FDA Expands ENBREL Psoriatic Arthritis Indication -- ENBREL Approved as First and Only Treatment to Improve Physical Function in These Patients

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Label Also Updated with ENBREL Data Demonstrating Inhibition of Joint Destruction among Most Psoriatic Arthritis Patients Treated Continuously for Two Years

THOUSAND OAKS, Calif. & COLLEGEVILLE, Pa.--(BUSINESS WIRE)--June 1, 2005-- Amgen Inc. (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(R) (etanercept) to improve physical function in patients with psoriatic arthritis. ENBREL is the first and only treatment to receive this expanded indication. In addition, the FDA approved an update to the ENBREL label to include new radiographic data demonstrating that ENBREL continued to inhibit the progression of joint destruction for two years among most psoriatic arthritis patients who received ongoing therapy.

ENBREL received its approval to treat signs and symptoms of psoriatic arthritis in 2002. With this expanded approval, ENBREL is now indicated for reducing signs and symptoms, inhibiting the progression of joint destruction of active arthritis associated with psoriatic arthritis, and improving physical function in patients with psoriatic arthritis. ENBREL is also approved to treat moderate-to-severe rheumatoid arthritis and juvenile rheumatoid arthritis, ankylosing spondylitis and moderate-to-severe plaque psoriasis.

"This approval for improving physical function and the addition of the two-year radiographic data builds on the well-established efficacy and safety profile of ENBREL in psoriatic arthritis. No other treatment has been FDA-approved to provide efficacy for psoriatic arthritis patients using these multiple clinical measures," said Will Dere, M.D., chief medical officer and senior vice president of global development, Amgen. "ENBREL is unique because it has received 10 FDA approvals in five distinct diseases and has been used by more than 280,000 patients worldwide across indications. ENBREL also has 12 years of collective clinical experience."

The expanded approval of ENBREL was based on significant improvements in physical function as assessed by the disability index of the Health Assessment Questionnaire (HAQ), a test used to evaluate a patient's ability to perform daily activities such as dressing, walking and grooming, and the Medical Outcomes Study Short-Form Health Survey (SF-36), a measurement tool that also assesses the physical impact of a disease.

Almost 40 percent of psoriatic arthritis patients taking ENBREL in this study achieved a HAQ score of zero, indicating no functional disability at 24 weeks. In addition, the SF-36 found that many patients treated with ENBREL experienced a greater improvement from baseline, compared to placebo, in their ability to participate in physical activities such as walking, carrying groceries, or climbing a flight of stairs.

Psoriatic arthritis is a chronic, often destructive disease characterized by both joint inflammation and erosion, and is associated with psoriatic skin lesions. The progressive joint pain and swelling, which is often coupled with painful, scaly, red skin lesions, can disrupt a person's ability to perform activities of daily life that most people take for granted such as getting dressed, eating or walking. Approximately one million people suffer from psoriatic arthritis in the United States.

"We are pleased that ENBREL has shown the ability to inhibit the progression of joint destruction for a continuous two years in most psoriatic arthritis patients in this study, which is vital in helping to ease the debilitating effects of this disease," said Gary L. Stiles, M.D., executive vice president and chief medical officer of Wyeth Pharmaceuticals. "Similar to rheumatoid arthritis, ENBREL is the only treatment approved to provide long-term inhibition of joint destruction for most patients."

ABOUT ENBREL

ENBREL is the only soluble tumor necrosis factor (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 can be used alone or in combination with methotrexate.

ENBREL is the only treatment indicated to reduce the signs and symptoms, inhibit the progression of structural damage of active arthritis, and improve physical function in patients with psoriatic arthritis. It is approved to reduce the signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis (JRA) in patients four years of age or older who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). It is also the first biologic approved to reduce 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 280,000 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 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.

What important information do I need to know about taking ENBREL?

ENBREL is a type of protein called a tumor necrosis factor (TNF) blocker that blocks the action of a substance your body's immune system makes called TNF. People with an immune disease, such as rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and psoriasis, have too much TNF in their bodies. ENBREL can reduce the amount of TNF in the body to normal levels, helping to treat your disease. But, in doing so, ENBREL can also lower the ability of your immune system to fight infections.

All medicines have side effects, including ENBREL. Possible side effects of ENBREL include:

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

What not to do

- Do not start ENBREL if you have an infection or are allergic to ENBREL or its components

What to do

- 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 blockers, including ENBREL, a higher rate of lymphoma (a type of cancer) was seen compared to the general population. The risk of lymphoma may be up to several fold higher in rheumatoid arthritis and psoriasis patients
- The role of TNF blockers, including ENBREL, in the development of lymphoma is unknown
- ENBREL can cause injection site reactions.

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 website 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, 2004, 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 Amgen projects. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes even adequately, modeled by computer or cell culture systems or animal models. The length of time that it takes for Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied, and Amgen expects similar variability in the future. Amgen develops product candidates internally and through licensing collaborations, partnerships, and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify side effects or manufacturing problems with Amgen's products after they are on the market.

In addition, sales of Amgen's products are affected by the availability of reimbursement and the 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 health care 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 our products. In addition, Amgen competes with other companies with respect to some of Amgen's marketed products as well as for the discovery and development of new products. Amgen believes that some of its newer products, product candidates, or new indications for existing products, may face competition when and as they are approved and marketed. Amgen's products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with its products. 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 and there can be no guarantee of Amgen's ability to obtain or maintain patent protection for its products or product candidates. Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of its existing products. Amgen's stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of its products or product candidates. Further, the discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations.

The scientific information discussed in this news release related to Amgen's product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Further, the scientific information discussed in this news release relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the FDA for the products. The products are not approved for the investigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

Only the FDA can determine whether the products are safe and effective for these uses. Health care professionals should refer to and rely upon the FDA-approved labeling for the products and not the information discussed in this news release.

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 the timing and success of pharmaceutical research, product development, manufacturing, commercialization, economic conditions including interest and currency exchange rate fluctuations, changes in generally accepted accounting principles, the impact of competitive or generic products, trade buying patterns, wars or terrorist acts, product liability and other types of lawsuits, the impact of legislation and regulatory compliance and obtaining reimbursement, favorable drug pricing, access and other approvals, environmental liabilities, and patent, and other risks and uncertainties, including those detailed from time to time in the Company's periodic reports, including current reports on Form 8-K, 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. The Company 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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