Amgen Submits Data To FDA Supporting Use Of Enbrel To Improve Physical Function In Rheumatoid Arthritis Patients

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FOR IMMEDIATE RELEASE

THOUSAND OAKS, Calif., September 26, 2002 -- Amgen (NASDAQ:AMGN)

today announced that it has submitted a supplemental Biologics License Application (sBLA) with the U.S. Food and Drug Administration (FDA) for the use of ENBREL (etanercept) to improve physical function in patients with moderately to severely active rheumatoid arthritis. Approval of the submission would further expand the broad label currently approved for ENBREL.

"The data we are submitting to the FDA demonstrate that patients treated with ENBREL showed an improvement in physical functioning," said Daniel Burge, MD, Amgen vice president of clinical research. "We frequently hear from patients that they've been able to resume many of their daily activities, such as brushing their hair or picking up their child, that had become impossible due to their rheumatoid arthritis."

ENBREL is approved to reduce the signs and symptoms in patients with moderately to severely active RA who have had an inadequate response to at least one disease modifying antirheumatic drug (DMARD), such as methotrexate. It is also indicated to inhibit the progression of bone and joint damage in patients with moderately to severely active RA. Additionally, ENBREL is the only anti-TNF therapy approved:

To be used alone to treat patients with moderately to severely active RA;

To treat patients 4 years of age and older with moderately to severely active polyarticular-course juvenile rheumatoid arthritis who have had an inadequate response to DMARDs

To treat newly diagnosed RA patients with moderately to severely active disease; and

To treat active arthritis in patients with psoriatic arthritis.

ABOUT ENBREL

ENBREL is the only fully-human anti-TNF therapy approved for use without methotrexate, a drug that has been the most commonly used disease modifying drug for RA. ENBREL is also the only TNF receptor on the market. It acts by binding TNF, one of the dominant inflammatory cytokines or regulatory proteins that play an important role in both normal immune function and the cascade of reactions that causes the inflammatory process of RA and psoriatic arthritis. The binding of ENBREL to TNF renders the bound TNF biologically inactive, resulting in significant reduction in inflammatory activity.

ENBREL is indicated for reducing signs and symptoms and inhibiting the progression of structural damage in patients with moderately to severely active rheumatoid arthritis; reducing signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis in patients 4 years of age and older who have had an inadequate response to one or more DMARDs; and reducing signs and symptoms of active arthritis in patients with psoriatic arthritis.

Important Treatment Considerations

SINCE THE PRODUCT WAS FIRST INTRODUCED, SERIOUS INFECTIONS, SOME INVOLVING DEATH, HAVE BEEN REPORTED IN PATIENTS USING ENBREL. MANY OF THESE INFECTIONS OCCURRED IN PATIENTS WHO WERE PRONE TO INFECTIONS, SUCH AS THOSE WITH ADVANCED OR POORLY CONTROLLED DIABETES. RARE CASES OF TUBERCULOSIS HAVE ALSO BEEN REPORTED. ENBREL SHOULD BE DISCONTINUED IN PATIENTS WITH SERIOUS INFECTIONS. DO NOT START ENBREL IF YOU HAVE AN INFECTION OF ANY TYPE OR IF YOU HAVE AN ALLERGY TO ENBREL OR ITS COMPONENTS. ENBREL SHOULD BE USED WITH CAUTION IN PATIENTS PRONE TO INFECTION. CONTACT YOUR PHYSICIAN IF YOU HAVE ANY QUESTIONS ABOUT ENBREL OR INFECTIONS.

There have been reports of serious nervous system disorders such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes. Tell your doctor if you have ever had any of these disorders or if you develop them after starting ENBREL (etanercept). There have also been rare reports of serious blood disorders, some involving death. Contact your doctor immediately if you develop symptoms such as persistent fever, bruising, bleeding, or paleness. It is unclear if ENBREL has caused these nervous system or blood disorders. If your doctor confirms serious blood problems, you may need to stop using ENBREL.

The most frequent adverse events in placebo-controlled RA clinical trials involving 349 adults were injection site reactions (ISR) (37%), infections (35%), and headache (17%). Only the rate of ISR was higher than that of placebo. The most frequent adverse events in a methotrexate-controlled clinical trial of 415 adults with early-stage RA were infections (64%), ISR (34%), and headache (24%). Of these, only the rate of ISR was higher than that of methotrexate. In all 1,197 RA patients studied, malignancies were rare (1%).

Adverse events in the psoriatic arthritis trial were similar to those reported in RA clinical trials.

In a study of 69 patients with JRA, infections (62%), headache (19%), abdominal pain (19%), vomiting (13%), and nausea (9%) occurred more frequently than in adults. The types of infections reported in JRA patients were generally mild and consistent with those commonly seen in children. Serious adverse reactions reported rarely were chicken pox (3%), gastroenteritis (3%), serious infection (2%), depression/personality disorder (1%), skin ulcer (1%), inflammation in parts of the upper digestive tract (1%), and diabetes (1%).

Please see full Product Information.

Amgen and Wyeth Pharmaceuticals, a division of Wyeth, (NYSE: WYE), market ENBREL in North America. Other Wyeth affiliates market ENBREL outside of North America. Immunex Corp. manufactures ENBREL. Additional information about ENBREL, including full Prescribing Information, can be found on the Web site sponsored by the companies at www.enbrel.com or by calling toll free 888-4ENBREL (888-436-2735).

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-Q. 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 September 26, 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.

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EDITOR'S NOTES:

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