

REGENERON PHARMACEUTICALS INC

Form 8-K

December 05, 2011

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): December 5, 2011 (December 5, 2011)

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 7.01 Regulation FD Disclosure.

On December 5, 2011, at the Deutsche Bank BioFEST conference, Regeneron Pharmaceuticals, Inc. (Regeneron) announced top-line results of the Phase 2, open-label, 235-patient, two-arm, AFFIRM trial that studied ZALTRAP® (aflibercept) Concentrate for Intravenous Infusion in combination with the modified FOLFOX6 (oxaliplatin-5-fluorouracil-leucovorin) chemotherapy regimen in first-line therapy for metastatic colorectal cancer. The primary endpoint of the study was the Progression Free Survival (PFS) rate at one year. The results showed that in patients who received ZALTRAP in combination with mFOLFOX6, the PFS rate at one year was similar to that seen in the standard therapy arm for patients who received mFOLFOX6 alone. The study was not designed for a direct statistical comparison between arms. The control arm was used as an internal benchmark only. The side effect profile of ZALTRAP was similar to what has been seen in prior trials with ZALTRAP and consistent with other anti-VEGF agents. The full data set will be presented at a future medical conference. Regeneron s collaborator, Sanofi, has submitted a Biologics License Application to the U.S. Food and Drug Administration for marketing approval for ZALTRAP in previously treated metastatic colorectal cancer patients.

Item 8.01 Other Events.

On December 5, 2011, Bayer HealthCare and Regeneron issued a press release announcing two-year results from Phase 3 studies (VIEW 1 and VIEW 2) with EYLEA (aflibercept) Injection For Intravitreal Injection in patients with the neovascular form of age-related macular degeneration. 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 Reporting Two Year Results of Phase 3 Studies with ELYEA (aflibercept) Injection in wet AMD Show Sustained Improvement in Visual Acuity.

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: December 5, 2011

REGENERON PHARMACEUTICALS, INC.

By: /s/ Joseph J. LaRosa
Name: Joseph J. LaRosa
Title: Senior Vice President, General
Counsel and
Secretary

Exhibit Index

| Number | Description |
|--------|--|
| 99.1 | Press Release Reporting Two Year Results of Phase 3 Studies with ELYEA (aflibercept) Injection in wet AMD Show Sustained Improvement in Visual Acuity. |
