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## **Phase 3 Psoriatic Arthritis Data for ENBREL® (etanercept) Announced at a National Scientific Meeting**

Application for ENBREL Granted Priority Review by FDA as First Product To Be Considered for Treatment of Psoriatic Arthritis

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SAN FRANCISCO - Phase 3 results of ENBREL® (etanercept) studied in patients with psoriatic arthritis will be presented this week at the 65th Annual American College of Rheumatology National Scientific Meeting in San Francisco.

"Psoriatic arthritis is a devastating disease for which there are currently no approved treatments," says Philip Mease, MD, Seattle Rheumatology Associates, Swedish Medical Center Division of Clinical Research and Clinical Professor, University of Washington. "These data, currently under review by the FDA, indicate that ENBREL can significantly improve the signs and symptoms of psoriatic arthritis in many patients."

This 24-week, multicenter, randomized, double-blind, placebo-controlled study assessed the efficacy and tolerability of ENBREL (25-mg twice-weekly subcutaneous injections) or placebo in 205 patients with psoriatic arthritis. The primary endpoint was measured by the proportion of patients who met the American College of Rheumatology preliminary criteria for improvement (ACR20), which includes duration of morning stiffness, tender and swollen joint counts and a patient as well as a physician global assessment. In addition, two other measurements were utilized to study aspects of both the joint and skin manifestations of psoriatic arthritis: 1) The Psoriatic Arthritis Response Criteria (PsARC) measures improvement in tender and swollen joint score, along with a series of global assessments; and 2) a subset of clinical study patients was measured by improvement in the psoriasis area and severity index (PASI). PASI measures improvement in both the amount of psoriatic plaque throughout the body, as well as the severity of the disease. Results from the study include:

- 59 percent of 101 patients receiving ENBREL® (etanercept) achieved an ACR20 response compared to 15 percent of 104 patients receiving placebo, after 12 weeks of treatment.
- 72 percent of patients receiving ENBREL achieved a treatment response compared to 31 percent of patients receiving placebo after 12 weeks of treatment, using the PsARC measurement.
- 54 percent of patients receiving ENBREL for 24 weeks were assessed as having clear or almost clear skin manifestations, as measured by the dermatologists' global assessment, compared to 23 percent of patients receiving placebo. At baseline, 20 percent of patients in each group were clear or almost clear of skin disease.

Also in this study, a subset (62 patients receiving ENBREL and 66 patients receiving placebo who had greater than 3 percent of their body covered by psoriatic plaque) were evaluated for psoriasis activity. Results showed that:

- 23 percent of patients receiving ENBREL improved by 75 percent or better compared to 3 percent of patients receiving placebo, as measured by the psoriasis area and severity index (PASI) score.

Adverse events were similar to those reported in previous trials of ENBREL in patients with rheumatoid arthritis. There was no increase in the number of serious adverse events occurring in patients receiving ENBREL as compared with those receiving placebo. Only the rate of injection site reactions (ISRs) in patients receiving ENBREL was statistically different compared to placebo (36 percent vs. 9 percent).

These data are currently being reviewed by the U.S. Food & Drug Administration (FDA) for potential approval of ENBREL for the treatment of psoriatic arthritis. In September, the FDA granted "priority review" status requiring that the FDA act on the supplemental Biologics License Application (sBLA) within six months of submission date. Immunex submitted its sBLA for ENBREL on July 16, 2001. ENBREL is the first product to be reviewed by the FDA for the treatment of psoriatic arthritis.

"We are working with the FDA on this priority review of the application because we know the need for treatment is great," says Leslie Garrison, M.D., M.P.H, senior vice president of clinical research and development for Immunex Corporation [Nasdaq: IMNX].

## ABOUT PSORIATIC ARTHRITIS

Like rheumatoid arthritis (RA), psoriatic arthritis is a chronic inflammatory disease of the joints and connective tissue. The disease causes joint pain and swelling that can lead to crippling along with inflamed and irritated scaly red patches of skin throughout the body. It is a progressive and debilitating disease and because there are no treatments specifically approved for psoriatic arthritis, doctors often use therapies approved for RA, including nonsteroidal anti-inflammatory drugs (NSAIDs) and disease modifying anti-rheumatic drugs (DMARDs). However, no DMARDs are currently approved for use in psoriatic arthritis. There are approximately 300,000 patients with psoriatic arthritis in the United States and the disease affects both men and women most commonly between the ages 30 and 50. Psoriatic arthritis patients are generally treated by rheumatologists and dermatologists.

## ABOUT ENBREL

An application for marketing approval of ENBREL® (etanercept) to treat RA was fast-tracked by the U.S. Food and Drug Administration in 1998. Six months after the application was submitted, the FDA approved ENBREL for reducing the signs and symptoms of moderately to severely active RA in patients who have had an inadequate response to one or more DMARDs. The following year, the FDA approved ENBREL for reducing signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis in patients who have had an inadequate response to DMARDs. In June 2000, the FDA approved ENBREL for reducing signs and symptoms and inhibiting the progression of structural damage in patients with moderately to severely active RA. ENBREL is the only tumor necrosis factor (TNF) inhibitor approved for use without methotrexate. It is also the only TNF inhibitor approved for use as a first-line therapy for RA.

ENBREL acts by binding TNF, one of the dominant cytokines or regulatory proteins that play an important role in both normal immune function and the cascade of reactions that cause the inflammatory process of RA and psoriatic arthritis. ENBREL competitively inhibits binding of TNF molecules to the TNF receptor sites. The binding of ENBREL to TNF renders the bound TNF biologically inactive, resulting in significant reduction in inflammatory activity.

**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 rare 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® (etanercept) 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 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 treated with ENBREL with early-stage RA were infections (64%), ISR (34%), and headache (24%). Only the rate of ISR was higher than that of methotrexate. In all 1,197 RA patients studied, malignancies were rare (1%). Immunex Corporation and Wyeth-Ayerst Laboratories, a division of American Home Products Corporation (NYSE: AHP), market ENBREL in North America. Other AHP affiliates market ENBREL outside of North America. Immunex manufactures ENBREL. Additional information about ENBREL, including full prescribing information, can be found on the company-sponsored Web site at ([www.enbrel.com](http://www.enbrel.com)) or by calling toll-free 888-4ENBREL (888-436-2735).

Immunex Corporation is a leading biopharmaceutical company dedicated to improving lives through immune system science innovations.

Wyeth-Ayerst Laboratories, a division of AHP, is a major research-oriented pharmaceutical company with leading products in the areas of women's health care, cardiovascular therapies, central nervous system drugs, anti-inflammatory agents, infectious disease, hemophilia, oncology, and vaccines. AHP is one of the world's largest research-based pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing and marketing of prescription drugs and over-the-counter medications. It is also a leader in vaccines, biotechnology, and animal health care.

*NOTE: Except for the historical information contained herein, this news release contains forward-looking statements that involve substantial risks and uncertainties. Among the factors that could cause actual results or timelines to differ materially are risks associated with research and clinical development, regulatory approvals, our supply capabilities and reliance on third-party manufacturers, product commercialization, competition, litigation and other risk factors listed from time to time in reports filed by Immunex with the SEC, including but not limited to risks described under the caption "Important Factors That May Affect Our Business, Our Results of Operations and Our Stock Price" within our most recently filed Form 10-Q. The forward-looking statements contained in this news release represent our judgment as of the date of this release. Immunex undertakes no obligation to publicly update any forward-looking statements.*