

# Enbrel(R) (etanercept) Application for the Treatment of Pediatric Psoriasis to be Discussed at FDA Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) Meeting

June 18, 2008

ENBREL Reviewed As Potential New Treatment Option for Children and Adolescents with Chronic Moderate to Severe Plaque Psoriasis Who Have Tried Another Therapy

THOUSAND OAKS, Calif.--(BUSINESS WIRE)--June 18, 2008--Amgen (NASDAQ:AMGN) announced that the supplemental Biologics License Application (sBLA) for ENBREL for the treatment of pediatric patients with chronic moderate to severe plaque psoriasis who have tried another therapy will be discussed today at a meeting of the DODAC. Moderate to severe plaque psoriasis is a serious, chronic inflammatory disease that can have both physical and psychosocial impact. According to a study published in the British Journal of Dermatology, chronic psoriasis can have as much of an impact on a child's physical, psychological and social functioning as other serious childhood diseases such as asthma, epilepsy and diabetes.

"Despite the major impact of moderate to severe psoriasis on the lives of children living with this condition, no topical or systemic options are approved in the U.S. for chronic use in this indication," said Roger M. Perlmutter, M.D., Ph.D., executive vice president, Research and Development, Amgen. "There is a clear unmet medical need in this small, under-served population of children with chronic moderate to severe plaque psoriasis."

In September 2007, Amgen submitted a sBLA to the U.S. Food and Drug Administration (FDA) for the expanded use of ENBREL in treating pediatric patients with chronic moderate to severe plaque psoriasis who are inadequately controlled with topical therapy or who have received systemic therapy or phototherapy.

Amgen is proposing a risk management program to foster appropriate use of ENBREL in this patient population. Education will be an important tool to help physicians, patients, and their guardians understand, and therefore mitigate, known and potential risks associated with the use of ENBREL.

#### **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. Up to 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 soluble form of a fully human tumor necrosis factor (TNF) receptor and has 16 years of collective clinical experience with an established safety profile. ENBREL was first approved in 1998 for moderate to severe rheumatoid arthritis and was approved to treat children and adolescents with juvenile rheumatoid arthritis (now called juvenile idiopathic arthritis) in 1999. ENBREL was approved in 2004 to treat moderate to severe plaque psoriasis in adults.

#### ENBREL indications in the U.S.:

- -- 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 the signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 and older.
- -- 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.

Important Safety Information

What important safety information do I need to know about taking prescription 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, juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis, or psoriasis, have too much TNF in their bodies. ENBREL can reduce the amount of active 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.

Serious infections, including tuberculosis (TB), have happened in patients taking ENBREL. Some of these serious infections have been fatal. Many serious infections occurred in people prone to infection. Serious infections have also occurred in patients with advanced or poorly controlled diabetes. Do not start ENBREL if you have an infection or are allergic to ENBREL or its components. Once on ENBREL, if you get an infection or have any sign of an infection, including fever, cough, or flu-like symptoms, or have open sores, tell your doctor. Your doctor should test you for TB before starting ENBREL and should monitor you closely for signs and symptoms of TB.

Serious nervous system disorders, such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes have been reported. There have been rare reports of serious blood disorders (some fatal).

In medical studies, more cases of lymphoma (a type of cancer) were seen in patients taking TNF blockers compared to similar patients who were not taking TNF blockers. The risk of lymphoma may be several-fold higher in people with rheumatoid arthritis and psoriasis; the role of TNF blockers in the development of malignancies is unknown.

Tell your doctor if you:

- -- Think you have, are being treated for, have signs of, or are prone to infection
- -- Have any open sores
- -- Have or have had TB or hepatitis B
- -- Have ever been treated for heart failure
- -- Have ever had or develop a serious nervous system disorder
- -- Develop symptoms such as persistent fever, bruising, bleeding, or paleness while taking ENBREL

Common side effects in adult clinical trials were injection site reaction, infection and headache.

In a medical study of patients with JIA, 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, including serious infection and depression/personality disorder.

If you have any questions about this information, be sure to discuss them with your doctor. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please visit www.enbrel.com or call 1-888-4ENBREL to request additional information, including the full U.S. Prescribing Information.

#### About Amgen

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, manufactures 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.

## 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 June 18, 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 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 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.

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SOURCE: Amgen