Retinal Vein Occlusion

September 4, 2014

TARRYTOWN, N.Y., Sept. 4, 2014 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that Bayer HealthCare's Japanese subsidiary, Bayer Yakuhin, Ltd. has submitted a marketing authorization application for EYLEA® (aflibercept) Injection for macular edema following branch retinal vein occlusion (BRVO) to the Japanese Ministry of Health, Labour and Welfare (MHLW).

EYLEA has already been approved in Japan for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD), and macular edema secondary to central retinal vein occlusion (CRVO). Marketing authorization applications have been submitted in Japan for the treatment of choroidal neovascularization secondary to pathologic myopia (myopic CNV) and for the treatment of diabetic macular edema (DME).

EYLEA is approved in the United States, EU and other countries for the treatment of wet AMD, CRVO, and DME. Regulatory submissions have been made for EYLEA in the U.S. and EU for Macular Edema following BRVO.

About Macular Edema following Retinal Vein Occlusion (RVO)

RVO affects approximately one to two percent of adults over the age of 40.[2] There are two main types of RVO: BRVO and CRVO. BRVO is four times more common than CRVO, and CRVO generally is the most significant threat to vision.[1]

RVO occurs when a blood clot obstructs a vein in the retina, the light-sensitive nerve tissue lining the back of the eye. The blockage causes a backup of blood and leads to poor blood supply in the affected retina. This results in the release of Vascular Endothelial Growth Factor (VEGF), a naturally-occurring protein in the body that causes blood vessels in the eye to become leaky. The leaky vessels lead to swelling in the center portion of the eye called the macula (a condition called macular edema), which is the most common cause of vision loss in RVO.[1]

About EYLEA® (aflibercept) Injection for Intravitreal Injection

EYLEA is a vascular endothelial growth factor (VEGF) inhibitor formulated as an injection for the eye. EYLEA is designed to block the growth of new blood vessels and decrease the ability of fluid to pass through blood vessels (vascular permeability) in the eye by blocking VEGF-A and placental growth factor (PlGF), two growth factors involved in angiogenesis. EYLEA helps prevent VEGF-A and PlGF from interacting with their natural VEGF receptors as shown in preclinical studies.

IMPORTANT PRESCRIBING INFORMATION FOR EYLEA® (aflibercept) INJECTION IN THE UNITED STATES

EYLEA® (aflibercept) Injection is a prescription medicine approved for the treatment of:

- Neovascular (wet) AMD: The recommended dose for EYLEA is 2 mg administered by injection in the eye every 2 months (8 weeks) following 3 initial monthly (4 weeks) injections. EYLEA may be dosed once per month, but additional benefit was not seen with this dosing plan.
- Macular Edema following CRVO. The recommended dose for EYLEA is 2 mg administered by injection in the eye monthly (every 4 weeks).
- Diabetic Macular Edema. The recommended dose for EYLEA is 2 mg administered by injection in the eye every 2 months (8 weeks) following 5 initial monthly (4 weeks) injections. EYLEA may be dosed once per month, but additional benefit was not seen with this dosing plan.

IMPORTANT SAFETY INFORMATION FOR EYLEA® (aflibercept) INJECTION

EYLEA® (aflibercept) Injection is a prescription medication administered by injection into the eye. You should not use EYLEA if you have an infection in or around the eye, eye pain or redness, or known allergies to any of the ingredients in EYLEA, including aflibercept. As with all medications, EYLEA can cause side effects.

Injection into the eye can result in an infection in the eye and retinal detachment. Inflammation in the eye has been reported with the use of EYLEA.

In some patients, injections with EYLEA may trigger a temporary increase in eye pressure within 1 hour of the injection. Sustained increases in eye pressure have been reported with repeated injections, and your doctor may monitor this after each injection.

There is a potential risk of serious and sometimes fatal side effects related to blood clots, leading to heart attack or stroke in patients receiving EYLEA.

The most common side effects reported in patients receiving EYLEA are increased redness in the eye, eye pain, cataract, moving spots in the field of vision, increased pressure in the eye, and vitreous (gel-like substance) detachment.

Serious side effects related to the injection procedure are rare but can occur including infection inside the eye, retinal detachment, cataract, increased pressure in the eye, and vitreous detachment.

It is important that you contact your doctor right away if you think you might be experiencing any side effects.

EYLEA is for prescription use only. For additional safety information, please talk to your doctor and see the full Prescribing Information for EYLEA.

The product information in this site is intended only for residents of the United States. The product discussed herein may have different labeling in different countries.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

About the EYLEA® (aflibercept) Injection Global Collaboration
Bayer HealthCare and Regeneron are collaborating on the global development of EYLEA. Regeneron maintains exclusive rights to EYLEA in the United States. Bayer HealthCare has licensed the exclusive marketing rights outside the United States, where the companies share equally the profits from sales of EYLEA, except for Japan, where Regeneron receives a percentage of net sales.

About Regeneron Pharmaceuticals
Regeneron is a leading science-based biopharmaceutical company based in Tarrytown, New York that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron commercializes medicines for eye diseases, colorectal cancer, and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including hypercholesterolemia, oncology, rheumatoid arthritis, asthma, and atopic dermatitis. For additional information about the company, please visit www.regeneron.com.

About Bayer HealthCare
The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 18.9 billion (2013), 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 56,000 employees (Dec 31, 2013) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron's products, product candidates, and research and clinical programs now underway or planned, including without limitation EYLEA® (aflibercept) Injection; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron's product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products, such as EYLEA® (aflibercept) Injection in the treatment of macular edema following branch retinal vein occlusion, and choroidal neovascularization secondary to pathologic myopia; ongoing regulatory obligations and oversight impacting Regeneron's research and clinical programs and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its sales or other financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare LLC, to be cancelled or terminated without any further product success; and risks associated with intellectual property of other parties 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, 2013 and its Form 10-Q for the quarter ended June 30, 2014. The reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

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References

1. Wong TY, Scott IU. Retinal-vein occlusion. N Engl J Med. 2010;363:2135-2144.
2. Rogers S, McIntosh RL, Cheung N, et al. The prevalence of retinal vein occlusion: pooled data from population studies from the United States, Europe, Asia and Australia. Ophthalmology.2010;117(2):313-319.

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