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ENBREL® (etanercept) Is First Therapy Approved for Treatment of Psoriatic Arthritis

SEATTLE, WA - Immunex Corporation (Nasdaq: IMNX) and Wyeth-Ayerst Laboratories, a division of American Home Products (NYSE: AHP) announced today that the U.S. Food and Drug Administration (FDA) has approved ENBREL® (etanercept) to treat people with psoriatic arthritis. ENBREL is the first therapy to receive approval to reduce the signs and symptoms of active arthritis in patients with psoriatic arthritis. ENBREL can be used without methotrexate. ENBREL can also be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone. Psoriatic arthritis is an often painful chronic inflammatory disease characterized by both joint and skin manifestations.

"Unlike other types of arthritis, people with psoriatic arthritis often experience progressive joint pain and swelling, coupled with scaly red skin lesions," said Gail Zimmerman, president and CEO, National Psoriasis Foundation. "There is a definite need for new approved therapies to specifically treat this disease. Current therapies for psoriatic arthritis have been borrowed from other diseases and do not work for everyone."

Because this disease typically begins with skin plaque symptoms and then progresses to joint involvement, physicians have faced special diagnostic challenges in identifying patients with psoriatic arthritis.

"As a dermatologist, I have seen many psoriatic arthritis patients who have received conflicting diagnoses," said Kenneth Gordon, MD, Department of Dermatology, Northwestern University. "Now that there is an approved therapy for this disease, my hope is that this approval heightens physicians' and the public's awareness of the symptoms of psoriatic arthritis, which may lead to quicker and more accurate diagnoses, thus more effective treatment."

A supplemental Biologics License Application (sBLA) was submitted for use of ENBREL® (etanercept) in psoriatic arthritis on July 16, 2001. In September, the FDA granted "priority review" status requiring that the agency act on the sBLA within six months of submission date. The sBLA approval is based on two randomized, double-blind, multicenter trials.

A 24-week, multicenter, randomized, double-blind, placebo-controlled phase 3 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 (ACR 20), which includes tender and swollen joint counts, a patient as well as a physician global assessment, patient assessment of pain, a disability index, and acute phase reactant. In addition, 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 skin disease.

- 59 percent of 101 patients receiving ENBREL achieved an ACR 20 response compared to 15 percent of 104 patients receiving placebo, after 12 weeks of treatment
- 38 percent of 101 patients receiving ENBREL achieved an ACR 50 response compared to 4 percent of 104 patients receiving placebo after 12 weeks of treatment
- 11 percent of 101 patients receiving ENBREL achieved an ACR 70 response compared to 0 percent receiving placebo, after 12 weeks of treatment
- Similar results were seen at 24 weeks.

In a subset of patients with a pre-defined severity of psoriasis, responses increased over time, and at 6 months, the proportions of patients achieving a 50% or 75% improvement in the psoriasis area and severity index (PASI), were 47% and 23%, respectively, in the ENBREL group (n=66) compared to 18% and 3%,

respectively, in the placebo group (n=62).

The results of this study were similar to those seen in an earlier, single-center, randomized, placebo-controlled study of 60 patients with psoriatic arthritis.

Adverse events in the psoriatic arthritis trial were similar to those reported in previous clinical trials of ENBREL in patients with rheumatoid arthritis. There was no increase in the number of serious adverse events including serious infections occurring in psoriatic arthritis patients receiving ENBREL 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). The most common type of infection was upper respiratory infection (URI).

Following its launch in November 1998, ENBREL has been approved for reducing signs and symptoms and inhibiting the progression of structural damage in patients with moderately to severely active RA; and in 1999 for reducing signs and symptoms in patients four years of age and older with moderately to severely active polyarticular-course juvenile rheumatoid arthritis who have had an inadequate response to one or more disease modifying medicines. ENBREL is the only tumor necrosis factor (TNF) inhibitor that can be used as monotherapy (without methotrexate) and the only biologic response modifier approved for use as a first-line monotherapy for RA. The latest addition of psoriatic arthritis to the approved indications for ENBREL (etanercept) demonstrates the significant role of TNF in this condition.

"We have been laser-focused on developing ENBREL to its full potential," said Peggy Phillips, Immunex executive vice president and chief operating officer. "Psoriatic arthritis represents another significant market where there is true need for a breakthrough, effective product like ENBREL."

"Physicians will now, for the first time, have an approved medication to address the painful signs and symptoms of psoriatic arthritis from a unique biological perspective," said Victoria Kusiak, MD, vice president and North American medical director, global medical affairs, Wyeth-Ayerst Laboratories. "Our collaboration with Immunex continues to develop novel approaches to address potentially debilitating diseases."

ABOUT PSORIATIC ARTHRITIS

Like rheumatoid arthritis (RA), psoriatic arthritis is a chronic inflammatory disease causing 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. The disease affects both men and women most commonly between the ages 30 and 50. Psoriatic arthritis patients are generally comanaged by rheumatologists and dermatologists due to joint and skin manifestations of the disease.

The National Psoriasis Foundation is an independent, non-profit organization dedicated to improving the lives of people with psoriasis and psoriatic arthritis. For more information on the Foundation or psoriatic arthritis visit www.psoriasis.org.

ABOUT ENBREL

ENBREL is 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 cause 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.

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® (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%). 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%).

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) 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.