Treatment Has Demonstrated Improvement in Physical Function and Kept Joint Damage from Progressing at Three Years

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ENBREL Plus Methotrexate: First Treatment Regimen to Demonstrate Ability to Inhibit Radiographic Progression of Joint Damage for Three Consecutive Years

THOUSAND OAKS, Calif. & COLLEGEVILLE, Pa., Nov 13, 2005 (BUSINESS WIRE) -- Amgen (Nasdaq:AMGN) and Wyeth Pharmaceuticals, a division of Wyeth (NYSE:WYE), today announced data from a long-term blinded study of anti-TNF agent in patients with rheumatoid arthritis (RA) demonstrated that more than three quarters of patients treated with Enbrel(R) (etanercept) plus methotrexate combination therapy experienced no progression of joint damage at three years. These new results from the TEMPO (Trial of Etanercept and Methotrexate with Radiographic Patient Outcomes) study will be presented at the American College of Rheumatology's (ACR) Annual Scientific Meeting in San Diego, California.

"Rheumatoid arthritis is a chronic condition requiring long-term treatment. It is critical to provide patients with treatment options that not only reduce the signs and symptoms of the disease, but also inhibit the progression of joint damage," said Desiree van der Heijde, M.D., professor of rheumatology, University of Maastricht in the Netherlands. "The TEMPO results reinforce the benefits of ENBREL and methotrexate combination therapy and underscore the importance of effective treatment."

At three years, the majority of patients taking ENBREL and methotrexate combination therapy had no progression of joint damage(1). These results were significantly better than those achieved in ENBREL monotherapy and methotrexate monotherapy-treated patients. Patients receiving ENBREL monotherapy also had significantly better results than patients receiving methotrexate monotherapy. Total Sharp Score was calculated by assessing changes in joint space narrowing and bone erosion as captured by radiographic imaging.

Further, additional data presented at ACR showed that improvement in physical function was higher for the ENBREL combination group than for either therapy alone. Patients treated with ENBREL combination therapy experienced a 56 percent mean improvement in Health Assessment Questionnaire (HAQ) scores from baseline, compared to 37 percent mean improvement in patients treated with ENBREL alone and 33 percent mean improvement in patients treated with methotrexate alone. HAQ scores measure a patient's ability to perform activities of daily living such as dressing, walking, and grooming.

The ENBREL TEMPO study randomized 686 patients with RA, of which 638 were included in the three-year radiographic analysis. Patients received either ENBREL (25 mg twice weekly), methotrexate (up to 20 mg once weekly), or ENBREL (25 mg twice weekly) plus methotrexate once weekly. Patients in the ENBREL TEMPO trial had active RA and an inadequate response to at least one disease-modifying antirheumatic drug (DMARD) other than methotrexate. The primary radiographic endpoint was the change from baseline in the van der Heijde-modified TSS at one year. Secondary radiographic endpoints included changes in total erosions, changes in total joint space narrowing, number of eroded joints, and percent of patients with no radiographic progression.

ENBREL was generally well tolerated.

ABOUT RA

More than two million Americans suffer from RA, which can cause stiffness, swelling, and limitation in the motion and function of multiple joints. If RA is left untreated, patients can become disabled from joint damage caused by the disease, limiting their ability to function.

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 308,000 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 1-888-4ENBREL (1-888-436-2735).

Amgen discovers, develops and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses. With a broad and deep pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit www.amgen.com.

Wyeth Pharmaceuticals, a division of Wyeth (NYSE:WYE), 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.

SOURCE: Amgen

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