Regeneron Highlights EYLEA® (aflibercept) Injection Data to Be Presented at American Academy of Ophthalmology Annual Meeting

November 12, 2013

TARRYTOWN, N.Y., Nov. 12, 2013 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced that data from several studies of EYLEA® (aflibercept) Injection will be presented during the annual meeting of the American Academy of Ophthalmology (AAO) to be held November 16-19 in New Orleans. EYLEA presentations will be featured during the AAO scientific sessions (November 16-19), as well as during the Retina Subspecialty Days (November 15-16).

During the Retina Subspecialty Days, detailed results from the Phase 3 VIBRANT study of EYLEA in Macular Edema following BRVO will be presented for the first time. Retinal vein occlusion is a common cause of vision loss in the elderly and the second most frequent major retinal vascular disease.(1)

"Regeneron continues to study EYLEA across a range of eye diseases where Vascular Endothelial Growth Factor (VEGF) has demonstrated a role in disease development," said Robert Vitti, M.D., Vice President, Clinical Sciences, Ophthalmology, at Regeneron. "The presentations at this year's AAO meeting reflect our commitment to continually provide data from the full spectrum of on-going research with EYLEA."

Abstracts include:

Friday, November 15 (Retina Subspecialty Day)

- **Intravitreal aflibercept for macular edema due to branch retinal vein occlusion: 24 week results of the VIBRANT study**
  - Presenting author: W. Lloyd Clark, M.D.
  - Oral presentation at 1:51 p.m.; Morial Convention Center, Great Hall
- **Intravitreal aflibercept injection for diabetic macular edema: 12 month results of VISTA-DME and VIVID DME**
  - Presenting author: Diana Do, M.D.
  - Oral presentation at 1:58 p.m.; Morial Convention Center, Great Hall
- **VEGF Trap-Eye (VIEW) sub-analysis: Influence of anatomic characteristics on outcomes**
  - Presenting author: John Kitchens, M.D.
  - Oral presentation at 3:59 p.m.; Morial Convention Center, Great Hall

Saturday, November 16 (Retina Subspecialty Day)

- **VEGF Trap-Eye in CNV Secondary to Pathologic Myopia (MYRROR)**
  - Presenting author: Kyoko Ohno-Matsui, M.D.
  - Oral presentation at 1:39 p.m.; Morial Convention Center, Great Hall
- **VEGF Trap-Eye (VIEW) Extension Study**
  - Presenting author: Peter Kaiser, M.D.
  - Oral presentation at 1:46 p.m.; Morial Convention Center, Great Hall

Monday, November 18

- **Long-term safety of intravitreal aflibercept injection in neovascular age-related macular degeneration**
  - Presenting author: W. Lloyd Clark, M.D.
  - Scientific poster session II (P0435); 12:30 p.m. —2:00 p.m.; Morial Convention Center, Hall C
- **Factors affecting frequency of intravitreal aflibercept injections during PRN phase of COPERNICUS and GALILEO**
  - Presenting author: Julia A. Haller, M.D.
  - Scientific poster session II (P0467); 12:30 p.m. —2:00 p.m.; Morial Convention Center, Hall C

Tuesday, November 19

- **Identification of clinically relevant parameters in OCT over 2 years in the VIEW 2 trial**
  - Presenting author: Ursula M Schmidt-Erfurth, M.D.
  - Oral presentation at 11:24 a.m.; Morial Convention Center, Room 271-273
- **Effect of early, persistent macular fluid on visual acuity in wet AMD: Subgroup analyses of the VIEW 1, VIEW 2 studies**
  - Presenting author: Peter Kaiser, M.D.
  - Oral presentation at 11:36 a.m.; Morial Convention Center, Room 271-273

- **Anti-VEGF effect in eyes with retinal pigment epithelium elevation in the VIEW 1 and VIEW 2 Studies of wet AMD patients**
    - Presenting author: Chirag P. Shah, M.D., M.P.H.
    - Oral presentation at 11:48 a.m.; Morial Convention Center, Room 271-273

Bayer HealthCare and Regeneron are collaborating on the global development of EYLEA. Regeneron maintains exclusive rights to EYLEA in the United States. Bayer HealthCare 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 royalty on net sales.

About EYLEA® (aflibercept) Injection for Intravitreal Injection
Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body. Its normal role in a healthy organism is to trigger formation of new blood vessels (angiogenesis) supporting the growth of the body's tissues and organs. However, in certain diseases, such as wet Age-related Macular Degeneration, it is also associated with the growth of abnormal new blood vessels in the eye, which exhibit abnormal increased permeability that leads to edema. Scarring and loss of fine-resolution central vision often results. In Central Retinal Vein Occlusion (CRVO), a blockage occurs in the main blood vessel that transports deoxygenated blood away from the retina. VEGF levels are elevated in response contributing to macular edema. In Branch Retinal Vein Occlusion (BRVO), a blockage occurs in one of the branching retinal veins that drain blood from the retina. The blockage leads to a backup of blood and fluid collection (macular edema) that can cause impairment of vision.

EYLEA is a recombinant fusion protein, consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 and formulated as an iso-osmotic solution for intravitreal administration. EYLEA acts as a soluble decoy receptor that binds VEGF-A and placental growth factor (PlGF) and thereby can inhibit the binding and activation of their cognate VEGF receptors.

IMPORTANT PRESCRIBING INFORMATION FOR EYLEA® (aflibercept) INJECTION IN THE UNITED STATES
EYLEA® (aflibercept) Injection is indicated for the treatment of patients with neovascular (Wet) Age-related Macular Degeneration (AMD). The recommended dose for EYLEA is 2 mg administered by intravitreal injection every 4 weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg once every 8 weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every 4 weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every 4 weeks compared to every 8 weeks.

EYLEA is indicated for the treatment of patients with Macular Edema following Central Retinal Vein Occlusion (CRVO). The recommended dose for EYLEA is 2 mg administered by intravitreal injection every 4 weeks (monthly).

IMPORTANT SAFETY INFORMATION FOR EYLEA® (aflibercept) INJECTION
EYLEA® (aflibercept) Injection is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

Intravitreal injections, including those with EYLEA, have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering EYLEA. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately. Intraocular inflammation has been reported with the use of EYLEA.

Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with EYLEA. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.

There is a potential risk of arterial thromboembolic events (ATEs) following use of intravitreal VEGF inhibitors, including EYLEA, defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause). The incidence of ATEs in the VIEW 1 and VIEW 2 wet AMD studies in patients treated with EYLEA was 1.8% during the first year. The incidence of ATEs in the COPERNICUS and GALILEO CRVO studies was 0% in patients treated with EYLEA compared with 1.4% in patients receiving sham control during the first six months.

The most common adverse reactions (5% or more) noted in the U.S. prescribing information for the approved indications of EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure.

Serious adverse reactions related to the injection procedure have occurred in &< 0.1% of intravitreal injections with EYLEA including endophthalmitis, traumatic cataract, increased intraocular pressure, and vitreous detachment.

Please see the full U.S. Prescribing Information for EYLEA at www.EYLEA.com

About the EYLEA® (aflibercept) Injection Global Collaboration
Regeneron is collaborating with Bayer HealthCare on the global development of EYLEA. EYLEA is currently marketed for the treatment of wet AMD in over 15 countries outside the U.S., including Japan and Australia and countries in the E.U.

Regeneron maintains exclusive rights to EYLEA in the United States.

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 markets 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; 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 possible new indications of EYLEA® (aflibercept) Injection referenced in this news release; ongoing regulatory obligations and oversight and 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 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, to be cancelled or terminated without any further product success; and risks associated with third party intellectual property 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, 2012 and Form 10-Q for the quarterly period ended September 30, 2013. 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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1. Wong TY, et al. Retinal-vein occlusion. *New England Journal of Medicine*. 2010; 363:2135-2144.

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