Regeneron Announces EYLEA® (aflibercept) Injection Approved for the Treatment of Diabetic Macular Edema (DME) in Japan

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TARRYTOWN, N.Y., Nov. 18, 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 diabetic macular edema (DME).

EYLEA has already been approved in Japan for the treatment of patients with neovascular age-related macular degeneration (wet AMD), macular edema secondary to central retinal vein occlusion (CRVO), and myopic choroidal neovascularization (myopic CNV). A marketing authorization application has been submitted in Japan for the treatment of macular edema secondary to branch retinal vein occlusion (BRVO).

EYLEA is approved in the U.S. for wet AMD, DME and macular edema following retinal vein occlusion (RVO).

EYLEA has been approved in almost 80 countries for the treatment of patients with wet AMD and around 60 countries for the treatment of visual impairment due to macular edema secondary to central retinal vein occlusion. EYLEA is also approved for the treatment of DME in over 30 countries. Bayer has submitted an application for marketing authorization in Europe for EYLEA in macular edema following BRVO.

About Diabetic Macular Edema (DME)
Diabetic macular edema (DME) or "swelling of the macula" is a common complication in the eyes of patients with diabetes. It is the most frequent cause of vision loss in patients with diabetes and eventually can lead to blindness.[1,2] Visual impairment due to DME is estimated to affect around three percent of people with diabetes around the world and is the most frequent cause of blindness in young and mid-aged adults in most developed countries.[3,4]

DME occurs when blood vessels in the retina are damaged by chronic high blood sugar levels caused by diabetes. This allows fluid from blood vessels to leak into the retina, causing macular swelling. Fluid in the macula can cause severe vision loss or blindness. The macula is the part of the retina responsible for central, fine vision.

Vascular endothelial growth factor (VEGF), a naturally occurring family of growth factors in the body, appears to play a critical role in the development of DME. Increased VEGF production contributes to the vascular disruptions and leakage that characterize DME, as well as the formation of new blood vessels (a process known as angiogenesis).

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 patients with:

- Wet Age-related Macular Degeneration (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 Retinal Vein Occlusion (RVO): The recommended dose for EYLEA is 2 mg administered by injection in the eye monthly (every 4 weeks).
- Diabetic Macular Edema (DME): 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. Patients should not use EYLEA if they 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.

Serious side effects related to the injection procedure are rare but can occur including infection inside the eye and retinal detachment.

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.

It is important that patients contact their doctor right away if they think they might be experiencing any side effects.

EYLEA is for prescription use only. For additional safety information, see the full Prescribing Information for EYLEA.

Patients 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. Several Regeneron programs are based on human genetics findings.

For additional information about the company, please visit www.regeneron.com.

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 Pharmaceuticals, Inc. ("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 the approval of EYLEA® (aflibercept) Injection for the treatment of macular edema following branch retinal vein occlusion in Europe and Japan; 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 September 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.

Your Investor Relations Contact at Regeneron:
Michael Aberman, M.D. Tel. 914.847.7799
E-Mail: manisha.narasimhan@regeneron.com

Your Media Contact at Regeneron:
Sandy Sexton, Tel. 914.847.3358
E-Mail: sandra.sexton@regeneron.com

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