

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) **October 8, 2003 (October 7, 2003)**

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

NEW YORK
(State or other jurisdiction
of incorporation)

0-19034
(Commission
File Number)

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

777 OLD SAW MILL RIVER ROAD,
TARRYTOWN, NY
(Address of principal executive offices)

10591-6707
(Zip Code)

Registrant's telephone number, including area code

(914) 347-7000

NOT APPLICABLE

(Former name or former address, if changed since last report)

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INFORMATION TO BE INCLUDED IN REPORT

Item 5. Other Events.

On October 7, 2003, the Company issued a press release, a copy of which is included as an exhibit to this filing.

Item 7. Financial Statements and Exhibits.

(c) Exhibits

99(a) Press Release dated October 7, 2003.

SIGNATURE

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 thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

By: /s/ Stuart Kolinski

Stuart Kolinski
Vice President & General Counsel

Date: October 8, 2003

FOR IMMEDIATE RELEASE

REGENERON REPORTS PHASE II RESULTS FOR IL-1 TRAP CLINICAL PROGRAM IN RHEUMATOID ARTHRITIS

**IL-1 Trap Phase II Study Demonstrates Clinical Activity
and Favorable Safety and Tolerability Profile**

Tarrytown, NY (October 7, 2003) – Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) announced today that the Company's IL-1 Trap demonstrated evidence of efficacy and safety in patients with rheumatoid arthritis (RA) in a Phase II dose-ranging study in approximately 200 patients. Patients treated with the highest dose, 100 milligrams (mg), of the IL-1 Trap exhibited improvements in primary and secondary end-points of the trial. When compared with placebo, subjects receiving 100 mg of IL-1 Trap demonstrated the following clinical and laboratory effects:

- An increase in the proportion of ACR 20 responses (primary endpoint) – 46% vs. 30.9% (p=0.11)
- An increase in the average ACR-N Score – 24.1% vs. 13.5%, (p=0.02)
- An increase in the proportion of ACR 50 responses – 20.0 % vs. 9.1%, (p=0.11)
- An increase in the proportion of ACR 70 responses – 12.0 % vs. 3.6%, (p=0.11)
- A greater decrease in the Disease Activity Score (DAS) – -1.1 vs. -0.7 (p=0.02)
- A faster time of onset of ACR 20 response (median time to onset) – 36 days vs. 77 days (p=0.03)
- Increased benefit in those patients on concomitant disease modifying anti-rheumatic drugs (DMARDs) – ACR 20 of 50.0% vs. 33.3%, (p=0.16) and ACR 50 of 29.4% vs. 11.1% (p=0.06)
- A decrease in C-Reactive Protein (CRP) a systemic marker of inflammation – -1.36 vs. + 0.07 (p=0.004)

The IL-1 Trap was generally well tolerated and was not associated with any serious adverse events. Of the patients treated with the IL-1 Trap, less than 5 percent developed antibodies against the molecule.

“This positive study, demonstrating evidence for clinical efficacy and the lack of safety concerns, clearly supports further development of this exciting new agent that is being studied for the treatment of patients with rheumatoid arthritis,” said Larry Moreland, M.D., Professor of Medicine, Division of Clinical Immunology and Rheumatology, University of Alabama at Birmingham School of Medicine.

“This Phase II study provides strong evidence for clinical activity of the IL-1 Trap in rheumatoid arthritis. Moreover, it appears that we may not yet have achieved the optimal dose level, allowing for the potential of

even greater efficacy at higher doses,” said Leonard S. Schleifer, M.D., Ph.D., Regeneron’s President and Chief Executive Officer. “We plan to move quickly to complete our detailed evaluation of these results and work with Novartis to determine the most efficient path forward for the IL-1 Trap in rheumatoid arthritis. Furthermore, given the favorable safety profile observed, we also intend to pursue a broader clinical development program for this promising molecule in several additional therapeutic categories.”

Regeneron and Novartis Pharma AG, who formed a collaborative arrangement to develop and commercialize the IL-1 Trap, indicated that they will be working together to evaluate the data gathered in the study and determine the best path forward for the next clinical study.

Trial Design and Preliminary Data Summary

The multi-center Phase II trial was a randomized, placebo-controlled, double-blind study in people with active RA who have had an inadequate response to at least one disease-modifying anti-rheumatic drug (DMARDs). The study included approximately 200 participants, who were randomized equally into placebo or one of three fixed-dose groups (25, 50, or 100 mg) and received weekly subcutaneous injections. A substantial proportion of the subjects in each group were on DMARDs at baseline and continued their treatment with DMARDs during the trial (65%, 63%, 60%, and 68% of patients in the placebo, 25 mg, 50 mg, and 100 mg groups, respectively). The double-blind treatment period ran for 12 weeks, and participants were evaluated for 10 weeks following the cessation of treatment for safety and to track disease progression. The American College of Rheumatology (ACR20) criteria for improvement in RA as a function of IL-1Trap dose was the pre-specified primary efficacy endpoint. ACR50, ACR70, and ACR-N scores and other measures of disease activity were evaluated as secondary efficacy and exploratory endpoints.

The data from the study is summarized in the table below:

	Placebo	25 mg	50 mg	100 mg	100 mg vs. Pbo p value
Intent to Treat (ITT)					
Last Observation Carried Forward (LOCF)	n = 55	n = 46	n = 48	n = 50	
ACR 20 (%)	30.9	34.8	20.8	46.0	0.11
ACR 50 (%)	9.1	17.4	10.4	20.0	0.11
ACR 70 (%)	3.6	2.2	2.1	12.0	0.11
Sustained ACR 20 (%)	12.7	19.6	18.8	30.0	0.03
Sustained ACR 50 (%)	3.6	0	4.2	10	0.19
ACR-N (%)	13.5	18.0	13.2	24.1	0.02
ACR-N AUC	787	1146	988	1357	0.02
CRP (mean change) mg/dL	0.072	-0.675	-1.021	-1.363	0.004

	n = 53	n = 44	n = 48	n = 50	
Disease Activity Score	-0.70	-0.88	-0.85	-1.12	0.02
	n = 53	n = 43	n = 47	n = 48	
Disease Activity Score AUC	394	367	391	345	0.008
Patients on DMARDs	n = 36	n = 29	n = 29	n = 34	
ACR 20 (%)	33.3	34.5	27.6	50.0	0.16
ACR 50 (%)	11.1	17.2	13.8	29.4	0.06
ACR 70 (%)	5.6	0.0	3.4	17.6	0.11

Safety and Tolerability

The IL-1 Trap appeared to have a favorable safety and tolerability profile. There was no evidence of an increased rate of infection and no clinically significant effect on laboratory parameters, including hematology, serum chemistries, or vital signs. Only two serious adverse events, both of which occurred in the off-treatment period, were reported among treated patients and were not considered related to the IL-1 Trap. The most common side effect was a generally mild to moderate injection-site reaction. This reaction is, in part, associated with the formulation used for this trial, which will be changed for subsequent trials. Other side effects were experienced infrequently and do not appear to be dose-related. Antibodies were not dose-related and occurred in only a very small proportion (less than 5 percent) of treated patients and were not dose-related.

Webcast:

Leonard S. Schleifer, M.D., Ph.D., President & CEO of Regeneron Pharmaceuticals, Inc. invites you to join him and members of senior management from Regeneron in a webcast with the investment community to discuss the results of the Phase II trial for the IL-1 Trap on Tuesday, October 7, 2003 at 10:00 a.m. Eastern; 9:00 a.m. Central; 8:00 a.m. Mountain; and 7:00 a.m. Pacific.

The audio portion of the conference call will be available live, with accompanying slides, by webcast at www.regeneron.com on the Events page, under the Investor heading. The online archive as well as the dial-in replay of the call will be available for 30 days, beginning approximately two hours after the live call ends at the following numbers:

USA / Canada Replay Dial-In: (800) 642-1687

International Replay Dial-In: (706) 645-9291

Conference Call ID# 3084565

About Regeneron

Regeneron 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 obesity, rheumatoid arthritis, cancer, and asthma and has preclinical programs in other diseases and disorders.

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 drugs and biologics, determinations by regulatory and administrative governmental authorities, competitive factors, technological developments, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement to be canceled or to terminate without any product success, and other material risks. A more complete description of these 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, 2002 and the Form 10-Q for the quarter ended June 30, 2003. 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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Additional information about Regeneron and recent news releases are available on Regeneron's Worldwide Web Home Page at www.regeneron.com.