FDA Approves Enbrel(R) as Treatment to Improve Physical Function in Rheumatoid Arthritis Patients

July 31, 2003

THOUSAND OAKS, Calif., and COLLEGEVILLE, Pa., July 31 - Amgen (NASDAQ: AMGN) and Wyeth Pharmaceuticals, a division of Wyeth (NYSE: WYE), today announced that the U.S. Food and Drug Administration (FDA) approved an expanded indication for ENBREL® (etanercept) as a treatment to improve physical function in patients with moderately to severely active rheumatoid arthritis (RA). Rheumatoid arthritis is a chronic and progressively disabling disease that affects more than two million Americans. Patients can become disabled from irreversible joint damage caused by the disease, limiting their ability to function.

The ability of ENBREL to improve physical function and disability was assessed in three placebo-controlled trials in patients (n=955) with late-stage or early RA. In open-label ENBREL studies, improvements in physical function and disability measures have been maintained for up to four years. The primary tool used to assess improvement was the Health Assessment Questionnaire (HAQ), in which a score of zero indicates no disability.

"Moderate to severe active RA can have devastating effects on patients' lives, limiting their ability to perform even the simplest daily activities like buttoning a shirt or holding a cup of coffee," said Kevin Young, Vice President and General Manager of Amgen's Inflammation Business Unit. "This approval demonstrates the ability of ENBREL to help patients resume normal daily activities, which can be the patients' ultimate goal of therapy."

"Over the past several years, overall improvement in daily activities, including physical function and disability, have become important outcome measures of treatment success for RA patients," said Dr. Victoria Kusiak, Vice President of Global Medical Affairs and North American Medical Director of Wyeth Pharmaceuticals. "By evaluating improvement in physical ability, we gain a deeper understanding of the impact ENBREL can have on the lives of patients with RA."

Patients with early RA treated with ENBREL monotherapy achieved a mean improvement of 0.7 units in their HAQ scores after six months. A change of 0.22 units is considered clinically important. At one year 29% of patients achieved a zero HAQ score.

Many patients with late-stage RA treated with ENBREL (those who had failed at least one disease modifying antirheumatic drug or DMARD), alone or in combination with methotrexate, had significant improvement in their HAQ disability scores, compared with patients who received placebo or methotrexate alone. Improvement occurred within the first month of treatment and was sustained throughout the studies. Across the clinical studies, at six months, mean improvements in the HAQ were approximately 0.6 units in the ENBREL groups vs. 0 and 0.2 units in the placebo groups. At six months 15% of patients on Enbrel alone and 15% of patients on Enbrel plus methotrexate achieved a zero HAQ score vs 0% and 3% on placebo respectively.

The most frequent adverse events in placebo-controlled RA clinical trials (n=349) 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 trial (n=415) were infections (64%), ISR (34%), and headache (24%). Only the rate of ISR was higher than that of methotrexate.

"When I was diagnosed with RA, I couldn't dress myself, go for a walk with my husband, or do other simple things in life that are really important to me," said Michelle Berry, a psychotherapist from Denver, Colo. who lives with rheumatoid arthritis. “ENBREL treated my joint pain and swelling and it helped me get back to doing the things I did before.”

ABOUT ENBREL

ENBREL is the only fully human anti-TNF receptor approved to reduce signs and symptoms, improve physical function, and inhibit structural damage in patients with moderately to severely active RA, and to reduce the signs and symptoms 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 in combination or alone. 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 disease-modifying medicines. It is also the first biologic approved to treat the signs and symptoms in patients with active ankylosing spondylitis (AS).

The benefits and proven long-term tolerability profile of ENBREL have been established in the treatment of over 180,000 patients worldwide across all 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 psoriatic arthritis, RA 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
- 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 (2%) and depression/personality disorder (1%) 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.

CONTACT: Media 805-447-4587 Wyeth Pharmaceuticals
Investors: 800-84-AMGEN Douglas Petkus (media)
. 484/865-5140
Justin Victoria (investors)
973/660-5340