
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): August 13, 2007 (August 8, 2007)

REGENERON PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

New York

(State or other jurisdiction of
Incorporation)

000-19034

(Commission File No.)

133444607

(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))
-
-

TABLE OF CONTENTS

[Item 8.01 Other Events.](#)

[Item 9.01 Financial Statements and Exhibits.](#)

[SIGNATURES](#)

[Exhibit Index](#)

[EX-99.1: PRESS RELEASE](#)

[EX-99.2: PRESS RELEASE](#)

[Table of Contents](#)

Item 8.01 Other Events.

On August 8, 2007, Regeneron Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has accepted for filing and granted priority review status to the Biologics License Application (BLA) for riloncept, the Interleukin-1 (IL-1) Trap, for the long-term treatment of Cryopyrin-Associated Periodic Syndromes (CAPS). A copy of this press release is attached as Exhibit 99.1 and is incorporated herein by reference.

On August 13, 2007, Regeneron Pharmaceuticals, Inc. issued a press release announcing that it received a milestone payment of \$20 million from Bayer HealthCare following dosing of the first patient in the Phase 3 study of the VEGF Trap-Eye in the neovascular form of age-related macular degeneration (wet AMD). A copy of this press release is attached as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated August 8, 2007.

99.2 Press Release dated August 13, 2007

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.

By: /s/ Stuart Kolinski

Name: Stuart Kolinski

Title: Senior Vice President and General Counsel

Date: August 13, 2007

[Table of Contents](#)

Exhibit Index

<u>Number</u>	<u>Description</u>
99.1	Press Release dated August 8, 2007
99.2	Press Release dated August 13, 2007



Press Release

Riloncept (IL-1 Trap) Granted FDA Priority Review for the Treatment of CAPS

Regeneron's first marketing application is accepted for review by the FDA

Tarrytown, NY (August 8, 2007) — Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing and granted priority review status to the Biologics License Application (BLA) for riloncept, the Interleukin-1 (IL-1) Trap, for the long-term treatment of Cryopyrin-Associated Periodic Syndromes (CAPS). The FDA has previously granted Orphan Drug status and Fast Track designation to riloncept for the treatment of CAPS.

The FDA grants priority review to drugs that may offer a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious or life-threatening disease. Under priority review status, a target date is established for the FDA to complete their review of a BLA within six months from their receipt of the submission. The FDA is expected to take action on the riloncept application by the end of November 2007. Currently, there are no medicines approved for patients suffering from CAPS, a spectrum of rare inherited inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS).

“The FDA’s decision to grant priority review to riloncept underscores the need for an effective therapy for patients suffering from this serious, debilitating disease,” said Leonard S. Schleifer, M.D., Ph.D., president and chief executive officer of Regeneron. “Acceptance of the BLA filing brings us one step closer to our goal of providing the first approved treatment for patients with CAPS. We look forward to continuing to work with the FDA during their ongoing review of our marketing application.”

About Riloncept

Interleukin-1 (IL-1) is a protein secreted by certain cells in the body. In many cases, IL-1 acts as a messenger to help regulate immune and inflammatory responses by attaching to cell-surface receptors in cells that participate in the body’s immune system. In excess, it can be harmful and has been shown to be a key driver of inflammation in a variety of diseases, including CAPS.

Riloncept is a potent, long-acting, investigational agent that inhibits IL-1. It is designed to attach to and neutralize IL-1 in the blood stream before the IL-1 can attach to cell-surface receptors and

generate signals that can trigger disease activity in body tissue. Once attached to riloncept, IL-1 cannot bind to the cell surface receptors and, together with riloncept, is flushed from the body.

About Cryopyrin-Associated Periodic Syndromes (CAPS)

Cryopyrin-Associated Periodic Syndromes (CAPS) is a spectrum of rare inherited inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS). These autoinflammatory diseases are characterized by spontaneous and environmentally triggered systemic inflammation. Inflammatory symptoms in patients with FCAS and MWS include fever, chills, rash, fatigue, joint pain, and eye redness. Currently, there are no medicines approved for the treatment of CAPS.

CAPS is caused by a range of mutations in the gene CIAS1 (also known as NALP3) that encodes a protein named cryopyrin. This gene, and its causal relationship to FCAS and MWS, was discovered by Dr. Hal Hoffman and colleagues at the University of California at San Diego. Dr. Hoffman and others have studied the ability of IL-1 blocking agents to reduce signs and symptoms of CAPS, and Dr. Hoffman served as the key advisor in the design and conduct of the Phase 3 riloncept CAPS program.

CAPS has been reported primarily in North America and Europe. There are no reliable prevalence statistics for this disease. We estimate that the number of patients with CAPS in the United States is between 200 and 500.

About Regeneron Pharmaceuticals

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 for the potential treatment of cancer, eye diseases, and inflammatory diseases and has preclinical programs in other diseases and disorders. Additional information about Regeneron and recent news releases are available on Regeneron's worldwide web site at www.regeneron.com

Forward Looking Statement

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 may 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-Q for the quarter ended June 30, 2007. 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.

###

Contact Information:

Charles Poole
Investor Relations
914.345.7640
charles.poole@regeneron.com

Laura Lindsay
Corporate Communications
914.345.7800
laura.lindsay@regeneron.com

Lauren Tortorete
Media Relations
212.845.5609
ltortorete@biosector2.com

FOR IMMEDIATE RELEASE**Regeneron Receives \$20 Million Milestone Payment for Initiation of Phase 3 Study of VEGF Trap-Eye in Wet AMD**

Tarrytown, NY (August 13, 2007) — Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) announced today that it has received a \$20 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of the VEGF Trap-Eye in the neovascular form of age-related macular degeneration (wet AMD).

“Age-related macular degeneration continues to be one of the leading causes of blindness in adults today,” said Leonard S. Schleifer, M.D., Ph.D., president and chief executive officer of Regeneron. “Results of early phase studies have shown that VEGF Trap-Eye has the potential to be an important addition to the treatment alternatives available for patients with wet AMD. We are especially pleased to be collaborating with Bayer HealthCare on this program. Bayer is an established leader in specialty pharmaceutical products, and we believe that they add important global expertise as we continue the development of the VEGF Trap-Eye.”

About the Phase 3 Study

The Phase 3 study will be a non-inferiority comparison of the VEGF Trap-Eye and ranibizumab (Lucentis®, a registered trademark of Genentech, Inc.), an anti-angiogenic agent approved for use in wet AMD. The randomized, double-masked Phase 3 study is expected to enroll approximately 1,200 patients in more than 200 centers throughout the United States and Canada. This trial, known as VIEW 1 (VEGF Trap: Investigation of Efficacy and safety in Wet age-related macular degeneration), will be conducted pursuant to a Special Protocol Assessment from the U.S. Food and Drug Administration (FDA) and is the first in the companies’ Phase 3 global development program in wet AMD to be carried out in the U.S., Europe, and other parts of the world.

About the VEGF Trap-Eye

Vascular endothelial growth factor (VEGF) is a naturally occurring protein in the body whose normal role is to trigger 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. The 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). The VEGF Trap-Eye is a specific and highly potent blocker of these growth factors. Blockade of VEGF, which can prevent abnormal blood vessel formation and vascular leak, has proven beneficial in the treatment of wet AMD.

About AMD

Age-related macular degeneration (AMD) is a leading cause of acquired blindness. Patients with this condition can experience a loss of vision due to the development of abnormal, fragile blood

vessels in the back of the eye. A particular type of AMD, called wet AMD, accounts for approximately 90 percent of AMD-related blindness. Wet AMD is the leading cause of blindness for people over the age of 65 in the U.S. and Europe.

About Regeneron Pharmaceuticals

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 for the potential treatment of cancer, eye diseases, and inflammatory diseases and has preclinical programs in other diseases and disorders. Additional information about Regeneron and recent news releases are available on Regeneron's worldwide web site at www.regeneron.com

Forward Looking Statement

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 may 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-Q for the quarter ended June 30, 2007. 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.

###

Contact Information:

Charles Poole
Investor Relations
914.345.7640
charles.poole@regeneron.com

Laura Lindsay
Corporate Communications
914.345.7800
laura.lindsay@regeneron.com

Lauren Tortorete
Media Relations
212.845.5609
ltortorete@biosector2.com