EYLEA® (aflibercept) Injection Accepted for Priority Review by FDA for Diabetic Retinopathy in Patients with Diabetic Macular Edema

December 1, 2014

TARRYTOWN, N.Y., Dec. 1, 2014 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that the U.S. Food and Drug Administration (FDA) has accepted for priority review the supplemental biologics license application (sBLA) for EYLEA® (aflibercept) Injection for the treatment of diabetic retinopathy in patients with diabetic macular edema (DME). Under the Prescription Drug User Fee Act (PDUFA), the goal for a priority review is six months, for a target action date of March 30, 2015.

In September 2014, the FDA granted EYLEA® (aflibercept) Injection Breakthrough Therapy designation for the treatment of diabetic retinopathy in patients with DME. The FDA created the Breakthrough Therapy designation to expedite the development and review of drugs for serious or life-threatening conditions. A Breakthrough Therapy drug must show preliminary clinical evidence of a substantial improvement on a clinically significant endpoint over available therapies, or over placebo if there is no available therapy.

"Diabetic retinopathy coupled with DME is a significant threat to vision for people with diabetes," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer of Regeneron and President of Regeneron Laboratories. "Regeneron looks forward to working with the FDA to help address this significant treatment gap in a leading cause of blindness in working-age adults."

The Phase 3 VIVID-DME and VISTA-DME trials, which supported the approval of EYLEA in DME, included a pre-specified secondary endpoint evaluating diabetic retinopathy based on an established grading scale in patients with DME. The two-year results from these trials on the primary endpoint of best-corrected visual acuity (BCVA) and overall safety have been previously reported.

EYLEA® (aflibercept) Injection is available as a single, 2 milligram (mg) strength intravitreal injection for all approved indications. EYLEA is approved in the U.S. for the treatment of wet age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), and DME.

About the VIVID-DME and VISTA-DME Trials

The Phase 3 VISTA-DME and VIVID-DME studies of 862 patients compared EYLEA 2 mg given monthly, EYLEA 2 mg given every two months (after five initial monthly injections), or macular laser photocoagulation (at baseline and then as needed). In the DME studies, at one year, the mean changes in Best Corrected Visual Acuity (BCVA), as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) chart for the monthly and every two month EYLEA groups, were statistically significantly improved compared to the control group and were similar to each other. Across both trials at one year, patients in both EYLEA dosing groups gained, on average, the ability to read approximately two additional lines on an eye chart compared with almost no change in the control group. A secondary endpoint of the trials was the proportion of patients who achieved a 2-step or greater improvement on the ETDRS diabetic retinopathy (DR) severity scale at two years.

In these trials, EYLEA had a similar overall incidence of adverse events (AEs), ocular serious AEs, and non-ocular serious AEs across treatment groups and the control group. Arterial thromboembolic events as defined by the Anti-Platelet Trialists' Collaboration (non-fatal stroke, non-fatal myocardial infarction, and vascular death) also occurred at similar rates across treatment groups and the control group. The most frequent ocular treatment emergent AEs (TEAEs) observed in the VISTA-DME and VIVID-DME trials included conjunctival hemorrhage, eye pain, cataract, and vitreous floaters. The most common nonocular TEAEs included hypertension and nasopharyngitis, which occurred with similar frequency in the treatment groups and the control group.

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

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 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 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. Several Regeneron programs are based on human genetic 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 diabetic retinopathy in patients with diabetic macular edema; ongoing regulatory obligations and oversight impacting Regeneron's products, 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: michael.aberman@regeneron.com

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

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/eylea-aflibercept-injection-accepted-for-priority-review-by-fda-for-diabetic-retinopathy-in-patients-with-diabetic-macular-edema-300002312.html

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