

# Amgen Announces Positive Results of Phase 3 Enbrel Study in Psoriasis

January 17, 2003

### FOR IMMEDIATE RELEASE

## THOUSAND OAKS, Calif., January 17, 2003 - Amgen (NASDAQ: AMGN)

today announced that a phase 3 clinical study assessing the efficacy and tolerability of ENBRELâ (etanercept) in the treatment of moderate to severe plaque psoriasis had positive results, achieving the primary and all key secondary endpoints. Psoriasis is an inflammatory disease affecting nearly 7 million people in the United States.

"It is encouraging to see that nearly half of the patients in the study quickly and significantly responded to ENBREL with at least a 75 percent improvement of their Psoriasis Area and Severity Index (PASI) score after 12 weeks," said Dr. Beth Seidenberg, Amgen's senior vice president of development. "In addition, patients continued to show improvement over the entire treatment period with nearly 60 percent of patients treated with ENBREL achieving this endpoint after 24 weeks."

ENBREL was generally well tolerated in the study and adverse events at 12 weeks were similar to those occurring in patients receiving placebo.

"These results are gratifying and advance our understanding of ENBREL as a potential future therapy for patients with this life-impacting disease," said Dr. Alice Gottlieb, professor of medicine at the University of Medicine and Dentistry of the Robert Wood Johnson Medical School, and a primary investigator in the study. "Dermatologists will likely welcome seeing the complete results of this study when they are presented at a scientific meeting later this spring."

Psoriasis, a disease that can significantly impact a patient's quality of life, is characterized by chronic inflammation of the skin. This inflammation drives the formation of skin plaques that are painful and disfiguring. Tumor necrosis factor (TNF) is found at high levels in psoriatic plaques, and plays a critical role in their formation and maintenance.

ENBREL is not approved by the U.S. Food and Drug Administration for the treatment of psoriasis but clinical development continues with a second Phase 3 study that is currently underway.

### **ABOUT ENBREL**

ENBREL is the only fully human anti-TNF receptor approved for use to reduce the signs and symptoms of active arthritis in patients with psoriatic arthritis and to reduce the signs and symptoms and inhibit the progression of structural damage in patients with moderately to severely active rheumatoid arthritis (RA). ENBREL is the only biologic therapy approved to treat newly diagnosed RA patients, and can be used alone. It is also approved to reduce the signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis (JRA) in patients who have had an inadequate response to disease-modifying medicines.

Physicians have become familiar with the benefits and proven long-term tolerability profile of ENBREL. It has been used to treat over 130,000 patients worldwide since becoming commercially available four years ago, making it one of the fastest-growing prescription products ever launched.

ENBREL 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. The binding of ENBREL to TNF renders the bound TNF biologically inactive, resulting in significant reduction in inflammatory activity.

### **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.

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. Patients have been observed in clinical trials for over 3 years. The incidence of malignancies has not increased with extended exposure to ENBREL and is similar to the projected background rate.

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%).

Amgen and Wyeth Pharmaceuticals, a division of Wyeth, market ENBREL in North America. Other Wyeth affiliates market ENBREL outside of North America. Immunex Corporation, a wholly owned subsidiary of Amgen, 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).

Amgen is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology.

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, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. In addition, sales of Amgen's 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 products.

In addition, while Amgen routinely obtains patents for its products and technology, the protection offered by patents and patent applications may be challenged, invalidated or circumvented by 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 January 17, 2003, and expressly disclaims any duty to update information contained in this press release.

###

CONTACT: Amgen Rebecca Hamm (media) 805/447-3872 Cary Rosansky (investors) 805/447-4634

EDITOR'S NOTE: An electronic version of this news release may be accessed via www.amgen.com. Visit the Corporate Center and click on Amgen News. Journalists and media representatives may sign up to receive all news releases electronically at time of announcement by filling out a short form.