Regeneron Submits Biologics License Application to U.S. FDA for IL-1 Trap (Rilonacept) for Treatment of CAPS

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As part of the BLA submission, Regeneron has requested a Priority Review from the FDA, which, if granted, would provide a target for the FDA to complete their review within six months from their receipt of the submission under current guidelines. The FDA has previously granted Orphan Drug status and Fast Track designation to the IL-1 Trap for the treatment of CAPS.

"Currently, there are no medicines approved for patients suffering from CAPS, and we are hopeful that the IL-1 Trap will play an important role in the future treatment of this rare condition," said Leonard S. Schleifer, M.D., Ph.D., Regeneron's president and chief executive officer. "This submission marks a major corporate milestone for Regeneron. I want to express my appreciation for the hard work and dedication shown by the many people at Regeneron who discovered and developed the IL-1 Trap and completed the submission of this, our first BLA."

About the Interleukin-1 and the IL-1 Trap (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.

The IL-1 Trap is a potent, long-acting inhibitor of IL-1. It is designed to attach to and neutralize IL-1 in the blood stream before it can attach to cell-surface receptors and generate signals that can trigger disease activity in body tissue. Once attached to the Trap, IL-1 cannot bind to the cell surface receptors and, together with the Trap, is flushed from the body.

Regeneron has completed a Phase 3 program evaluating self-administration by weekly subcutaneous injection of the IL-1 Trap in patients with CAPS. It is also conducting a proof-of-concept study of the IL-1 Trap in patients with gout.

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 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) which 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 IL-1 Trap CAPS program.

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 March 31, 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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