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Rilonacept (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, N.Y., Aug 08, 2007 (BUSINESS WIRE) -- 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 rilonacept, 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 rilonacept 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 rilonacept 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 rilonacept 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 Rilonacept

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.

Rilonacept 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 rilonacept, IL-1 cannot bind to the cell surface receptors and, together with rilonacept, 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 rilonacept 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.

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