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October 6, 2014 at 4:58 PM EDT

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EYLEA® (AFLIBERCEPT) INJECTION RECEIVES FDA APPROVAL FOR MACULAR EDEMA FOLLOWING RETINAL VEIN OCCLUSION (RVO)

TARRYTOWN, N.Y., Oct. 6, 2014 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that the U.S. Food and Drug Administration (FDA) has approved EYLEA® (aflibercept) Injection for the treatment of Macular Edema following Retinal Vein Occlusion (RVO), which includes Macular Edema following Branch Retinal Vein Occlusion (BRVO) in addition to the previously-approved indication of Macular Edema following Central Retinal Vein Occlusion (CRVO). The recommended dosage of EYLEA in patients with Macular Edema following RVO is 2 milligrams (mg) every month (4 weeks).

"RVO is a significant cause of vision impairment in the U.S., and this expanded indication across all forms of RVO will provide an important new treatment option for retina specialists and their patients," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer of Regeneron and President of Regeneron Laboratories. "Regeneron remains committed to studying EYLEA for the treatment of multiple VEGF-driven retinal diseases."

RVO is the second most common retinal vascular disease.[1] It occurs when there is an obstruction in 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 blood vessels that causes them to become leaky. The leaky vessels result in swelling in the center portion of the eye called the macula (a condition called macular edema), which is the most common cause of vision impairment in RVO.[1] In CRVO, the blockage occurs in the central retinal vein, the main blood vessel that carries de-oxygenated blood out of the back of the eye. In BRVO, the blockage occurs in a smaller retinal vein that drains blood away from the retina.[1] RVO affects approximately one to two percent of adults over the age of 40.[2] While BRVO is four times more common than CRVO, CRVO generally is the most significant threat to vision.[1]

The expanded indication is based on the previously-approved indication for Macular Edema following CRVO and the positive results from the double-masked, randomized, controlled Phase 3 VIBRANT study of 181 patients with Macular Edema following BRVO. The VIBRANT study compared EYLEA 2 mg once every 4 weeks with macular laser photocoagulation (control). At 24 weeks, significantly more patients treated with EYLEA gained at least 15 letters in vision (three lines on an eye chart) from baseline as measured on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, the primary endpoint of the study, compared with patients who received control (53 percent vs. 27 percent; P less than 0.01). Patients treated with EYLEA achieved a 17.0 letter mean improvement over baseline in best-corrected visual acuity (BCVA) compared to a 6.9 letter mean improvement in patients who received control (P less than 0.01), a key secondary endpoint.

The incidence of non-ocular serious adverse events (SAE) was 8.8 percent in the EYLEA group and 9.8 percent in the control group. One death and one Anti-Platelet Trialists' Collaboration (APTC)-defined arterial thromboembolic event (non-fatal stroke) occurred during the trial, both in patients in the control group. The most common ocular adverse events in patients treated with EYLEA included conjunctival hemorrhage and cataract. There were no cases of intraocular inflammation in either group. There was one ocular SAE in a patient in the EYLEA group, which was traumatic cataract.

VIBRANT is the first Phase 3 trial in Macular Edema following BRVO in which an anti-VEGF agent was directly compared to laser photocoagulation at baseline (control). The study continued through 52 weeks, and the one-year results were presented at the American Society of Retina Specialists annual meeting in August 2014.

EYLEA is available as a single, 2-mg strength intravitreal injection for all approved indications. EYLEA is approved in the U.S. for the treatment of wet AMD, Macular Edema following RVO, and DME. In the EU and other countries, EYLEA is approved for the treatment of wet AMD, Macular Edema following CRVO, and DME. Regulatory submissions have been made for EYLEA in the EU and other countries for Macular Edema following BRVO.

About EYLEA® (aflibercept) Injection for Intravitreal Injection

EYLEA is a vascular endothelial growth factor (VEGF) inhibitor formulated as an injection for the eye. EYLEA i

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(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

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 doctors 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, please 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 Regeneron Pharmaceuticals, Inc.
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)

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.

Your Investor Relations Contact at Regeneron:
Manisha Narasimhan, Ph.D. Tel. 914.847.5126
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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