

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): September 14, 2009 (September 11, 2009)

**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))

**Item 8.01 Other Events.**

On September 11, 2009, Regeneron Pharmaceuticals, Inc., together with sanofi-aventis, issued a press release announcing the discontinuation of the Phase 3 trial that evaluated aflibercept (VEGF Trap) plus gemcitabine versus placebo plus gemcitabine for the first-line treatment of metastatic pancreatic cancer (VANILLA), based on the recommendations by an Independent Data Monitoring Committee (IDMC). As part of a planned interim efficacy analysis, the IDMC determined that the addition of aflibercept to gemcitabine would be unable to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to placebo plus gemcitabine in this study. A copy of this press release is filed as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

On September 14, 2009, Regeneron Pharmaceuticals, Inc. issued a press release announcing the completion of patient enrollment in two randomized, double-masked, Phase 3 clinical trials evaluating VEGF Trap-Eye in the treatment of the neovascular form of age-related macular degeneration (wet AMD). A copy of this press release is filed as Exhibit 99.2 to this Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press Release dated September 11, 2009.

99.2 Press Release dated September 14, 2009.

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.

REGENERON PHARMACEUTICALS, INC.

Date: September 14, 2009

By: /s/ Stuart Kolinski

Name: Stuart Kolinski

Title: Senior Vice President and General Counsel

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Exhibit Index

Exhibit No.	Description
99.1	Press Release dated September 11, 2009.
99.2	Press Release dated September 14, 2009.

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**FOR IMMEDIATE RELEASE****Press Release****Phase 3 Trial of Aflibercept in Metastatic Pancreatic Cancer Discontinued**

*Phase 3 studies in colorectal cancer, non-small cell lung cancer, and prostate cancer continue with over 70 percent enrollment completed*

**Paris, France and Tarrytown, NY (September 11, 2009)** -- Sanofi-aventis (Euronext: **SAN** and NYSE:**SNY**) and Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced the discontinuation of the Phase 3 trial that evaluated aflibercept (VEGF Trap) plus gemcitabine versus placebo plus gemcitabine for the first-line treatment of metastatic pancreatic cancer (VANILLA), based on the recommendations by an Independent Data Monitoring Committee (IDMC). As part of a planned interim efficacy analysis, the IDMC determined that the addition of aflibercept to gemcitabine would be unable to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to placebo plus gemcitabine in this study. The types and frequencies of adverse events reported on the combination arm with aflibercept were generally as anticipated.

With the closure of the study, a detailed analysis of the efficacy and safety results will be conducted by the companies and results will be presented at a future medical meeting. Sanofi-aventis and Regeneron have notified the study investigators and appropriate regulatory authorities of the decision to discontinue the study. Patients in the study will continue to be provided access to aflibercept at the determination of the study investigators in consultation with the patients.

Metastatic pancreatic cancer is among the most intractable cancers. Clinical development of new therapies, including anti-VEGF agents, has been generally characterized by a failure to achieve significant incremental clinical benefit over existing treatments.

“We are disappointed with the result of this study and we will continue our efforts to bring new and effective treatments for these patients,” said Dr. Marc Cluzel, Senior Vice President, Research and Development sanofi-aventis. “We remain committed to the other ongoing Phase 3 trials of aflibercept in colorectal cancer, non-small cell lung cancer, and hormone-refractory metastatic prostate cancer.”

Three Phase 3 studies continue, each of which is currently over 70 percent enrolled:

- VELOUR study: 2nd-line metastatic colorectal cancer in combination with fluorouracil, leucovorin, and irinotecan (FOLFIRI)
- VITAL study: 2nd-line non-small cell lung cancer in combination with docetaxel
- VENICE study: 1st-line hormone-refractory metastatic prostate cancer in combination with docetaxel and prednisone

**About Pancreatic Cancer**

Each year in the United States, more than 42,000 individuals are diagnosed with pancreatic cancer and over 35,000 die. The prognosis is generally poor; less than five percent of those diagnosed are still alive five years after diagnosis. Gemcitabine is considered the standard backbone of first-line treatment in patients with first-line metastatic pancreatic cancer.

**About Aflibercept**

Aflibercept is an anti-angiogenesis inhibitor with a unique mechanism of action. This fusion protein binds all forms of Vascular Endothelial Growth Factor-A (VEGF-A), as well as VEGF-B and placental growth factor (PlGF), additional angiogenic growth factors that appear to play a role in tumor angiogenesis and inflammation. Aflibercept has been shown to bind VEGF-A, VEGF-B, and PlGF with higher affinity than their natural receptors.

**About sanofi-aventis**

Sanofi-aventis, a leading global pharmaceutical company, discovers, develops, and distributes therapeutic solutions to improve the lives of everyone. Sanofi-aventis is listed in Paris (EURONEXT PARIS: SAN) and in New York (NYSE: SNY).

**About Regeneron Pharmaceuticals, Inc.**

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, inflammatory diseases, and pain, and has preclinical programs in other diseases and disorders. Additional information about Regeneron and recent news releases are available on Regeneron's web site at [www.regeneron.com](http://www.regeneron.com).

**Forward Looking Statement - sanofi-aventis**

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include product development, product potential projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future events, operations, products and services, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans" and similar expressions. Although sanofi-aventis' management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of sanofi-aventis, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMEA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such products candidates, the absence of guarantee that the products candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives as well as those discussed or identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in sanofi-aventis' annual report on Form 20-F for the year ended December 31, 2008. Other than as required by applicable law, sanofi-aventis does not undertake any obligation to update or revise any forward-looking information or statements.*

**Forward Looking Statement - Regeneron Pharmaceuticals, Inc.**

*This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of aflibercept, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize aflibercept, competing drugs that may be superior to aflibercept, uncertainty of market acceptance of aflibercept, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. 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 (SEC), including its Form 10-K for the year ended December 31, 2008 and Form 10-Q for the quarter ending June 30, 2009. 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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**For Immediate Release****Press Release****Enrollment Completed in Regeneron and Bayer HealthCare Phase 3 Studies of VEGF Trap-Eye in Neovascular Age-related Macular Degeneration (Wet AMD)**

*One-year primary endpoint data expected in Q4 2010*

**TARRYTOWN, New York (September 14, 2009)** -- Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced the completion of patient enrollment in two randomized, double-masked, Phase 3 clinical trials evaluating VEGF Trap-Eye in the treatment of the neovascular form of age-related macular degeneration (wet AMD). In each study of the VIEW (VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD) program, VEGF Trap-Eye is being evaluated for its effect on maintaining and improving vision when dosed as an intravitreal injection on a schedule of 0.5 milligram (mg) every four weeks, 2.0 mg every four weeks, or 2.0 mg every eight weeks (following three monthly doses), as compared with intravitreal ranibizumab (Lucentis<sup>®</sup>, a registered trademark of Genentech, Inc.) administered 0.5 mg every four weeks during the first year of the studies. As-needed (PRN) dosing with both agents is being evaluated during the second year of each study. These studies are part of the global development program for VEGF Trap-Eye being conducted by Regeneron and Bayer HealthCare AG. Each study has enrolled in excess of the targeted 1,200 patient goal. One-year primary endpoint data from both studies are expected in the fourth quarter of 2010.

VEGF Trap-Eye, an investigational drug, is being developed by Regeneron and Bayer HealthCare AG for the potential treatment of eye diseases, including wet AMD, diabetic macular edema (DME), and Central Retinal Vein Occlusion (CRVO). Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States. Bayer HealthCare has exclusive rights to market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye.

“Even with recent advances in the treatment of wet AMD, vision is not improved or stabilized in all patients despite monthly office visits and examinations that are inconvenient for these often elderly patients,” said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. “This Phase 3 program is exploring various doses and dosing schedules with our novel anti-VEGF investigational agent to evaluate whether further improvements in vision and/or longer dosing intervals than monthly administration are possible.”

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**About the VIEW Program**

The VIEW 1 study is being conducted in the United States and Canada by Regeneron and the VIEW 2 study is being conducted in Europe, Asia Pacific, Japan, and Latin America by Bayer HealthCare. In the first year of the studies, the safety and efficacy of VEGF Trap-Eye at doses of 0.5 mg and 2.0 mg administered at four-week intervals and 2.0 mg at an eight-week dosing interval following one additional 2.0 mg dose at week four are being evaluated. Patients randomized to the ranibizumab arm of the trial will receive a 0.5 mg dose every four weeks. After the first year of treatment, patients will continue to be followed and treated for another year on a flexible, criteria-based extended PRN regimen with a dose administered at least every 12 weeks, but not more often than every four weeks until the end of the study.

The primary endpoint of these non-inferiority studies is the proportion of patients treated with VEGF Trap-Eye who maintain vision at the end of one year, compared to ranibizumab patients. Visual acuity is defined as the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, a standard chart used in research to measure visual acuity. Maintenance of vision is defined as losing fewer than three lines (equivalent to 15 letters) on the ETDRS chart. Key secondary endpoints include the mean change from baseline in visual acuity as measured by ETDRS and the proportion of patients who gained at least 15 letters of vision at week 52.

**About VEGF Trap-Eye**

Vascular Endothelial Growth Factor (VEGF) is a naturally occurring protein in the body whose normal role is to trigger the formation of new blood vessels (angiogenesis) to support the growth of the body's tissues and organs. It has also been associated with the abnormal growth and fragility of new blood vessels in the eye, which lead to the development of wet AMD. VEGF Trap-Eye is a fully human, soluble VEGF receptor fusion protein that binds all forms of VEGF-A along with the related placental growth factor (PlGF). Investigational VEGF Trap-Eye is a specific blocker of VEGF-A and PlGF that has been demonstrated in preclinical models to bind these growth factors with greater affinity than their natural receptors. Blockade of VEGF can prevent abnormal blood vessel formation as well as vascular leak and has proven beneficial in the treatment of wet AMD.

VEGF Trap-Eye is also in Phase 3 development for the treatment of Central Retinal Vein Occlusion (CRVO), another cause of blindness. The COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study is being led by Regeneron and the GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. Patients in both studies will receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients will be dosed on a PRN (as needed) basis for another six months. All patients will be eligible for rescue laser treatment. Initial data from the program are anticipated in early 2011.

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VEGF Trap-Eye is also in Phase 2 development for the treatment of Diabetic Macular Edema (DME). VEGF Trap-Eye dosed at 0.5 mg or 2 mg monthly, 2 mg every eight weeks after three monthly loading doses, or 2 mg on an as-needed (PRN) basis after three monthly loading doses is being compared to focal laser treatment, the current standard of care in DME. The primary efficacy endpoint evaluation is mean improvement in visual acuity at six months. Patient enrollment has been completed with initial data expected in the first half of 2010.

**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**

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