

# ENBREL is the First Biologic to Publish Data Showing Safety and Sustained Efficacy for up to Nine Years in Patients with Moderate-to-Severe Rheumatoid Arthritis

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THOUSAND OAKS, Calif.--(BUSINESS WIRE)--Nov. 12, 2006--Amgen (NASDAQ:AMGN) today announced that Enbrel(R) (etanercept) is the first biologic with published data to show improvements in multiple measures of efficacy that were sustained in rheumatoid arthritis (RA) patients completing up to nine years of therapy. These new data are being presented at the American College of Rheumatology (ACR) Scientific Meeting in Washington, D.C.

"The current data in Rheumatoid Arthritis suggest that Enbrel is both effective and safe in long-term use," said Mark Genovese, M.D., Stanford University Medical Center, Palo Alto, California. "These findings are significant because they provide a degree of reassurance to both the patient and the physician that unexpected safety concerns do not appear to be developing after nine years of use."

ENBREL continues to have a strong safety profile for extended periods of use. In the studies presented at ACR, rates of serious adverse events and serious infections remained low and were consistent with controlled portions from the double-blind phases of the studies. The overall number of observed malignancies (excluding nonmelanoma skin cancers) were similar in type and number to what would be expected in the general population.

Additionally, data showed that 77 early rheumatoid arthritis (ERA) and 280 long-standing rheumatoid arthritis (LRA) patients who completed ENBREL treatment for up to eight years experienced substantial improvements in their ACR scores. Additionally, 73 LRA patients who completed ENBREL treatment for up to nine years experienced similar improvements. ACR scores are a composite measure of improvement in RA symptoms, including joint swelling and tenderness, pain, level of disability, overall patient and physician assessment, and an objective marker of inflammation, such as erythrocyte sedimentation rate.

Data being presented at ACR showed that ENBREL provided sustained improvement in the signs and symptoms of RA, in those patients who continued in the study, regardless of duration of disease. Following eight years of ENBREL therapy: 75 percent of ERA patients and 76 percent of LRA patients achieved ACR 20; 60 percent of ERA patients and 52 percent of LRA patients achieved ACR 50; 35 percent of ERA patients and 26 percent of LRA patients achieved ACR 70. Further, for those patients with LRA who received ENBREL treatment for nine years, 74 percent achieved ACR 20, 41 percent achieved ACR 50, and 22 percent achieved ACR 70.

The ability to perform daily activities is an important goal for many people with RA, and data presented at ACR showed that treatment with ENBREL may help them achieve this goal. Through eight years of treatment with ENBREL, data showed that 73 to 85 percent of patients with ERA and 53 to 72 percent of patients with LRA achieved a clinically significant improvement in the Health Assessment Questionnaire (HAQ) score, a patient questionnaire that measures disability. A clinically significant improvement in HAQ was defined as at least a 0.22 improvement from baseline.

"Before I was diagnosed with RA, the pain, stiffness and fatigue stopped me from doing many of the activities I enjoyed," said Gloria Treece, a participant in the study. "Since starting ENBREL treatment approximately nine years ago, I'm now able to take part in many activities with my family."

These studies were designed to assess the safety and long-term efficacy of ENBREL in adult LRA patients who have failed to respond to at least one disease-modifying antirheumatic drug, and adult patients with ERA (defined as less than or equal to three years of disease duration). Patients with RA who participated in controlled clinical trials of ENBREL were eligible to enroll in open-label extension studies (LRA, N=644; ERA, N=207).

# 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 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  $\ensuremath{\mathsf{ENBREL}}$ , 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 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.

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. 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.

CONTACT: Amgen Sonia Fiorenza (media), 805-447-1604 Investor Relations (investors), 805-447-1060

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