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Regeneron Announces EYLEA® (aflibercept) Injection Approved for the Treatment of Patients with Myopic Choroidal Neovascularization (CNV) in Japan

TARRYTOWN, N.Y., Sept. 22, 2014 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that Bayer HealthCare's Japanese subsidiary, Bayer Yakuhin, Ltd. has received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for EYLEA® (aflibercept) Injection for myopic choroidal neovascularization (myopic CNV).

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

EYLEA is approved in the United States, European Union (EU) and other countries for the treatment of wet AMD, Macular Edema following CRVO, and DME. Regulatory submissions have been made for EYLEA in the U.S., EU, and Japan for Macular Edema following Branch Retina Vein Occlusion (BRVO).

About Myopic Choroidal Neovascularization (Myopic CNV)

Myopic CNV is a disease of the retina where new, abnormal blood vessels grow into the retina in persons who are severely myopic (typically more than minus six diopters). The disease is characterized by an abnormally elongated eye with a physical stretching of the sclera, choroid, and retina resulting in degenerative and progressive changes. These degenerative changes can induce the development of choroidal neovascularization.

Severe myopia is particularly common in Asia. Myopic CNV is associated with high degrees of myopia and leads to progressive vision loss. Myopic CNV has a poor prognosis and, if left untreated, can lead to legal blindness in the majority of patients. In East Asia, the prevalence of myopia is significantly higher than in West Asia, and appears to have an earlier onset. In Japan myopic CNV is the second most common cause of blindness.

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.

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 retinal vein occlusion (branch retinal vein occlusion and central 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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