

TARRYTOWN, N.Y., Sept. 17, 2013 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: [REGN](#)) today announced that detailed results from the Phase 3 VIVID and VISTA trials of EYLEA

® (aflibercept) Injection in Diabetic Macular Edema (DME) will be presented at an oral session during the upcoming annual meeting of the Retina Society to be held September 26-29

in
Los Angeles

,
United States

. These data will be presented on
Friday, September 27

, at
4:51 PM PDT

. Separately, these data are also scheduled to be presented at an oral presentation on
September 27

, at
3:58 PM CEST

, at the EURETINA Congress in
Hamburg, Germany

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Regeneron will host a webcast investor meeting on Saturday, September 28, at 7:00 AM PDT/10:00 AM EDT

to discuss these data. The event will be webcast and can be accessed at

www.regeneron.com

or by dialing in via the following numbers: (888) 660-6127 (U.S. toll free) or (973) 890-8355 (international dial-in).

EYLEA was approved in the United States for the treatment of neovascular (wet) Age-related Macular Degeneration (AMD) in November 2011 and for Macular Edema following CRVO in September 2012. EYLEA has also been approved in Europe

,
Japan

,
Australia

, and in several other countries for use in wet AMD and in Europe and selected countries in South America for Macular Edema following CRVO.

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 patients with diabetic macular edema (DME), hyperglycemia-induced vascular dysfunction and hypoxia result in elevated intraocular VEGF levels in the eye and resultant blood vessel permeability that leads to macular edema, which can result in vision loss.

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, allergic

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 application of EYLEA®*

(aflibercept) Injection in the treatment of Diabetic Macular Edema; 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 quarter ended June 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.

Regeneron to Present Phase 3 Data for EYLEA® (afibercept) Injection in Diabetic Macular Edema at Upco

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