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Regeneron's Rilonacept Granted European Marketing Authorization for Treatment of Cryopyrin-Associated Periodic Syndromes (CAPS)

TARRYTOWN, N.Y., Oct 27, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced it has received marketing authorization in the European Union for rilonacept, an interleukin-1 blocker, for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) with severe symptoms, including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS), in adults and children aged 12 years and older. Marketing authorization for rilonacept was granted by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) under exceptional circumstances.

"Rilonacept, which is known as ARCALYST(R) in the United States, has been prescribed to treat the majority of patients documented to have been treated for CAPS symptoms to date in the U.S. ARCALYST is the only treatment for CAPS in the U.S. that has demonstrated a significant improvement in CAPS symptoms as reported by patients in a pivotal clinical program and is approved for self-administration at home," said Robert Terifay, Senior Vice President, Commercial at Regeneron. "Currently, rilonacept is available to patients in the European Union through their prescribers on a named-patient or individualized case review basis. We are evaluating our broader commercialization options for this very small, ultra-orphan patient population, which is dispersed across Europe."

CAPS include 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. Rilonacept 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 rilonacept reported a greater improvement in overall symptom scores than patients treated with placebo. These improvements were sustained over time with continued rilonacept treatment. Patients reported their symptoms using a validated daily diary instrument. These assessments represent a critical measure of effectiveness in a disease characterized by frequent, unpredictable symptom flares of variable severity and duration. Unlike other agents used in the treatment of CAPS, rilonacept is supported by patient-reported symptoms data using a validated assessment instrument.

Rilonacept has been developed as a once-weekly injection which can be administered at home by the patient or their care giver following appropriate training. The most commonly reported adverse reactions with rilonacept were injection-site reaction and upper respiratory tract infection. IL-1 blockade may interfere with immune response to infections and treatment should not be initiated in patients with active or chronic infections. There have been reports of serious, life-threatening infections in patients taking rilonacept. Rilonacept should be discontinued if a patient develops a serious infection.

The authorization for approval of rilonacept in the E.U. under exceptional circumstances is permissible for products for which a company can demonstrate that comprehensive data cannot be provided, for example because of the rarity of the condition. Each year, Regeneron will need to provide the EMEA with any new information that may become available for review.

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). Rilonacept 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 estimated to be approximately 1 in 1,000,000 people in the European Union.

About Rilonacept

Rilonacept 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 rilonacept, change in disease activity was measured using a composite patient-reported symptom score composed of a daily evaluation of rash, feelings of fever/chills, joint pain, eye redness/pain, and fatigue. Patients treated with rilonacept experienced an improvement in overall symptom scores as compared with patients treated with placebo. These improvements were sustained over time with continued treatment with rilonacept. The most commonly reported adverse reactions with rilonacept were injection-site reaction and upper respiratory tract infection.

In the United States, rilonacept (ARCALYST(R)) 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. ARCALYST was approved by the U.S. Food and Drug Administration in February 2008 and has been available in the United States since March 2008.

IL-1 blockade may interfere with immune response to infections. Serious, life-threatening infections have been reported in patients taking rilonacept. Rilonacept should be discontinued if a patient develops a serious infection. Treatment with rilonacept should not be initiated in patients with active or chronic infections. *Taking rilonacept with tumor necrosis factor inhibitors is not recommended because this may increase the risk of serious infections.* Patients should not receive a live vaccine while taking rilonacept. It is recommended that patients receive all recommended vaccinations prior to initiation of treatment with rilonacept. Patients should be monitored for changes in their lipid profiles and provided with medical treatment if warranted. Hypersensitivity reactions associated with rilonacept administration have been rare. Please see the full U.S. Prescribing Information for ARCALYST(R) (rilonacept), available online at *www.regeneron.com/ARCALYST-fpi.pdf*. Please see the European Summary of Product Characteristics at *www.regeneron.com/RILONACEPT-EU.pdf*.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST(R) (rilonacept) Injection for Subcutaneous Use, its first commercialized product in the United States, Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, inflammatory diseases, and pain 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, 2008 and Form 10-Q for the quarter ended June 30, 2009. 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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