Regeneron's ARCALYST(R) (rilonacept) Reduced Incidence of Gout Flares by 81 Percent in a Phase 2 Study in Gout Patients Initiating Urate-Lowering Therapy

September 3, 2008

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In the first 12 weeks of treatment, 45.2 percent of patients treated with placebo experienced a gout flare and, of those, 47.4 percent had more than one flare. Among patients treated with ARCALYST, only 14.6 percent experienced a gout flare (p=0.0037 versus placebo) and none had more than one flare. No serious drug-related adverse events were reported in patients receiving ARCALYST treatment. Injection-site reaction was the most commonly reported adverse event with ARCALYST treatment. Detailed data from the study will be presented at a future scientific conference.

This Phase 2 study evaluated the efficacy and safety of ARCALYST versus placebo in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy that is used to control gout. ARCALYST patients received an initial 320 milligram (mg) dose, followed by weekly doses of 160 mg. Gout is 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 months of allopurinol therapy while uric acid blood levels are being reduced, the break up of the uric acid crystals can result in stimulation of inflammatory mediators, including interleukin-1 (IL-1), resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days. In this study a gout flare was defined as patient-reported acute joint pain that was deemed by the patient and/or investigator to require rescue treatment with an anti-inflammatory drug.

"These findings could be significant in the future management of patients with gout in that they address an impediment to successful long-term treatment. Allopurinol therapy is an important approach to lowering patients' high uric acid levels, which is the cause of their gout. However, the increased risk of painful gout flares over the first few months of initiation of uric acid-lowering therapy makes it difficult for patients to stick with treatment," said John Sundy, M.D., Ph.D., Division of Rheumatology, Department of Medicine, Duke University Medical Center. "Currently, colchicine or anti-inflammatory drugs are recommended for use to reduce the risk of gout flares in patients taking allopurinol, but these drugs may cause side effects and some patients do not tolerate them. The results from this study suggest that concomitant use of rilonacept during the first several months of allopurinol therapy may help avoid gout flares, which could, in turn, improve patient outcomes."

"We are encouraged about the potential role of ARCALYST® (rilonacept) therapy in the treatment of gout. The results of this study, together with the findings of a previous small study of ARCALYST in patients with chronic, active gout, suggest that ARCALYST may provide utility in a number of different gout patient populations," stated George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. "Based upon these results, we plan to initiate a Phase 3 clinical development program early next year with ARCALYST in the prevention of gout flares in patients initiating urate-lowering drug therapy. Studies in other gout settings are also planned."

Conference Call

Regeneron will host a webcast conference call to discuss these results today, September 3, 2008, at 8:30 a.m., Eastern Time. The dial-in information is:

Domestic Dial-in Number: (866)314-5050
International Dial-in Number: (617)213-8051
Participant Passcode: 16355081

For those unable to participate during the call, a replay will be available from 10:30 a.m. Eastern Time on September 3, 2008 through October 3, 2008. The call can be accessed by dialing:

Domestic Dial-in Number: (888)286-8010
International Dial-in Number: (617)801-6888
Participant Passcode: 58761816

The replay will be available over the Internet and can be accessed by visiting the Regeneron website at www.regeneron.com on the Presentations page of the Investor Relations section.

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 acid crystals cause inflammation, which leads to pain, swelling, redness, heat, and stiffness in the joints. More than three million Americans currently suffer from gout. Treatment guidelines recommend that patients with elevated uric acid levels who experience multiple gout attacks each year should receive chronic urate-lowering therapy, such as allopurinol. Allopurinol reduces the production of uric acid in the body to prevent the occurrence of gout attacks with long-term use. Approximately 750,000 gout patients initiate allopurinol therapy each year. During the first months of allopurinol therapy while uric acid blood levels are being reduced, the break up of the uric acid crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. Anti-inflammatory therapy with colchicine is sometimes used to help prevent these flares. However, the side effects associated with prophylactic dosing with colchicine, which include diarrhea, abdominal cramps, nausea, and vomiting, can limit patients' adherence to both colchicine and allopurinol treatment.

Rationale for the Clinical Exploration of Use of ARCALYST® (rilonacept) in the Treatment of Gout

Interleukin-1 (IL-1) is a protein secreted by infection-fighting cells in the blood and tissues. 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 gout. In gout, uric acid crystals stimulate the production of IL-1, which causes an inflammatory response in the joints and surrounding tissues.

ARCALYST is an 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 ARCALYST, IL-1 cannot bind to the cell-surface receptors and is eventually eliminated from the body.

Important Information About ARCALYST

ARCALYST is indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. IL-1 blockade may interfere with immune response to infections. Serious, life-threatening infections have been reported in patients taking ARCALYST® (rilonacept). ARCALYST should be discontinued if a patient develops a serious infection. Taking ARCALYST with tumor necrosis factor inhibitors is not recommended because this may increase the risk of serious infections. Treatment with ARCALYST should not be initiated in patients with active or chronic infections. Patients should not receive a live vaccine while taking ARCALYST. It is recommended that patients receive all recommended vaccinations prior to initiation of treatment with ARCALYST. Patients should be monitored for changes in their lipid profiles and provided with medical treatment if warranted. Hypersensitivity reactions associated with ARCALYST administration have been rare. Please see the full Prescribing Information for ARCALYST, available online at www.regeneron.com/ARCALYST-fpi.pdf.

About Regeneron Pharmaceuticals, Inc.

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in clinical trials 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 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, development programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's 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-K for the year ended December 31, 2007 and Form 10-Q for the quarter ended June 30, 2008. 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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