Enbrel(R) Only TNF Receptor With Five Years Sustained Data In Treatment Of Rheumatoid Arthritis

October 25, 2002

THOUSAND OAKS, Calif., and RADNOR, PENN., October 25, 2002 -- New data from multiple studies evaluating the use of ENBREL(R) (etanercept), the only fully human TNF receptor, in patients with long-standing disease, as well as newly diagnosed patients, will be presented this week as part of the 66th American College of Rheumatology Annual Scientific Meeting in New Orleans. These data include results from a study evaluating up to five years of ENBREL monotherapy to treat patients with rheumatoid arthritis (RA) who have previously failed a disease modifying anti-rheumatic drug (DMARD) therapy.

ENBREL is indicated for reducing signs and symptoms and inhibiting the progression of structural damage in patients with moderately to severely active rheumatoid arthritis.

"The consistent and sustained efficacy and long-term tolerability of ENBREL continue to distinguish it as an important therapeutic option available for people suffering from the often debilitating effects of RA," said Dr. Mark Genovese, assistant professor of medicine at Stanford University School of Medicine, and lead investigator in the early RA trial.

LONG-TERM MONOTHERAPY STUDY OF ENBREL TO TREAT RA

During a poster session, data will be presented from an ongoing study involving 629 adult patients with moderate to severe RA who have failed at least one DMARD and are being treated with ENBREL monotherapy. Three hundred and nineteen patients have been observed for between four and five years, and 68 of these patients have been observed for five years or more.

The poster includes data supporting the sustained response demonstrated for those patients observed for five years.

- 71% of patients achieved the ACR 20
- 48% of patients achieved the ACR 50
- 27% of patients achieved the ACR 70
- 24% of patients had no tender or swollen joints
- 16% had no disability as measured by the Health Assessment Questionnaire

ENBREL was generally well tolerated in this study. No increased rate of serious adverse events was observed over time. Serious adverse events occurred at a rate of 0.14 per patient year in this long-term study compared to 0.13 in patients treated with ENBREL and 0.20 in placebo patients in the previous controlled studies. Likewise, serious infection (associated with hospitalization or IV antibiotics) occurred at a rate of 0.05 per patient year in the long-term study, compared to 0.04 per patient year in the patients treated with ENBREL and 0.05 in placebo patients in the previous controlled studies. The number of malignancies reported in patients treated with ENBREL was similar to the expected number calculated from the National Cancer Institute SEER database (16 observed vs. 20 predicted). No opportunistic infections have been observed in patients treated with ENBREL in this long-term study.

NEW RADIOGRAPHIC DATA FROM ONGOING 4-YEAR STUDY OF ENBREL TO TREAT EARLY EROSIVE RHEUMATOID ARTHRITIS

New data from an ongoing study of patients with early-erosive rheumatoid arthritis (ERA) was presented during a poster session at ACR demonstrating that ENBREL provided sustained improvement in signs and symptoms over 4 years. Additionally, 58% of 142 patients who remained on ENBREL for 3 years had no radiographic progression of their disease.

"We're pleased that the data from this trial continue to support long-term improvement in both signs and symptoms of early erosive rheumatoid arthritis, in addition to demonstrating no progression of bone and joint damage in the majority of these patients," said Dr. Daniel Burge, Amgen's vice president of clinical research. "It is significant to note that at year four 73% of 49 patients treated with corticosteroids were able to reduce or discontinue corticosteroid therapy when treated with ENBREL, while 81% of 124 patients originally treated with methotrexate have discontinued or reduced use of methotrexate."

Patients in the ongoing open-label study initially participated in a 2-year, double-blind, multicenter trial assessing the efficacy of ENBREL or methotrexate to treat ERA. The open-label study includes those patients randomized to receive ENBREL (25 mg twice weekly subcutaneous) in the original study who continued this dose (n=161), and 143 patients previously receiving methotrexate who chose to receive ENBREL.

Response was sustained for patients originally treated with ENBREL 25 mg twice weekly (n=109) observed at 4 years:

- 79% of patients achieved the ACR 20
- 58% of patients achieved the ACR 50
- 31% of patients achieved the ACR 70

In this study, there was no increase of serious infections (requiring hospitalization or IV antibiotics), malignancies, or significant adverse events in the ENBREL group compared to the methotrexate group from the original controlled study.

ABOUT ENBREL

ENBREL is the only fully human 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 structural damage in patients with moderately to severely active RA. ENBREL is the only biologic therapy approved to treat newly diagnosed RA patients, and can be used alone.

Approved since 1998, ENBREL has been used to treat more than 129,000 patients.

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 of psoriatic arthritis and RA. 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® (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. 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%).

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 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.

Wyeth Pharmaceuticals, a division of Wyeth, has leading products in the areas of women's health care, cardiovascular disease, central nervous system, inflammation, hemophilia, oncology and vaccines. Wyeth (NYSE:WYE) is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing, and marketing of pharmaceuticals, vaccines, biotechnology products and non-prescription medicines that improve the quality of life for people worldwide. The Company's major divisions include Wyeth Pharmaceuticals, Wyeth Consumer Healthcare and Fort Dodge Animal Health.

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EDITOR'S NOTES:

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Data in this release refer to Abstracts # 1427 (Board # 387) and #1419 (Board # 344) being presented at the poster session, Monday, October 28, 8:00 a.m. - 4:00 p.m. CT