Regeneron Announces Phase 2 Study of Aflibercept Co-Formulated with Rinucumab (anti-PDGFR-beta) Shows No Benefit Over Aflibercept Alone in Neovascular Age-Related Macular Degeneration

September 30, 2016

TARRYTOWN, N.Y., Sept. 30, 2016 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced topline results from the Phase 2 CAPELLA study evaluating aflibercept co-formulated with rinucumab, an anti-platelet-derived growth factor receptor beta (anti-PDGFR-beta) antibody, in patients with neovascular age-related macular degeneration (wet AMD). The combination therapy did not demonstrate an improvement in best corrected visual acuity (BCVA) compared to intravitreal aflibercept injection monotherapy at 12 weeks, the primary endpoint of the study. At 12 weeks, patients in both combination aflibercept/rinucumab groups showed a 5.8 letter improvement in BCVA. Patients treated with aflibercept alone showed a 7.5 letter improvement in BCVA.

"EYLEA® (aflibercept) injection is an established, effective therapy that has set a high bar in the treatment of wet AMD," said George D. Yancopoulos M.D., Ph.D., Chief Scientific Officer of Regeneron and President of Regeneron Laboratories. "The addition of rinucumab did not improve on the efficacy of aflibercept alone. We are committed to continuing to innovate for patients with serious vision-threatening diseases, and look forward to the results of our ongoing combination studies of aflibercept and nesvacumab, an anti-angiopoietin 2 antibody, for which the preclinical data is more supportive."

EYLEA results in this study were consistent with the efficacy and safety seen in Phase 3 pivotal studies in wet AMD. The efficacy results in the CAPELLA trial were consistent across all choroidal neovascularization (CNV) subtypes. Adding rinucumab to aflibercept showed no benefit on anatomic endpoints including reduction in retinal thickness or in resolution of subretinal hyper-reflective material. Ocular adverse events at 12 weeks were more common in the combination treatment groups (23.5 and 20 percent) compared to aflibercept alone (16 percent), primarily driven by an increase in conjunctival hemorrhage, eye irritation and eye pain.

The ongoing Phase 2, double-masked, randomized, controlled, multiple-dose, regimen-ranging study has enrolled approximately 500 patients with wet AMD. Efficacy was evaluated using the Early Treatment Diabetic Retinopathy Scale (ETDRS) BCVA. Patients were randomized into one of three groups and received fixed doses every four weeks of either aflibercept monotherapy 2mg, aflibercept 2mg/rinucumab 1mg or aflibercept 2mg/rinucumab 3mg. The co-formulation was administered as a single intravitreal injection. At week 12, two of the three treatment groups were re-randomized, resulting in five total dosing groups in the second phase of the study. Data will be evaluated at 28 weeks and again at 52 weeks, when the study is completed.

More detailed results will be submitted for presentation at a future medical congress.

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.

Injection into the eye with EYLEA can result in an infection in the eye and retinal detachment (separation of retina from back of the eye). Inflammation in the eye has been reported with the use of EYLEA.

In some patients, injections with EYLEA may cause 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 with EYLEA 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 talk to your doctor and see the full Prescribing Information for EYLEA.

Please see the full U.S. Prescribing Information for EYLEA at www.EYLEA.com. The product information 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 Regeneron Pharmaceuticals, Inc.
Regeneron (NASDAQ: REGN) 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, high LDL cholesterol and a rare inflammatory condition and has product candidates in development in other areas of high unmet medical need, including rheumatoid arthritis, asthma, atopic dermatitis, pain, cancer, and infectious diseases. For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

Regeneron Forward-Looking Statements and Use of Digital Media

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" or the "Company"), 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 and the combination product comprised of an antibody to Ang2 co-formulated with aflibercept for intravitreal injection for use in ophthalmology ("nesvacumab/aflibercept"); the extent to which the results from the research and development programs conducted by Regeneron or its collaborators (including without limitation the development of nesvacumab/aflibercept) may lead to therapeutic applications; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's late-stage product candidates and new indications for marketed products; unforeseen safety issues and possible liability resulting from the administration of products and product candidates in patients, including without limitation nesvacumab/aflibercept; serious complications or side effects in connection with the use of Regeneron's products and product candidates in clinical trials; coverage and reimbursement determinations by third-party payers, including Medicare, Medicaid, and pharmacy benefit management companies; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to the enrollment, completion, and meeting of the relevant endpoints of post-approval studies; 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) 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; 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 (or their respective affiliated companies, as applicable), 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, 2015 and its Form 10-Q for the quarterly period ended June 30, 2016. Any forward-looking statements are made based on management's current beliefs and judgment, and 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.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (http://newsroom.regeneron.com) and its Twitter feed (http://twitter.com/regeneron).

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