

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K  
CURRENT REPORT

Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 18, 2011 (November 18, 2011)

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**REGENERON PHARMACEUTICALS, INC.**  
(Exact Name of Registrant as Specified in Charter)

**New York**  
(State or other jurisdiction of  
Incorporation)

**000-19034**  
(Commission File No.)

**13-3444607**  
(IRS Employer Identification No.)

**777 Old Saw Mill River Road, Tarrytown, New York 10591-6707**  
(Address of principal executive offices, including zip code)

**(914) 347-7000**  
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 8.01 Other Events.**

On November 18, 2011, Regeneron Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration approved EYLEA™ (afibercept) Injection for the treatment of patients with neovascular (wet) Age-related Macular Degeneration (AMD).

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference into this Item.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press Release Announcing FDA Approval of EYLEA™ (afibercept) Injection for the Treatment of Wet Age-Related Macular Degeneration, dated November 18, 2011.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 18, 2011

REGENERON PHARMACEUTICALS, INC.

By: /s/ Joseph J. LaRosa

Name: Joseph J. LaRosa

Title: Senior Vice President, General Counsel and Secretary

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Exhibit Index

| Number | Description   |
|--------|---|
| 99.1   | Press Release Announcing FDA Approval of EYLEA™ (aflibercept) Injection for the Treatment of Wet Age-Related Macular Degeneration, dated November 18, 2011. |

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# REGENERON

## For Immediate Release

### Press Release

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## **Regeneron Announces FDA Approval of EYLEA™ (aflibercept) Injection for the Treatment of Wet Age-Related Macular Degeneration**

*EYLEA is the only FDA-approved treatment for wet AMD labeled for less than monthly dosing that demonstrated clinical equivalence to the monthly standard of care*

*Regeneron to host conference call on November 18, at 6:30 p.m. Eastern Time*

**Tarrytown, NY (November 18, 2011)** -- Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced that the U.S. Food and Drug Administration (FDA) has approved EYLEA (aflibercept) Injection, known in the scientific literature as VEGF Trap-Eye, for the treatment of patients with neovascular (wet) Age-related Macular Degeneration (AMD) at a recommended dose of 2 milligrams (mg) every four weeks (monthly) for the first 12 weeks, followed by 2 mg every eight weeks (2 months).

The approval of EYLEA was granted under a Priority Review, a designation that is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. This approval was based upon the results of two Phase 3 clinical studies. In these studies, EYLEA dosed every eight weeks, following three initial monthly injections, was clinically equivalent to the standard of care, Lucentis® (ranibizumab injection) dosed every four weeks, as measured by the primary endpoint of maintenance of visual acuity (less than 15 letters of vision loss on an eye chart) over 52 weeks. The most common adverse reactions (frequency of 5% or more) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure. The adverse event profile was similar to that seen with ranibizumab.

“The approval of EYLEA offers a much needed new treatment option for patients with wet AMD,” said Jeffrey Heier, M.D., a clinical ophthalmologist and retinal specialist at Ophthalmic Consultants of Boston, Assistant Professor of Ophthalmology at Tufts School of Medicine, and Chair of the Steering Committee for the VIEW 1 trial. “EYLEA offers the potential of achieving the efficacy we’ve come to expect from current anti-VEGF agents, but with less frequent injections and no monitoring requirements. This may reduce the need for costly and time-consuming monthly office visits for patients and their caregivers.”

“This approval is an important step forward for Regeneron and for patients suffering with wet AMD, the most common cause of blindness in the U.S. in older adults,” said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. “We thank the patients and clinical investigators who participated in our clinical studies, the FDA, and the Regeneron employees who helped make this day possible. Now that EYLEA is approved, we plan to make EYLEA available to patients within the next few days.”

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### **About EYLEA™ (aflibercept) 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.

EYLEA, known in the scientific literature as VEGF Trap-Eye, 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 indicated for the treatment of patients with neovascular age-related macular degeneration (wet AMD). 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 recommended dose for EYLEA is 2 mg administered by intravitreal injection every four weeks (monthly) for the first 12 weeks (3 months), followed by 2 mg once every eight weeks (2 months). Although EYLEA may be dosed as frequently as 2 mg every four weeks (monthly), additional efficacy was not demonstrated when EYLEA was dosed every four weeks compared to every eight weeks.

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 with EYLEA in clinical trials was low (1.8%) .

Serious adverse reactions related to the injection procedure have occurred in less than 0.1% of intravitreal injections with EYLEA and include endophthalmitis, traumatic cataract, 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 visual acuity at week 52 compared to baseline. Data are available through week 52. 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.

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Select results of the VIEW 1 and VIEW 2 studies as described in the full Prescribing

Information for the EYLEA 2 mg every four weeks and EYLEA 2 mg every eight weeks dosing groups as compared to ranibizumab dosed monthly group are shown below.

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

|  | VIEW 1                                 |                           |  | VIEW 2                                 |                           |  |
|--|--|---------------------------|--|--|---------------------------|--|
|  | EYLEA<br>2 mg Q8<br>weeks <sup>a</sup> | EYLEA<br>2 mg Q4<br>weeks | ranibizu-<br>mab<br>0.5 mg Q4<br>weeks | EYLEA<br>2 mg Q8<br>weeks <sup>a</sup> | EYLEA<br>2 mg Q4<br>weeks | ranibizu-<br>mab<br>0.5 mg Q4<br>weeks |
| Full Analysis Set  | N=301                                  | N=304                     | N=304                                  | N=306                                  | N=309                     | N=291                                  |
| <b>Efficacy Outcomes</b>   |  |                           |  |  |                           |  |
| Proportion of patients who maintained visual acuity (%) (<15 letters of BCVA loss) | 94%                                    | 95%                       | 94%                                    | 95%                                    | 95%                       | 95%                                    |
| Differences (%) (95.1% CI)   | 0.6<br>(-3.2, 4.4)                     | 1.3<br>(-2.4, 5.0)        |  | 0.6<br>(-2.9, 4.0)                     | -0.3<br>(-4.0, 3.3)       |  |
| Mean change in BCVA as measured by ETDRS letter score from Baseline                | 7.9                                    | 10.9                      | 8.1                                    | 8.9                                    | 7.6                       | 9.4                                    |
| Differences in LS mean (95.1% CI)  | 0.3<br>(-2.0, 2.5)                     | 3.2<br>(0.9, 5.4)         |  | -0.9<br>(-3.1, 1.3)                    | -2.0<br>(-4.1, 0.2)       |  |

BCVA = Best Corrected Visual Acuity; CI = Confidence Interval; ETDRS = Early Treatment Diabetic Retinopathy Study; LOCF = Last Observation Carried Forward (baseline values are not carried forward); 95.1% confidence intervals were presented to adjust for safety assessment conducted during the study.

<sup>a</sup> After treatment initiation with 3 monthly doses

<sup>b</sup> EYLEA group minus the ranibizumab group

**IMPORTANT SAFETY INFORMATION**

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.

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 with EYLEA in clinical trials was low (1.8%) .

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

The most common adverse reactions (greater than or equal to 5%) reported in patients receiving EYLEA were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure.

Please see the full Prescribing Information for EYLEA, available online at [www.regeneron.com/EYLEA-fpi.pdf](http://www.regeneron.com/EYLEA-fpi.pdf).

#### **About the EYLEA™ (aflibercept) Injection Global Collaboration**

Regeneron is collaborating with Bayer HealthCare on the global development of EYLEA. Bayer submitted an application for marketing authorization in Europe for wet AMD in June 2011.

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.

#### **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 distortion and/or blind spots in central vision. Wet AMD is the leading cause of blindness for people over the age of 65 in the U.S. and Europe.

#### **Conference Call Information**

Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron, and other members of senior management will host a conference call to discuss the FDA approval of EYLEA for the treatment of patients with wet AMD and launch plans, as well as other corporate matters. The interactive call will be held on November 18, 2011 at 6:30 p.m. Eastern Time and can be accessed live through the Regeneron website at [www.regeneron.com](http://www.regeneron.com) on the Investor Relations page. The call, including the question and answer session, can also be accessed by dialing:

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 company's website at [www.regeneron.com](http://www.regeneron.com) on the Investor Relations page.

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## **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 two products, ARCALYST<sup>®</sup> (rilonacept) Injection For Subcutaneous Use and EYLEA<sup>™</sup> (afibercept) Injection. Regeneron also has completed several Phase 3 studies and is conducting an additional Phase 3 clinical trial for the product candidate ZALTRAP<sup>®</sup> (afibercept) Concentrate for Intravenous Infusion. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on the Regeneron web site at [www.regeneron.com](http://www.regeneron.com).

## **Regeneron Forward Looking Statement**

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 EYLEA and Regeneron's product candidates and research and clinical programs now underway or planned, 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 EYLEA and other products and drug candidates, competing drugs that may be superior to EYLEA and Regeneron's products and drug candidates, uncertainty of market acceptance of EYLEA and Regeneron's products and drug candidates, unanticipated expenses, the availability and cost of capital, 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 without any 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, 2010 and Form 10-Q for the quarter ended September 30, 2011. 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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