European Commission Approves Amgen's Kineret for the Treatment of Rheumatoid Arthritis; First Interleukin-1 Receptor Antagonist Represents New Way to Treat RA

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THOUSAND OAKS, Calif. & LUCERNE, Switzerland, Mar 13, 2002 (BW HealthWire) -- Amgen (Nasdaq:AMGN) today announced that the European Commission has approved Kineret(R) (anakinra) for the treatment of the signs and symptoms of rheumatoid arthritis (RA) in combination with methotrexate, in patients with an inadequate response to methotrexate alone.

Kineret is the first direct and selective blocker of interleukin-1 (IL-1), a protein present in excess in RA patients. By blocking IL-1, Kineret counteracts damaging cellular events in RA, reducing pain and inflammation. Rheumatoid arthritis is the most serious and disabling type of arthritis, affecting more than 3 million Europeans.

"Kineret is the first therapy from Amgen's rheumatology research program and demonstrates our commitment to discovering and developing new medicines for the treatment of inflammation," said Kevin Sharer, Amgen's Chairman and Chief Executive Officer.

Keith Leonard, Amgen's Vice President for European operations, added, "Kineret is a significant new treatment for patients with RA, which reduces the signs and symptoms of the disease and improves some measurements of patient function. Our studies demonstrate that Kineret is well tolerated and has a favourable safety profile. Kineret represents an important new therapy for patients with RA whose symptoms are not controlled by methotrexate therapy alone."

Proven in Clinical Trials

Approval of Kineret was based on more than 2,600 patients treated with Kineret in randomized, double-blinded, placebo-controlled clinical trials. Kineret, taken in combination with methotrexate, improves the signs and symptoms of RA. Many clinical responses, including a decrease in inflammation and pain, were seen by the fourth week of treatment and most were seen by week 13.

After six months of Kineret therapy in a confirmatory efficacy study (n=501), 38 percent of Kineret patients (n=250) as compared with 22 percent of placebo patients (n=251) achieved a 20 percent improvement in the American College of Rheumatology (ACR) score (ACR20). These patients were receiving background methotrexate therapy. ACR20 criteria include a 20 percent improvement in the number of swollen and tender joints, plus a greater than or equal to 20 percent improvement in at least three of five of the following criteria: physician assessment of disease, patient assessment of disease, pain, C-reactive protein (a general laboratory marker of inflammation) and health assessment questionnaire.

"For rheumatoid arthritis patients, maintaining a `normal' lifestyle in terms of function and being able to work, are extremely high priorities," said Prof. Barry Bresnihan, Professor of Rheumatology at St. Vincent's University Hospital, Dublin, Ireland and a clinical investigator in the Kineret trials. "Kineret represents an important new treatment option for patients with rheumatoid arthritis and has been shown to improve patient signs and symptoms," he said.

Safety Tested

Throughout the clinical trial program Kineret was shown to be well tolerated and to have a favourable safety profile. The most common side effect was a reaction at the site of injection, usually mild to moderate, characterized by redness, swelling and pain. There was an increased risk of serious infections (2 percent in Kineret patients vs. less than 1 percent in placebo patients) in the clinical trials. Although Kineret should be discontinued if a patient develops an infection, most patients can continue taking Kineret after their infection resolves. Kineret should not be used with TNF blocking agents etanercept and infliximab. Preliminary data suggest a higher incidence of serious infection (7 percent) and the occurrence of neutropenia (3 percent) when Kineret is used with these agents.

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent Form 10-K. Amgen conducts research in the biotechnology/pharmaceutical field where movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product.

Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. In addition, sales of our products are affected by reimbursement policies imposed by third party payors, including governments, private insurance plans and managed care providers. These government regulations and reimbursement policies may affect the development, usage and pricing of our products.

In addition, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors.

Because forward-looking statements involve risks and uncertainties, actual results may differ materially from current results expected by Amgen. Amgen is providing this information as of March 13, 2002, and expressly disclaims any duty to update information contained in this press release.

Amgen is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology. Amgen is headquartered in Thousand Oaks, CA, USA, with European headquarters in Lucerne, Switzerland.

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