



## Data Shows ENBREL Provides Sustained Clinical Improvements for People with Ankylosing Spondylitis for up to Three Years

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### Data Show Sustained Improvements in Clinical Measures for up to Three Years

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Nov. 13, 2006--Amgen (NASDAQ:AMGN), today announced that data from an ongoing open-label, multinational, phase 4 extension study showed that patients with ankylosing spondylitis (AS) who received treatment with Enbrel(R) (etanercept) experienced sustained improvement in signs and symptoms, spinal mobility and physical function over 148 to 160 weeks of therapy. These results are consistent with an ENBREL phase 3 clinical trial at 24 weeks. The 160-week results will be presented at the American College of Rheumatology (ACR) Scientific Meeting in Washington, D.C.

"These data demonstrate that ENBREL can provide substantial long-term improvement in AS symptoms such as total back pain and spinal mobility," said Joachim Sieper, M.D., professor of rheumatology, Charite University in Berlin, Germany. "Because AS is a chronic inflammatory disease that requires ongoing management, it is important to offer patients a treatment option that is effective, has an established safety profile, and can be used over the long-term."

Data presented at ACR showed that 59 patients who received open-label ENBREL treatment for up to 160 weeks experienced sustained clinical improvements. Overall, 78 percent of patients (n=46) continuing treatment with ENBREL achieved a 20 percent improvement in the Assessment on Ankylosing Spondylitis Response Criteria (ASAS 20) after 160 weeks of treatment. ASAS is a composite measure of improvement in AS symptoms that include total back pain, patient assessment of disease activity, inflammation and physical function. Thirty-one percent of patients (n=18) achieved partial remission at week 160. Partial remission, as defined by ASAS, is a low disease activity level (score less than 20 units out of 100 in each of the four ASAS criteria).

Additional ENBREL data presented at ACR from this phase 4 extension study show that improvement in spinal mobility was also sustained through 148 to 160 weeks of treatment with ENBREL.

Patients with ankylosing spondylitis have reported that their condition has negatively impacted their ability to perform daily activities including exercising, rising from a seated position and climbing stairs without aid. Overall, patients treated with ENBREL achieved a 46 percent improvement in physical function, as measured by the Bath Ankylosing Spondylitis Functional Index (BASFI), and these results were sustained through 160 weeks. The BASFI is a 10-question, patient self-assessment instrument consisting of 8 specific questions regarding physical function in AS and 2 questions reflecting the patient's ability to cope with everyday life. Each question is answered on a 10 cm horizontal visual analog scale, the mean of which gives the BASFI score (0-10).

ENBREL was generally well tolerated over 148 to 160 weeks of therapy.

This study was designed to assess the safety and long-term efficacy of ENBREL in patients with AS, using clinical measures to assess disease activity, physical function, improvement in AS symptoms, and ongoing surveillance to assess the incidence of adverse events. The study is a 96-week open-label, multinational, phase 4 extension study in 59 patients with AS who completed each of two earlier trials, a 12-week randomized, double-blind, placebo-controlled study and a 96-week open-label study. The data presented at ACR is from the first 52-weeks of an ongoing 96-week extension study (total ENBREL treatment 148 - 160 weeks).

Enbrel received FDA approval to treat the signs and symptoms of active AS in 2003 following a randomized, double-blind, placebo-controlled phase 3 study in 277 patients with active ankylosing spondylitis. Treatment with ENBREL (n=138) resulted in significant clinical improvements through 24 weeks, compared to placebo (n=139). At 12 weeks, the ASAS 20 response was achieved by 60 percent of patients receiving ENBREL, compared to 27 percent of patients receiving placebo (p less than or equal to 0.0001, ENBREL vs. placebo). These results were maintained through 24 weeks. Patients in this study were between 18 and 70 years of age and had ankylosing spondylitis as defined by the modified New York Criteria for Ankylosing Spondylitis. Patients with complete ankylosis of the spine were excluded from study participation. Patients taking hydroxychloroquine, sulfasalazine, methotrexate, or prednisone (less than or equal to 10 mg/day) could continue these drugs at stable doses for the duration of the study. Doses of 25 mg ENBREL or placebo were administered subcutaneously twice a week for 6 months. The primary measure of efficacy was a 20 percent improvement in the Assessment in Ankylosing Spondylitis (ASAS) response criteria.

### ABOUT AS

Ankylosing spondylitis, which affects up to half a million people in the United States, is a chronic, painful and progressive inflammatory disease affecting joints and ligaments that normally allow a person's back to move and flex. The disease most often occurs in the lower back but can affect the upper spine, chest and neck. In more advanced disease, the spine can fuse, causing loss of motion and a permanent stooped-over posture. AS may also involve other joints, such as the hips, shoulders, knees and ankles. Unlike other forms of arthritis, AS frequently affects individuals between the ages of 17 and 35. It tends to affect more men than women.

### ABOUT ENBREL

ENBREL is a fully human soluble TNF receptor. ENBREL has more than 14 years of collective clinical experience.

ENBREL is indicated for:

-- reducing signs and symptoms, keeping joint damage from getting worse, and improving physical function in patients with moderate to severe rheumatoid arthritis. ENBREL can be taken with methotrexate or used alone.

-- reducing signs and symptoms of moderate to severe polyarticular-course juvenile rheumatoid arthritis in patients who have failed one or more

disease modifying anti-rheumatic drugs (DMARDs).

- reducing signs and symptoms, keeping joint damage of active arthritis from getting worse, and improving physical function in patients with psoriatic arthritis. ENBREL can be used with methotrexate in patients who do not respond adequately to methotrexate alone.
- reducing signs and symptoms in patients with active ankylosing spondylitis.

- 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 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, such as an open sore or the flu, 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
- 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%)

#### About Amgen and Wyeth

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](http://www.enbrel.com) or by calling toll free 888-4ENBREL (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](http://www.amgen.com).

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 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.

#### Forward-Looking Statement

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, 2005, 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. 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 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 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 the 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 statements in this press release that are not historical facts are forward-looking statements based on current expectations of future events and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include risks associated with the inherent uncertainty of the timing and success of product research, development and commercialization (including with respect to our pipeline products), drug pricing and payment for our products by government and third-party payors, manufacturing, data generated on the safety and efficacy of our products, 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, global business operations, product liability and other types of litigation, the impact of legislation and regulatory compliance, intellectual property rights, strategic relationships with third parties, environmental liabilities, and other risks and uncertainties, including those detailed from time to time in our periodic reports filed with the Securities and Exchange Commission, including our current reports on Form 8-K, quarterly reports on Form 10-Q and annual report on Form 10-K, particularly the discussion under the caption "Item 1A, RISK FACTORS." We assume no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

EDITOR'S NOTE: An electronic version of this news release may be accessed via our Web site at [www.amgen.com](http://www.amgen.com). Journalists and media representatives may sign up to receive all news releases electronically at time of announcement by filling out a short form in the Media section of the Web site.

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