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**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 and Exchange Act of 1934

Date of Report (Date of earliest event reported): October 31, 2006 (October 30, 2006)

**REGENERON PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**New York**

(State or other jurisdiction of  
incorporation)

**000-19034**

(Commission File Number)

**133444607**

(I.R.S. Employer  
Identification Number)

**777 Old Saw Mill River Road, Tarrytown, New York**

(Address of principal executive offices)

**10591-6707**

(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 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 October 30, 2006, Regeneron Pharmaceuticals, Inc. announced positive data from a Phase 3 clinical program designed to provide two separate demonstrations of efficacy for the investigational drug Interleukin-1 (IL-1) Trap (rilonacept) within a single group of patients suffering from a rare chronic disease known as CAPS (CIAS1-related autoinflammatory periodic syndromes). A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(c) Exhibits

99.1 Press Release dated October 30, 2006

Pursuant to the requirements of the Securities and 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.

Dated: October 31, 2006

By: /s/ Stuart Kolinski  
Stuart Kolinski  
Vice President and General Counsel

## Exhibit Index

<u>Number</u>	<u>Description</u>
99.1	Press Release dated October 30, 2006.

**FOR IMMEDIATE RELEASE**

**REGENERON REPORTS POSITIVE PHASE 3 DATA  
FOR IL-1 TRAP IN CAPS**

**IL-1 Trap (rilonacept) Markedly Reduced Disease Activity  
in Patients with Rare Chronic Autoinflammatory Disease**

Tarrytown, NY (October 30, 2006) – Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) announced positive data from a Phase 3 clinical program designed to provide two separate demonstrations of efficacy for the investigational drug Interleukin-1 (IL-1) Trap within a single group of patients suffering from a rare chronic disease known as CAPS (*CIAS1*-related autoinflammatory periodic syndromes). The Phase 3 program of the IL-1 Trap (rilonacept) included two studies (Part A and Part B). Both studies met their primary endpoints (Part A:  $p < 0.0001$  and Part B:  $p < 0.001$ ). The primary endpoint of both studies was the change in disease activity, which was measured using a composite symptom score composed of a daily evaluation of fever/chills, rash, fatigue, joint pain, and eye redness/pain.

Regeneron plans to file a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) in the second quarter of 2007, following completion of a 24-week open-label extension phase. The FDA has granted Orphan Drug status and Fast Track designation to the IL-1 Trap program for the treatment of CAPS.

The first study (Part A) was a double-blind and placebo-controlled 6-week trial, in which patients randomized to receive IL-1 Trap had an approximately 85% reduction in their mean symptom score compared to an approximately 13% reduction in patients treated with placebo ( $p < 0.0001$ ). Following a 9-week interval during which all patients received IL-1 Trap, a “randomized withdrawal” study (Part B) was performed, in which the same patients were re-randomized to either switch to placebo or continue treatment with IL-1 Trap in a double-blind manner. During the 9-week randomized withdrawal period, patients who were switched to placebo had a five-fold increase in their mean symptom score, compared with those remaining on IL-1 Trap who had no significant change ( $p < 0.001$ ). Both the Part A and Part B studies achieved statistical significance in all of their pre-specified secondary and exploratory endpoints, including responder analyses as detailed below.

“Many of my CAPS patients who participated in the trial described dramatic responses to this investigational therapy. Since the onset of the syndrome is at birth, these individuals experienced for the first time a life without suffering from this serious disease,” said Hal Hoffman, M.D., Associate Professor of Pediatrics and Medicine, Division of Rheumatology, Allergy, and Immunology at the University of California at San Diego

School of Medicine, who with his colleagues discovered the *CIAS1* gene and its causal relationship to CAPS.

Preliminary analysis of the safety data from both studies indicated that there were no drug-related serious adverse events. Injection site reactions and upper respiratory tract infections, all mild to moderate in nature, occurred more frequently in patients while on IL-1 Trap than on placebo. In these studies, the IL-1 Trap appeared to be well tolerated; 46 of 47 randomized patients completed the Part A study, and 44 of 45 randomized patients completed the Part B study. The 24-week open-label extension phase is ongoing.

#### **Additional Key Study Results**

All pre-specified secondary and exploratory endpoints in both studies demonstrated statistically significant effects of the IL-1 Trap compared to placebo. For example:

- An exploratory “responder” analysis of Part A indicated that 70% of patients treated with the IL-1 Trap had at least a 75% reduction in their symptom score compared with 0% of patients treated with placebo ( $p < 0.000001$ ).
- IL-1 Trap significantly reduced the number of days in which patients experienced any moderate or severe symptoms compared with placebo ( $p < 0.0001$ ). Patients administered IL-1 Trap in the Part A study experienced only 5% of days with moderate or severe symptoms compared with 50% of days prior to treatment.
- Exploratory analyses indicated that, compared with placebo, IL-1 Trap therapy significantly lowered all of the individual components of the composite symptom score and reduced laboratory measures of inflammation such as serum C- Reactive Protein (CRP) and serum amyloid A (SAA) by about 90% (both  $p$  values  $< 0.01$ ).

A detailed presentation of the data from both the Part A and Part B studies will be submitted to an upcoming medical meeting.

“For the first time in Phase 3 studies, blocking IL-1 with IL-1 Trap demonstrated a significant effect on relieving the symptoms of patients suffering from this serious, life-long hereditary disease that produces recurring symptoms such as fever, rash, joint pain, fatigue and eye redness or pain,” said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. “We are also evaluating additional inflammatory diseases in which the IL-1 Trap could potentially provide benefit.”

“The Regeneron ‘Trap Technology’ was designed to provide highly potent and specific blockers of cytokines and growth factors that are implicated in a variety of disease processes. It is particularly gratifying that the first Phase 3 studies of a Regeneron Trap demonstrated such a remarkable reduction of symptoms in patients with a cytokine driven, genetic disease,” said George D. Yancopoulos, M.D., Ph.D., President, Regeneron Research Laboratories and Chief Scientific Officer of Regeneron. “We are grateful to the patients and investigators who participated in this study.”

## **About *CIAS1*-related Autoinflammatory Periodic Syndromes (CAPS)**

*CIAS1*-related Autoinflammatory Periodic Syndromes (CAPS) is a spectrum of rare inherited inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and Neonatal Onset Multisystem Inflammatory Disease (NOMID). These syndromes are characterized by spontaneous systemic inflammation and are termed autoinflammatory disorders. A novel feature of these conditions (particularly FCAS and MWS) is that exposure to mild degrees of cold temperature can provoke a major inflammatory episode that occurs within hours.

CAPS are caused by a range of mutations in the gene *CIAS1* (also known as NALP3) which encodes a protein named cryopyrin (“icy-fire”). This gene, and its causal relationship to FCAS and MWS, was discovered by Dr. Harold Hoffman and colleagues at the University of California at San Diego. Dr. Hoffman and others have demonstrated the ability of IL-1 blocking agents to reduce signs and symptoms of CAPS. Currently, there are no medicines approved for the treatment of CAPS.

## **About the CAPS Pivotal Study**

The Phase 3 clinical program is designed to evaluate the efficacy and safety of the IL-1 Trap, a long-acting IL-1 inhibitor, in adult patients with CAPS. The IL-1 Trap has not been evaluated in NOMID. The first study (Part A) was a double-blind and placebo-controlled 6-week trial, in which patients were randomized to receive a self-injected 160 milligram (mg) dose of the IL-1 Trap or placebo once a week. Following a 9-week interval during which all patients received a 160 mg dose of the IL-1 Trap, a “randomized withdrawal” study (Part B) was performed in which the same patients were re-randomized to switch either to placebo or continue treatment with IL-1 Trap in a double-blind manner.

## **About Regeneron Pharmaceuticals**

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic medicines for the treatment of serious medical conditions. Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, and inflammatory diseases, and has preclinical programs in other diseases and disorders. For more information on Regeneron, visit the Company’s web site at [www.regeneron.com](http://www.regeneron.com).

*This news release discusses historical information and includes forward-looking statements about Regeneron and its products, programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of our drug candidates, determinations by regulatory and administrative governmental authorities which delay or restrict our ability to continue to develop or commercialize our drug candidates, competing drugs that are superior to our product candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our 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, 2005 and its Form 10-Q for the quarter ended June 30, 2006. 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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