FDA Approves New and Easy Way to Take ENBREL; Benefits of ENBREL Delivered in Convenient Once-Weekly 50 mg/mL Prefilled Syringe

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THOUSAND OAKS, Calif., & COLLEGEVILLE, Pa.--(BUSINESS WIRE)--Sept. 28, 2004--Amgen Inc. (NASDAQ:AMGN) and Wyeth Pharmaceuticals, a division of Wyeth (NYSE:WYE), today announced that the new 50 mg/mL prefilled syringe of Enbrel(R) (etanercept) has been approved by the U.S. Food and Drug Administration (FDA) as the recommended dosing form for treatment in all approved adult indications. The new prefilled syringe, available for patient use in the fourth quarter 2004, will eliminate the need to mix drug prior to injecting and allows most patients receiving ENBREL to take only one injection per week, instead of the two 25 mg injections currently used weekly by patients.

"Since the rheumatoid arthritis approval in 1998, ENBREL has helped thousands of people better manage their disease," said Beth Seidenberg, M.D., chief medical officer and senior vice president of global development, Amgen. "This approval provides physicians with the opportunity to offer their patients an easy-to-use prefilled syringe that delivers the same drug patients and physicians have grown to trust."

The FDA approval was based on a study, which found that the ENBREL 50 mg/mL prefilled syringe was shown to be biologically equivalent to two 25 mg vials. The 25 mg formulation will still be available for juvenile rheumatoid arthritis patients and those that prefer that dosing method.

"This new delivery system can make it easier for patients to receive the proven efficacy and established tolerability of ENBREL," said Joseph Camardo, M.D., senior vice president, global medical affairs, Wyeth Pharmaceuticals. "It may be especially beneficial to people who have rheumatoid arthritis or active psoriatic arthritis, as their hands may be affected by the disabling joint destruction these conditions can cause."

ENBREL is a leading biologic treatment for moderately to severely active rheumatoid arthritis and is the first and only TNF inhibitor approved to treat chronic moderate to severe plaque psoriasis, active psoriatic arthritis, active ankylosing spondylitis (arthritis of the spine) and children with moderately to severely polyarticular-course active juvenile rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs).

ABOUT ENBREL

ENBREL is the only fully human TNF receptor approved to reduce signs and symptoms, induce major clinical response, improve physical function, and inhibit the progression of structural damage in patients with moderately to severely active rheumatoid arthritis (RA). ENBREL is also indicated 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.

ENBREL is also 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 is indicated for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

ENBREL has been used by more than 250,000 patients worldwide across indications.

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 are involved in the inflammatory process of RA, JRA, psoriasis, 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 to 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.
- Tell your doctor if you have ever been treated for heart failure.

- 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 and psoriasis 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, transplantation, hemophilia, oncology, vaccines and nutritional products. 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 nonprescription 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, 2003, 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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