



FDA Approves Regeneron's ARCALYST(TM) (rilonacept) for Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS)

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TARRYTOWN, N.Y., Feb 27, 2008 (BUSINESS WIRE) -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced it has received marketing approval from the U.S. Food and Drug Administration (FDA) for ARCALYST (rilonacept) Injection for Subcutaneous Use, an interleukin-1 blocker, 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. ARCALYST is the only therapy approved for patients with CAPS, a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

ARCALYST is a targeted inhibitor of interleukin-1 (IL-1), the key driver of inflammation in CAPS. In the pivotal clinical development program, patients treated with ARCALYST experienced a greater improvement in overall symptom scores than patients treated with placebo. These improvements were sustained over time with continued ARCALYST treatment. The most commonly reported adverse reactions reported with ARCALYST were injection-site reaction and upper respiratory tract infection.

"The approval of ARCALYST represents a major advance in the treatment of CAPS patients," said Hal Hoffman, M.D., Associate Professor, University of California, San Diego and a leading expert on CAPS. "Much-needed treatment will now be available to patients suffering from debilitating CAPS symptoms. I hope that the approval of ARCALYST will also contribute to increased awareness of this rare disease which currently is frequently misdiagnosed and insufficiently treated."

Regeneron expects to launch ARCALYST, its first commercial product, within the next 30 days.

"This approval exemplifies Regeneron's commitment to discover, develop, and commercialize important medicines for patients suffering from serious diseases, such as CAPS. I would like to take this opportunity to thank the clinical investigators and CAPS patients participating in our studies, the FDA, and everyone at Regeneron for their collaborative effort in making ARCALYST available to patients who need it," said Leonard S. Schleifer, M.D., Ph.D., Regeneron's president and chief executive officer. "We recognize that ARCALYST may help address a significant unmet medical need that exists among CAPS patients and are therefore committed to helping these patients obtain access to this new treatment."

About Cryopyrin-Associated Periodic Syndromes (CAPS)

Recently, medical researchers have identified and described a group of rare, inherited, auto-inflammatory disorders, known as Cryopyrin-Associated Periodic Syndromes or CAPS. Three related conditions make up the broader disease known as CAPS: Familial Cold Auto-inflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and Neonatal-Onset Multisystem Inflammatory Disease (NOMID). ARCALYST is not indicated for use in, and has not been studied in, patients with NOMID.

CAPS are characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

CAPS are generally caused by autosomal-dominant mutations (changes) in the NLRP-3 (previously known as CIAS1) gene and resultant alterations in the protein, cryopyrin, which it encodes. Cryopyrin, active in circulating, infection-fighting, white blood cells, controls the production of a protein called interleukin-1 (IL-1). As part of the body's infection-fighting defense system, IL-1 circulates throughout the body and can trigger inflammatory reactions when it binds to inflammatory cells. Researchers have found that alterations in the cryopyrin protein lead to over-production of IL-1, resulting in an inflammatory response and the symptoms of CAPS. Most, but not all, patients with CAPS have the NLRP-3 gene mutation.

The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States.

About ARCALYST (rilonacept)

ARCALYST is a targeted inhibitor of interleukin-1 (IL-1), the key driver of inflammation in Cryopyrin-Associated Periodic Syndromes (CAPS). In the pivotal clinical development program for ARCALYST, change in disease activity was measured using a composite symptom score composed of a daily evaluation of rash, feelings of fever/chills, joint pain, eye redness/pain, and fatigue. Patients treated with ARCALYST experienced an improvement in overall symptom scores as compared with patients treated with placebo. These improvements were sustained over time with continued treatment with ARCALYST. The most commonly reported adverse reactions reported with ARCALYST were injection-site reaction and upper respiratory tract infection.

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. 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

(rilonacept) administration have been rare. Please see the full Prescribing Information for ARCALYST, available online at www.regeneron.com/ARCALYST-fpi.pdf.

Conference Call

Dr. Leonard Schleifer, President and Chief Executive Officer of Regeneron, and other members of senior management will host a conference call to discuss the approval to market ARCALYST. The interactive call will be held at 8:30 a.m. Eastern Time on Thursday, February 28, 2008 and can be accessed live through the Regeneron website at www.regeneron.com on the presentations page of the Investor Relations section. The call, including the question and answer session, can also be accessed by dialing:

Domestic Dial-in Number: (800) 798-2884

International Dial-in Number: (617) 614-6207

Participant Passcode: 19033960

An archived version of the conference call will be available for 30 days on the company's website at www.regeneron.com on the presentations page of the Investor Relations section.

About Regeneron Pharmaceuticals

Regeneron is a biopharmaceutical company that discovers, develops, and commercializes therapeutic medicines for the treatment of serious medical conditions. In addition to ARCALYST, its first commercialized product, 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 website 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-K for the year ended December 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.

SOURCE: Regeneron Pharmaceuticals, Inc.

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