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New Phase 2 Study Shows Ankylosing Spondylitis Patients Respond to ENBREL® (etanercept)

SAN FRANCISCO - Data from a Phase 2 clinical study of ENBREL® (etanercept) in ankylosing spondylitis will be presented this week at the 65th Annual Scientific Meeting of the American College of Rheumatology. This study, conducted by Dr. John Davis and colleagues at the University of California, San Francisco, is the first randomized, placebo-controlled study of ENBREL for the treatment of ankylosing spondylitis. Phase 2 results showed that 80 percent of 20 patients receiving ENBREL reached the primary composite endpoint of improvement compared to 30 percent of 20 patients receiving placebo.

"This is pioneering work in ankylosing spondylitis," says Jane Bruckel, Executive Director, Spondylitis Association of America. "The community looks forward to additional data from the new study."

In the Phase 2 double-blind, placebo-controlled study, 40 patients with ankylosing spondylitis were randomized to receive either 25 mg of ENBREL via subcutaneous (under the skin) injection or placebo twice per week for a four-month period.

The primary endpoint was a comparison of the number of patients achieving a clinical response in the ENBREL and placebo groups. A clinical response was prespecified as a greater than or equal to 20 percent improvement in three of five outcome measures (duration of morning stiffness, nocturnal spinal pain, a functional index (BASFI), patient global assessment and swollen joint score).

Eligible patients fulfilled the modified New York clinical criteria for ankylosing spondylitis, and were required to have evidence of active spondylitis, which was defined as presence of inflammatory back pain, morning stiffness equal to or greater than 45 minutes, and patient and physician global assessment of moderate or higher disease activity. Patients were able to continue nonsteroidal anti-inflammatory drugs (NSAIDs), prednisone and disease modifying anti-rheumatic drugs (DMARDs) at stable dosages during the trial.

Results after four months showed that:

- 80 percent of patients receiving ENBREL® (etanercept) achieved a clinical response compared to 30 percent of patients receiving placebo (primary endpoint of the study), as measured by a composite measure.

ENBREL was generally well-tolerated with no differences in rates of adverse events between the two groups. There were no serious adverse events and no withdrawals due to adverse events.

A large, multicenter Phase 3 clinical study of ENBREL for the treatment of ankylosing spondylitis has been initiated. For information about enrolling in the study, call toll-free: 1-800-IMMUNEX (1-800-466-8639).

ABOUT ANKYLOSING SPONDYLITIS

Ankylosing spondylitis is a chronic inflammatory arthritis characterized by joint stiffness, pain and extra bone growth that can result in partial or complete fusion of the spine. The bones of the spine may grow together, causing the spine to become rigid and inflexible. Other joints such as the hips, shoulders, knees, or ankles also may become involved. About 300,000 people in the U.S. suffer from ankylosing spondylitis. Symptoms of the disease appear most frequently in young men between the ages of 16 and 35. There is currently no cure for ankylosing spondylitis. For more information regarding ankylosing spondylitis and the Spondylitis Association of America, please refer to www.StopAS.org or call 1.800.777.8189.

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) 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.