



## New Study Reports Enbrel(R) (Etanercept) Significantly Improved Moderate to Severe Plaque Psoriasis in Children and Adolescents

January 16, 2008

### Study Published in The New England Journal of Medicine

THOUSAND OAKS, Calif. & COLLEGEVILLE, Pa., Jan 16, 2008 (BUSINESS WIRE) -- Amgen (NASDAQ: AMGN) and Wyeth Pharmaceuticals, a division of Wyeth (NYSE: WYE), today announced data from a Phase 3 study which showed that children and adolescents with moderate to severe plaque psoriasis who received treatment with ENBREL experienced significant improvements in the signs and symptoms of their disease. This study will be published in the Jan. 17, 2008, issue of The New England Journal of Medicine.

"Moderate to severe plaque psoriasis is a chronic disease of the immune system that can significantly impact many aspects of the daily lives of children and teens," says Amy Paller, M.D., study investigator and Professor and Chair of Dermatology, Northwestern University School of Medicine. "These etanercept data are encouraging and reinforce the importance of continuing to investigate treatment options that may help this particularly vulnerable patient population manage their disease."

During the 48-week study, the percentage of patients achieving 75 percent or greater disease improvement from baseline, as measured by the standard Psoriasis Area and Severity Index (PASI 75), was used to evaluate the efficacy of ENBREL in patients between 4 and 17 years old. The primary efficacy endpoint was PASI 75 at week 12. There were 106 patients initially randomized to receive ENBREL and 105 patients randomized to receive placebo.

-- At week 12, which was the conclusion of the double-blind, placebo-controlled portion of the study, 57 percent (n=60) of pediatric patients treated with ENBREL achieved PASI 75, compared with 11 percent (n=12) of pediatric patients who received placebo (p less than 0.001).

-- At week 36, after 24 weeks of open-label treatment during which all patients in the study received ENBREL, PASI 75 was achieved by 68 percent (n=71) of the patients initially treated with ENBREL from the start of the study and 65 percent (n=67) of those who initially received placebo from the start of the study.

-- At the conclusion of the open-label treatment period (week 36), 138 patients were re-randomized to receive either ENBREL or placebo. During this period, patients who lost PASI 75 were re-treated and no patient had a rebound of psoriasis or a change in the type of their psoriasis.

There were no serious adverse events or serious infections during the 12-week placebo-controlled period and rates of adverse events were similar for ENBREL and placebo. During open-label treatment, three patients developed four serious adverse events. No deaths, cancers, opportunistic infections, tuberculosis or demyelination events were reported. The most common adverse events observed during the 48-week trial in patients treated with ENBREL were upper respiratory tract infection, headache, and nasopharyngitis.

This study was designed to assess the safety and efficacy of ENBREL therapy in children and adolescents between 4 and 17 years old with moderate to severe plaque psoriasis whose disease had been inadequately controlled with topical therapy or who received systemic therapy or phototherapy. In this 48-week study, 211 pediatric psoriasis patients were initially randomized to receive 12 once-weekly weight-based doses of ENBREL (0.8 mg/kg up to the intended dose of 50 mg) or placebo. After this double-blind portion, 208 patients entered a 24-week period of open-label ENBREL treatment once-weekly. At week 36, 138 patients were re-randomized to receive either ENBREL or placebo, to investigate withdrawal and re-treatment.

ENBREL is not indicated for the treatment of pediatric psoriasis. Amgen has filed a supplemental Biologics License Application (sBLA) with the U.S. Food and Drug Administration (FDA) for the use of ENBREL in treating pediatric patients with chronic moderate to severe plaque psoriasis who have tried another therapy. If approved by the FDA, ENBREL is expected to be the first biologic, as well as the first systemic medication, indicated to treat this disease in pediatric patients.

### ABOUT PSORIASIS

According to the National Institutes of Health, up to 7.5 million Americans have psoriasis, a noncontagious, chronic disease in which the immune system causes skin cells to grow at an accelerated rate. Approximately 80 percent of these patients have plaque psoriasis, which is characterized by painful and itchy, red, scaly patches. According to the National Psoriasis Foundation, about one-third of all psoriasis patients will develop the disease in childhood.

### ABOUT ENBREL

ENBREL is a fully human soluble tumor necrosis factor (TNF) receptor. ENBREL was first approved in 1998 for moderate to severe rheumatoid arthritis and has since been used in nearly 500,000 patients worldwide across indications.

### ENBREL Indications:

- 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.
- ENBREL is indicated for reducing signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis in patients who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs.
- ENBREL is indicated for reducing signs and symptoms, keeping joint damage from getting worse, and improving physical function in patients with psoriatic arthritis. ENBREL can be used in combination with methotrexate in patients who do not respond adequately to methotrexate alone.

-- ENBREL is indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

-- 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.

What important information do I need to know about taking prescription Enbrel(R) (etanercept)?

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 or have had hepatitis B
- 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 reaction

-- In a medical study of patients with JRA, infection, headache, 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 infection (2 percent) and depression/personality disorder (1 percent)

If you have any questions about this information, be sure to discuss them with your doctor. Please visit [www.enbrel.com](http://www.enbrel.com) or call 1-888-4ENBREL to request additional information, including the full U.S. Prescribing Information.

#### 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.

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 deep and broad 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, infectious disease, gastrointestinal health, 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. To learn more, visit [www.wyeth.com](http://www.wyeth.com).

#### AMGEN FORWARD-LOOKING STATEMENT

This news release contains forward-looking statements that are based on Amgen's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and most recent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Forms 10-K, 10-Q and 8-K for additional information on the uncertainties and risk factors related to Amgen's business. Unless otherwise noted, Amgen is providing this information as of Jan. 16, 2008 and expressly disclaims any duty to update information contained in this news release.

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 safety, side effects or manufacturing problems with Amgen's products after they are on the market. Amgen's business may be impacted by government investigations, litigation and products liability claims. Amgen depends on third parties for a significant portion of its manufacturing capacity for the supply of certain of its current and future products and limits on supply may constrain sales of certain of its current products and product candidate development.

In addition, sales of Amgen's products are affected by the reimbursement policies imposed by third-party payors, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and health care cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of Amgen's products. 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. 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 obtain 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 Amgen's 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 Amgen's products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration (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. Healthcare professionals should refer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

#### WYETH FORWARD-LOOKING STATEMENT

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 the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialization of our products, including with respect to our pipeline products; government cost-containment initiatives; restrictions on third-party payments for our products; substantial competition in our industry, including from branded and generic products; data generated on our products; the importance of strong performance from our principal products and our anticipated new product introductions; the highly regulated nature of our business; product liability, intellectual property and other litigation risks and environmental liabilities; uncertainty regarding our intellectual property rights and those of others; difficulties associated with, and regulatory compliance with respect to, manufacturing of our products; risks associated with our strategic relationships; economic conditions including interest and currency exchange rate fluctuations; changes in generally accepted accounting principles; trade buying patterns; the impact of legislation and regulatory compliance; risks and uncertainties associated with global operations and sales; 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." The forward-looking statements in this press release are qualified by these risk factors. We assume no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

SOURCE: Amgen

Amgen, Thousand Oaks  
Sonia Fiorenza, 805-447-1604 (media)  
Arvind Sood, 805-447-1060 (investors)  
or  
Wyeth  
Natalie de Vane, 484-865-5139 (media)  
Justin Victoria, 973-660-5340 (investors)