EYLEA® (aflibercept) Injection Demonstrates Significantly Greater Gains in Visual Acuity than Both Bevacizumab and Ranibizumab in NIH-Sponsored Diabetic Macular Edema Study

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TARRYTOWN, N.Y., Oct. 17, 2014 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that in the National Institutes of Health (NIH) sponsored, Diabetic Retinopathy Clinical Research Network (DRCR.net) comparative effectiveness study in patients with Diabetic Macular Edema (Protocol T), EYLEA® (aflibercept) Injection demonstrated a significantly greater improvement in mean change in best-corrected visual acuity (BCVA) from baseline at 52 weeks compared to both bevacizumab (Avastin® /Genentech) and ranibizumab injection (Lucentis®/Genentech), the primary endpoint of the study. The median number of injections using the protocol-specified retreatment regimen was one fewer in patients treated with EYLEA compared to bevacizumab and ranibizumab. Fewer patients in the EYLEA group received criteria-based macular laser treatments than those treated with bevacizumab and ranibizumab.

The rates of most ocular and systemic adverse events (AEs) were similar across the three study groups. The rates of arterial thromboembolic events as defined by the Anti-Platelet Trialists' Collaboration (non-fatal stroke, non-fatal myocardial infarction, and vascular death) in the trial were 2 percent in the EYLEA group, 4 percent in the bevacizumab group and 5 percent in the ranibizumab group. There were more overall cardiovascular events in the ranibizumab group, compared to the EYLEA group and the bevacizumab group (nominal p less than 0.01); this included more cardiac events and cerebrovascular events in the ranibizumab group.

DRCR.net has shared these top-line results with study investigators. DRCR.net is in the process of finalizing and verifiying the data prior to submission for publication. Regeneron understands that DRCR.net intends to present the final results at a future medical conference simultaneous to, or soon after, publication, and that the DRCR.net will not be publicly discussing the results prior to publication.

"The National Eye Institute and The National Institute of Diabetes and Digestive and Kidney Diseases of the NIH and the DRCR.net should be commended for a carefully designed and well-conducted study," said George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer of Regeneron and President of Regeneron Laboratories. "These data will provide useful information to retinal specialists and their patients to help guide treatment decisions."

The independent, government-sponsored study was designed to determine if one of three different anti-VEGF therapies is superior to the others for the treatment of diabetic macular edema (DME). In the study, 660 patients were randomized to receive either EYLEA 2 milligrams (mg), bevacizumab 1.25 mg, or ranibizumab 0.3 mg dosed according to a protocol-specified algorithm. Patients were treated with focal/grid laser at or after the 24 week visit if: 1) the OCT central subfield thickness was greater than or equal to 250 microns or there was edema that was threatening the fovea and 2) the eye did not improve on OCT or visual acuity from the last two consecutive injections. Full details of the protocol can be found at www.drcr.net.

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 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. Several Regeneron programs are based on human genetics findings. For additional information about the company, please visit www.regeneron.com.

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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; unforeseen safety issues resulting from the administration of products and product candidates in patients, including without limitation EYLEA® (aflibercept) Injection; 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; 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 and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary), such as the comparative effectiveness study discussed in this news release, on the 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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