TARRYTOWN, N.Y., Nov. 18, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc announced that the U.S. Food and Drug Administration (FDA) has approved EYLEA the scientific literature as VEGF Trap-Eye, for the treatment of patients with neovas Degeneration (AMD) at a recommended dose of 2 milligrams (mg) every four week followed by 2 mg every eight weeks (2 months).

The approval of EYLEA was granted under a Priority Review, a designation that is g advances in treatment, or provide a treatment where no adequate therapy exists. T results of two Phase 3 clinical studies. In these studies, EYLEA dosed every eight w monthly injections, was clinically equivalent to the standard of care, Lucentis® (ran four weeks, as measured by the primary endpoint of maintenance of visual acuity (on an eye chart) over 52 weeks. The most common adverse reactions (frequency receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachr increased intraocular pressure. The adverse event profile was similar to that seen

"The approval of EYLEA offers a much needed new treatment option for patients w M.D., a clinical ophthalmologist and retinal specialist at Ophthalmic Consultants of Ophthalmology at Tufts School of Medicine, and Chair of the Steering Committee f the potential of achieving the efficacy we've come to expect from current anti-VEGF injections and monitoring. This may reduce the need for costly and time-consumin and their caregivers."

"This approval is an important step forward for Regeneron and for patients sufferin common cause of blindness in the U.S. in older adults," said Leonard S. Schleifer, M Executive Officer of Regeneron. "We thank the patients and clinical investigators w studies, the FDA, and the Regeneron employees who helped make this day possible plan to make EYLEA available to patients within the next few days."

About EYLEA™ (aflibercept) Injection

Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the bo organism is to trigger formation of new blood vessels (angiogenesis) supporting th organs. However, in certain diseases, such as wet age-related macular degeneratio growth of abnormal new blood vessels in the eye, which exhibit abnormal increase edema. Scarring and loss of fine-resolution central vision often results.

EYLEA, known in the scientific literature as VEGF Trap-Eye, is a recombinant fusion human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of hu iso-osmotic solution for intravitreal administration. EYLEA acts as a soluble decoy placental growth factor (PlGF) and thereby can inhibit the binding and activation of

EYLEA is indicated for the treatment of patients with neovascular age-related macu EYLEA is contraindicated in patients with ocular or periocular infections, active intr hypersensitivity to aflibercept or to any of the excipients in EYLEA.

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EYLEA™ (aflibercept) Injection 2Q8 and 2Q4 dosing groups were shown to have eff
to the ranibizumab 0.5Q4 group for the primary endpoint.

Select results of the VIEW 1 and VIEW 2 studies as described in the full Prescribing
every four weeks and EYLEA 2 mg every eight weeks dosing groups as compared t
group are shown below.

Efficacy Outcomes at Week 52 (Full Analysis Set with LOCF) in VIEW 1 and VIEW 2

	VIEW 1		
	EYLEA 2 mg Q8 weeks(a)	EYLEA 2 mg Q4 weeks	ranibizu-mab 0.5 mg Q4 weeks
Full Analysis Set	N=301	N=304	N=304
Efficacy Outcomes			
Proportion of patients who maintained visual acuity (%) (<15 letters of BCVA loss)	94%	95%	94%
Difference(b) (%) (95.1% CI)	0.6 (-3.2, 4.4)	1.3 (-2.4, 5.0)	
Mean change in BCVA as measured by ETDRS letter score from Baseline	7.9	10.9	8.1
Difference(b) in LS mean (95.1% CI)	0.3 (-2.0, 2.5)	3.2 (0.9, 5.4)	

BCVA = Best Corrected Visual Acuity; CI = Confidence Interval; ETDRS = Early Treat
LOCF = Last Observation Carried Forward (baseline values are not carried forward)
presented to adjust for safety assessment conducted during the study.
(a) After treatment initiation with 3 monthly doses
(b) EYLEA group minus the ranibizumab group

IMPORTANT SAFETY INFORMATION

EYLEA™ (aflibercept) Injection is contraindicated in patients with ocular or periocul
inflammation, or known hypersensitivity to aflibercept or to any of the excipients in

Intravitreal injections, including those with EYLEA, have been associated with endo
detachments. Proper aseptic injection technique must always be used when admi
be instructed to report any symptoms suggestive of endophthalmitis or retinal deta
be managed appropriately.

Acute increases in intraocular pressure have been seen within 60 minutes of intrav
EYLEA. Sustained increases in intraocular pressure have also been reported after
VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head sh
appropriately.

There is a potential risk of arterial thromboembolic events (ATEs) following use of
including EYLEA, defined as nonfatal stroke, nonfatal myocardial infarction, or vasc
unknown cause). The incidence of ATEs with EYLEA in clinical trials was low (1.8%

Conference Call Information

Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regenero management will host a conference call to discuss the FDA approval of EYLEA for AMD and launch plans, as well as other corporate matters. The interactive call will 6:30 p.m. Eastern Time and can be accessed live through the Regeneron website a Investor Relations page. The call, including the question and answer session, can a

Domestic Dial-in Number: (888) 660-6127
International Dial-in Number: (973) 890-8355
Participant Passcode: 30193445

An archived version of the conference call will be available for 30 days on the comp www.regeneron.com on the Investor Relations page.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, invents commercializes medicines for the treatment of serious medical conditions. Regen ARCALYST® (rilonacept) Injection For Subcutaneous Use and EYLEA™ (aflibercept) completed several Phase 3 studies and is conducting an additional Phase 3 clinica ZALTRAP® (aflibercept) Concentrate for Intravenous Infusion. Additional therapeu proprietary Regeneron technologies for creating fully human monoclonal antibodie programs in rheumatoid arthritis and other inflammatory conditions, pain, choleste conditions, and cancer. Additional information about Regeneron and recent news r Regeneron web site at www.regeneron.com.

Regeneron Forward Looking Statement

This news release includes forward-looking statements that involve risks and unce and the future performance of Regeneron, and actual events or results may differ m looking statements. These statements concern, and these risks and uncertainties timing, and possible success and therapeutic applications of EYLEA and Regenero research and clinical programs now underway or planned, the likelihood and timing and commercial launch of Regeneron's late-stage product candidates, determinatio administrative governmental authorities which may delay or restrict Regeneron's ab commercialize EYLEA and other products and drug candidates, competing drugs th Regeneron's products and drug candidates, uncertainty of market acceptance of EY and drug candidates, unanticipated expenses, the availability and cost of capital, th and selling products, the potential for any license or collaboration agreement, inclu Sanofi and Bayer HealthCare, to be canceled or terminated without any product suc third party intellectual property and pending or future litigation relating thereto. A m these and other material risks can be found in Regeneron's filings with the United S Commission, including its Form 10-K for the year ended December 31, 2010 and Fo September 30, 2011. Regeneron does not undertake any obligation to update publ statement, whether as a result of new information, future events, or otherwise, unle