Regeneron Announces Publication of EYLEA® (aflibercept) Injection Phase 3 VIEW 1 and VIEW 2 Studies in Ophthalmology

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TARRYTOWN, N.Y., Oct. 18, 2012 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced that detailed one-year results from the VIEW 1 and VIEW 2 Phase 3 studies of EYLEA (aflibercept) Injection were published online in the journal *Ophthalmology* ahead of a future print publication. The publication can be accessed at http://digitalreprints.elsevier.com/t/28599.

"The article published today provides additional details about the VIEW 1 and VIEW 2 studies that demonstrated that EYLEA offered similar improvements in visual acuity to monthly ranibizumab, but with less frequent dosing," stated George D. Yancopoulos, M.D., Ph.D., Chief Scientific Officer of Regeneron and President of Regeneron Laboratories. "This message has resonated both with physicians and patients since the launch of EYLEA in November 2011. We are happy to be able to offer another treatment option to patients suffering from wet AMD, the most common cause of blindness in the U.S. among older adults."

EYLEA, for the treatment of patients with neovascular (wet) age-related Macular Degeneration (wet AMD) was granted a Priority Review by the U.S. Food and Drug Administration (FDA), a designation that is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists, and approved in November 2011. The approval was based upon the results of two Phase 3 clinical studies, VIEW 1 and VIEW 2, published today in the journal *Ophthalmology*. In these studies, EYLEA dosed every eight weeks, following three initial monthly injections, was shown to be clinically equivalent to Lucentis® (ranibizumab injection) dosed every four weeks, as measured by the primary endpoint of maintenance of best-corrected visual acuity (less than 15 letters of vision loss on an eye chart as measured on an ETDRS scale) over 52 weeks.

EYLEA 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.

The most common adverse reactions (frequency of 5% or more) reported in wet AMD patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure.

About the VIEW 1 and VIEW 2 Clinical Studies

The safety and efficacy of EYLEA® were assessed in two randomized, multi-center, double-masked, active-controlled studies in patients with wet AMD. A total of 2412 patients were treated and evaluable for efficacy (1817 with EYLEA) in the two studies (VIEW 1 and VIEW 2). In each study, patients were randomly assigned in a 1:1:1:1 ratio to one of four dosing regimens: 1) EYLEA administered 2 mg every eight weeks following three initial monthly doses (EYLEA 2Q8); 2) EYLEA administered 2 mg every four weeks (EYLEA 2Q4); 3) EYLEA 0.5 mg administered every four weeks (EYLEA 0.5Q4); and 4) ranibizumab administered 0.5 mg every four weeks (ranibizumab 0.5Q4). Patient ages ranged from 49 to 99 years with a mean of 76 years.

In both studies, the primary efficacy endpoint was the proportion of patients who maintained vision, defined as losing fewer than 15 letters of best-corrected visual acuity at week 52 compared to baseline. Both the EYLEA® (aflibercept) Injection 2Q8 and 2Q4 dosing groups were shown to have efficacy that was clinically equivalent to the ranibizumab 0.5Q4 group for the primary endpoint.

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.

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 these cognate VEGF receptors. EYLEA is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

In the United States, EYLEA was also approved for the treatment of Macular Edema following Central Retinal Vein Occlusion (CRVO) in September 2012. Phase 3 trials are currently underway with EYLEA for the treatment of diabetic macular edema (DME) and Macular Edema following Branch Retinal Vein Occlusion (BRVO).

Bayer HealthCare will market EYLEA outside the United States, where the companies will share equally the profits from any future sales of EYLEA. Regeneron maintains exclusive rights to EYLEA in the United States.

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.

In the United States, 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 during the post approval 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) reported in patients receiving 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 Prescribing Information at www.EYLEA.com.

About Wet AMD

Age-related macular degeneration (AMD) is a leading cause of acquired blindness. Macular degeneration is diagnosed as either dry (non-exudative) or wet (exudative). In wet AMD, new blood vessels grow beneath the retina and leak blood and fluid. This leakage causes disruption and dysfunction of the retina creating blind spots in central vision, and it can account for blindness in wet AMD patients. Wet AMD is the leading cause of blindness for people over the age of 65 in the U.S. and Europe.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. Regeneron markets three products in the United States, EYLEA® (aflibercept) Injection, ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion, and ARCALYST® (rilonacept) Injection for Subcutaneous Use; ZALTRAP is co-commercialized with Sanofi. Phase 3 studies are in progress with EYLEA in two additional indications and with product candidates sarilumab and REGN727. Regeneron has active research and development programs in many disease areas, including ophthalmology, inflammation, cancer, and hypercholesterolemia. Additional information and recent news releases are available on the Regeneron web site at 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, and actual events or results may differ materially from these forward-looking statements. 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), 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, 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 drug candidates, competing drugs that may be superior to Regeneron's products and drug candidates, uncertainty of market acceptance of Regeneron's products and drug candidates, unanticipated expenses, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi and Bayer HealthCare, to be canceled or terminated, 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, 2011 and its Form 10-Q for the quarter ended June 30, 2012. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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