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Regeneron Announces Positive Results in Exploratory Proof-of-Concept Study of Rilonacept in Chronic Active Gout

Phase 2 Study of Prevention of Gout Flares Being Initiated

TARRYTOWN, N.Y.--(BUSINESS WIRE)--Sept. 10, 2007--Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced that treatment with rilonacept (IL-1 Trap) demonstrated a statistically significant reduction in patient pain scores in a single-blind, placebo run-in-controlled study of 10 patients with chronic active gout. Mean patients' pain scores, the key symptom measure in persistent gout, were substantially reduced during blinded active treatment (-41%, $p=0.025$, during the first two weeks of active treatment, and -56%, p less than 0.004, after six weeks of active treatment), as compared to changes during the blinded two-week placebo run-in period (-13%, which was not statistically significant). In this study in which safety was the primary endpoint measure, treatment with rilonacept was generally well tolerated with mild injection-site reaction being the only reported drug-related adverse event.

This study enrolled patients with chronic active gout, who had been suffering ongoing persistent joint pain and inflammation for at least four weeks and for whom standard therapies were ineffective or associated with risks related to side effects. Disease activity changes during a blinded placebo run-in period were compared to changes during subsequent blinded treatment with rilonacept. After six weeks of rilonacept treatment, 70 percent of patients achieved at least a 50 percent improvement in their pain scores; none of the patients achieved a 50 percent improvement in their pain scores during the placebo run-in period. Other efficacy measures, including patients' and physicians' global assessments of disease activity and joint assessment scores, were improved with rilonacept treatment. Detailed data from the study will be presented at an upcoming scientific conference.

"Rilonacept clearly improved patients' symptoms in this small pilot study that included refractory gout patients with chronic disease complicated by acute exacerbations," said Robert Terkeltaub, M.D., Professor of Medicine and Associate Division Director at the University of California at San Diego and Chief of Rheumatology at the Veterans Administration Medical Center. "These results are particularly noteworthy given that refractory patients such as these do not typically show spontaneous improvement in symptoms. Further studies of rilonacept are warranted in a variety of gout conditions, as large numbers of patients are dissatisfied with or intolerant to existing therapies."

"We are very pleased with the outcome of this exploratory proof-of-concept study. While this was a small study in a heterogeneous group of gout sufferers, it represents the first controlled and blinded study of an interleukin-1 (IL-1) blocking agent in gout. It is consistent with a wealth of preclinical data suggesting that IL-1 could be an important driver of pain and inflammation in gout," stated George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "Based upon these results, we are committed to further studying rilonacept in a variety of gout settings."

Regeneron is currently initiating a double-blind, placebo-controlled Phase 2 study of rilonacept in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy used to control the disease. Gout is often characterized by high blood levels of uric acid, a bodily waste product normally excreted by the kidneys. The uric acid can form crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Chronic treatment with uric acid-lowering medicines, such as allopurinol, is prescribed to eliminate the uric acid crystals and prevent reformation. During the first several months of therapy and before uric acid blood levels are sufficiently reduced, dissolution of the uric acid crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. This Phase 2 study will explore the safety and efficacy of rilonacept in preventing gout flares in patients initiating allopurinol therapy.

About Gout

Gout is a condition that occurs when the bodily waste product uric acid is deposited in the joints and/or soft tissues. In the joints, these uric crystals cause inflammation, which leads to pain, swelling, redness, heat, and stiffness in the joints. More than three million Americans currently suffer from gout. 9.4 million prescriptions are written for uric acid-lowering therapy each year. Large numbers of patients are dissatisfied with or intolerant to existing therapies that prevent spontaneous or drug-induced pain and flares.

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.

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. Regeneron has submitted a Biologics License Application to the U.S. Food and Drug Administration for rilonacept for the long-term treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), a spectrum of rare inherited inflammatory conditions.

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

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