New Phase 3 ENBREL Data Show Psoriasis Patients Achieved a Therapeutic Response From 'Step Down' Dosing Regimen

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THOUSAND OAKS, Calif. and COLLEGEVILLE, Pa., Feb. 7 -- A global Phase 3 study of Enbrel(R) (etanercept) demonstrated that a significant number of psoriasis patients given initial loading doses of ENBREL for three months rapidly achieved psoriasis clearing and then maintained the response while receiving half the drug dose. These data were presented at the American Academy of Dermatology annual meeting in Washington, D.C.

In this double-blind, placebo-controlled study, 583 patients with moderate to severe psoriasis were randomized to receive placebo (n=193), 25 mg of ENBREL twice weekly (n=196), or a loading dose of 50 mg of ENBREL twice weekly (n=194), for 12 weeks. Following this initial period, patients then continued treatment for an additional 12 weeks. During the second 12 weeks, those taking the loading dose of ENBREL were "stepped down" to half the dose (25 mg twice weekly), while patients taking 25 mg twice weekly continued with the same dose. Patients initially taking placebo were started on 25 mg ENBREL twice weekly. As previously reported, patients in both groups initially receiving ENBREL experienced improvement in psoriasis in as early as two weeks.

The new data show that during the second 12 weeks of the study, ENBREL continued to provide significant relief of psoriasis symptoms in all groups. Forty-nine percent of patients treated with the loading dose achieved 75 percent improvement in the Psoriasis Area Severity Index (also known as PASI 75) in the first 12 weeks of the study as compared to 34 percent of patients taking 25 mg twice weekly and three percent of patients taking placebo. A large majority (77 percent) of the patients treated with the loading dose who had achieved a PASI 75 response at week 12 maintained this response through week 24 while receiving the stepped down dose. In addition, at week 24, the percentage of step down patients achieving PASI 75 increased to 54 percent.

"In this study, more step down patients achieved the clinical milestone of PASI 75 by week 12," said Craig Leonardi, M.D., clinical associate professor of dermatology at Saint Louis University. "It was very exciting to see that a large majority of these patients maintained the effect while receiving half the loading dose."

Psoriasis Patients Treated with ENBREL Stopped And Re-Started Treatment Without Serious Side Effects From Their Psoriasis

In another presented Phase 3 study not involving step down therapy, 409 patients who had achieved at least a PASI 50 response at the conclusion of 24 weeks stopped treatment and were monitored for relapse. Patients withdrawn from ENBREL treatment did not have serious adverse events due to psoriasis including disease flares, hospitalizations or transformation of psoriasis to a more severe form of the disease. After discontinuing ENBREL, the median time to relapse (loss of half of PASI improvement achieved while on ENBREL) was approximately three months.

After patients relapsed, they were retreated with the same dose they had received at the end of the double-blind period of the study. Overall PASI 75 response rates at both week 12 and 24 of re-treatment (n=297 and n=174, respectively) were similar to those seen after initial treatment in all groups.

"Psoriasis is a chronic condition and patients must sometimes stop treatment due to life circumstances such as pregnancy or surgery," said Alice Gottlieb, M.D., Ph.D., director of the Clinical Research Center at University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School. "These data show that ENBREL was stopped and restarted without severe side effects due to psoriasis or loss of efficacy."

ENBREL was generally well tolerated in both Phase 3 studies. Adverse events were similar to those reported in previous clinical trials, with injection site reactions occurring more frequently than in the placebo group.

ABOUT PSORIASIS

An estimated 4.5 million people in the United States suffer from psoriasis and 1.5 million have moderate to severe plaque psoriasis. The disease is characterized by chronic inflammation of the skin. This inflammation drives the formation of red, itchy 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 currently approved for the treatment of moderately to severely active psoriatic arthritis and is currently under review by the U.S. Food and Drug Administration for the treatment of psoriasis.

ABOUT ENBREL

ENBREL is the only fully human TNF receptor approved to reduce signs and symptoms, improve physical function, and inhibit the progression of structural damage in patients with moderately to severely active rheumatoid arthritis (RA), and to reduce the signs and symptoms and inhibit the progression of structural damage of active arthritis in patients with psoriatic arthritis. ENBREL is the only biologic therapy approved for first-line treatment of RA patients, and can be used alone or in combination with methotrexate. It is 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 one or more disease-modifying antirheumatic drugs (DMARDs). It is also the first biologic approved to treat the signs and symptoms in patients with active ankylosing spondylitis (AS).

ENBREL has been used by more than 215,000 patients worldwide across indications since becoming commercially available more than five years ago.

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 RA, JRA, psoriatic arthritis and AS. 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, the following have been reported in patients using ENBREL:

* Serious Infections
  -- Many occurred in people prone to infection, such as those with advanced or poorly controlled diabetes
  -- Some serious infections were fatal
  -- Rare cases of tuberculosis

  What to do/Not do
  -- Do not start ENBREL if you have an infection or are allergic to ENBREL or its components
  -- Tell your doctor if you are prone to infection
  -- Stop ENBREL if a serious infection occurs
  -- Contact your doctor if you have questions about ENBREL or develop an infection

* 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.

* Rare reports of serious blood disorders (some fatal)
  -- Contact your doctor immediately if you develop symptoms such as persistent fever, bruising, bleeding, or paleness

* In medical studies of all TNF-inhibitors, a higher rate of lymphoma (a type of cancer) was seen compared to the general population, however, the risk of lymphoma may be up to several fold higher in RA patients. The role of TNF-inhibitors in the development of lymphoma is unknown.

* The incidence of other cancers has not increased with extended exposure to ENBREL and is similar to the expected rate.

* ENBREL can also cause injection site reactions.

* In a medical study of patients with JRA, infections, headaches, abdominal pain, vomiting, and nausea occurred more frequently than in adults.
  -- The kinds of infections reported were generally mild and similar to those usually seen in children
  -- Other serious adverse reactions were reported rarely, including serious infections (2 percent) and depression/personality disorder (1 percent)

Amgen and Wyeth Pharmaceuticals, a division of Wyeth, market ENBREL in North America. Wyeth markets 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 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.

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in Amgen's Form 10-K for the year ended December 31, 2002, and in Amgen's periodic reports on Form 10-Q and Form 8-K. Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise. No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Amgen's results may be affected by its ability to successfully market both new and existing products domestically and internationally, sales growth of recently launched products, difficulties or delays in manufacturing its products, and regulatory developments (domestic or foreign) involving current and future products and manufacturing facilities. 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, and may be affected by domestic and international trends toward managed care and healthcare cost containment as well as possible U.S. legislation affecting pharmaceutical pricing and reimbursement. Government regulations and reimbursement policies may affect the development, usage and pricing of Amgen's products. Furthermore, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by

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In addition, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third party suppliers.

The statements in this press release that are not historical facts are forward-looking statements based on current expectations of future events that involve risks and uncertainties including, without limitation, risks associated with the inherent uncertainty of pharmaceutical research, product development, manufacturing, and commercialization, and economic conditions, including interest and currency exchange rate fluctuations, the impact of competitive or generic products, product liability and other types of lawsuits, the impact of legislative and regulatory compliance and obtaining approvals, and patents, and other risks and uncertainties, including those detailed from time to time in Wyeth's periodic reports, including quarterly reports on Form 10-Q and the Annual Report on Form 10-K, filed with the Securities and Exchange Commission.

Actual results may vary materially from the forward-looking statements. Wyeth assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

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