



FDA Approves ENBREL for Once-Weekly Dosing

October 20, 2003

- New Dosing Option Offers Convenience to Patients While Providing

Comparable Efficacy and Tolerability -

THOUSAND OAKS, Calif. and COLLEGEVILLE, Pa., Oct. 20 -- Amgen (Nasdaq: AMGN) and Wyeth Pharmaceuticals, a division of Wyeth (NYSE: WYE) today announced that the U.S. Food and Drug Administration (FDA) has approved a 50 mg once-weekly dosage of Enbrel(R) (etanercept) for adult patients across all indications, including moderately-to-severely active rheumatoid arthritis (RA), active arthritis in patients with psoriatic arthritis and active ankylosing spondylitis (AS), and a 0.8mg/kg once-weekly dosage (maximum 50 mg per week) for patients ages four to 17 years with moderately-to-severely active juvenile rheumatoid arthritis. Instead of taking two 25 mg injections three to four days apart, patients can now take both injections on the same day.

"Patients receiving ENBREL can benefit from the long-term efficacy and tolerability profiles of ENBREL while also now enjoying the convenience of once-weekly dosing," said Dr. Willard Dere, vice president of clinical development for Amgen.

Data supporting the efficacy and tolerability of the ENBREL once-weekly dosage are from a Phase 3 double-blind, placebo-controlled study of 420 patients with active RA. In a 16-week study, patients either were treated with ENBREL 50 mg once weekly (administered in two 25 mg injections), ENBREL 25 mg twice weekly, or placebo for eight weeks followed by ENBREL 25 mg twice weekly for the remaining eight weeks.

After eight (the primary endpoint) and 16 weeks, there were no significant differences in ACR 20 response scores (a 20 percent improvement in signs and symptoms) between the two ENBREL groups. The tolerability profile for once-weekly dosing was comparable to that of twice-weekly dosing.

"This approval allows rheumatologists and dermatologists to provide their patients with more convenient dosing," said Victoria Kusiak, M.D., vice president of global medical affairs and North American medical director of Wyeth Pharmaceuticals. "And, of course, doctors can feel confident that the new once-weekly dosing provides comparable efficacy and tolerability to twice-weekly dosing of ENBREL."

Adverse events were similar to those reported in previous clinical trials of ENBREL, with injection site reactions occurring more frequently than in the placebo group.

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 200,000 patients worldwide across indications since becoming commercially available nearly 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 cancer 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 (two percent) and depression/personality disorder (one 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 domestic and foreign government regulatory authorities. Amgen or others could identify side effects or manufacturing problems with its products after they are on the market. In addition, Amgen competes with other companies with respect to some of its marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product.

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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Web site: <http://www.enbrel.com>

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