Enbrel(R) (etanercept) Significantly Improved Scalp Involvement in Patients with Moderate to Severe Plaque Psoriasis

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THOUSAND OAKS, Calif. and COLLEGEVILLE, Pa., Feb. 4, 2011 /PRNewswire via COMTEX/ --

Amgen (Nasdaq: AMGN) and Pfizer Inc. (NYSE: PFE) today announced results from a new trial that demonstrated Enbrel(R) (etanercept) significantly improved scalp involvement in adult patients with moderate to severe plaque psoriasis, compared with placebo. The data will be presented today at the 69th Annual American Academy of Dermatology (AAD) meeting in New Orleans, La.

"At least half of people with plaque psoriasis have involvement on their scalp, which may contribute to feelings of embarrassment associated with this condition," said lead author Jerry Bagel, M.D., medical director, Psoriasis Treatment Center of Central New Jersey. "These data reinforce the efficacy and safety profile of ENBREL for adult patients with moderate to severe plaque psoriasis with scalp involvement."

In this trial, patients were randomized to either 12 weeks of ENBREL 50 mg twice weekly followed by 12 weeks of ENBREL 50 mg once weekly (Group A), or 12 weeks of placebo twice weekly followed by 12 weeks of ENBREL 50 mg twice weekly (Group B). This trial met its primary endpoint of mean percent improvement from baseline in Psoriasis Scalp Severity Index (PSSI) with 87 percent PSSI improvement in Group A compared with 20 percent in Group B at week 12 (P<0.0001). The PSSI response to ENBREL for patients in Group A was maintained through 24 weeks despite patients switching to a lower dose (91 percent). Patients in Group B saw a mean percent improvement in their PSSI score of 79 percent at week 24, similar to that achieved by the Group A patients at week 12.

In addition to the improvement in scalp involvement, in an exploratory analysis, the mean percent improvement from baseline in Psoriasis Area Severity Index (PASI) was 74 percent in Group A compared with 11 percent in Group B at week 12 (P<0.0001). At week 24, the mean percent improvement from baseline was 78 percent in Group A and 68 percent in Group B.

At week 12 in this study, 75 percent of patients treated with ENBREL (n=43) were either satisfied or very satisfied with their treatment, compared with 21 percent of patients on placebo (n=11, P<0.0001).

Among the 121 patients evaluable for safety, 67.8 percent reported at least one adverse event (AE) through week 24; the most common were upper respiratory tract infections (11.6 percent), nasopharyngitis (8.3 percent), injection site reaction (5.8 percent), arthralgia (5.0 percent), and headache (5.0 percent). Three patients reported five serious AEs: cholecystitis/cholelithiasis, fall/rib fracture and metastatic malignant melanoma.

ABOUT THE TRIAL

The trial was a Phase IV, randomized, placebo-controlled, double-blind study evaluating the efficacy and safety of ENBREL in adult patients with moderate to severe plaque psoriasis with scalp involvement. The 124 eligible patients were at least 18 years old with a PASI greater than or equal to 10, affected body surface area greater than or equal to 10 percent, PSSI greater than or equal to 15, and affected scalp surface area greater than or equal to 30 percent. Patients were randomized to either 12 weeks of ENBREL 50 mg twice weekly followed by 12 weeks of ENBREL 50 mg once weekly (Group A), or 12 weeks of placebo twice weekly followed by 12 weeks of ENBREL 50 mg twice weekly (Group B). The primary endpoint was the mean percent improvement from baseline in PSSI at week 12. Patient satisfaction with treatment was a patient-reported secondary endpoint and was determined by a 5-point scale (very dissatisfied to very satisfied).

ABOUT PSORIASIS

Psoriasis affects approximately 7.5 million American adults and is a chronic disease of the immune system that causes the skin cells to grow at an accelerated rate. Although there are several types of psoriasis, approximately 80 percent of patients suffer from plaque psoriasis, which can cause painful and itchy red, scaly patches to appear on the skin.

According to the National Psoriasis Foundation, at least half of all the people who have psoriasis have scalp involvement. Scalp involvement can be very mild, with slight, fine scaling or very severe with thick, crusted plaques covering the entire scalp. Psoriasis can extend beyond the hairline onto the forehead, the back of the neck and around the ears.

ABOUT ENBREL

ENBREL is a soluble form of a fully human tumor necrosis factor (TNF) receptor with a clinical efficacy and safety profile established over 18 years of collective clinical experience. ENBREL was first approved in 1998 for moderate to severe rheumatoid arthritis and was later approved to treat children and adolescents with moderate to severe juvenile rheumatoid arthritis (now called juvenile idiopathic arthritis) in 1999. ENBREL was approved in 2004 to treat adult chronic moderate to severe plaque psoriasis. Prescription ENBREL is given by injection.

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 signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in children ages 2 years 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 is the most important information I should know about ENBREL?

ENBREL is a medicine that affects your immune system. ENBREL can lower the ability of your immune system to fight infections. Serious infections have happened in patients taking ENBREL. These infections include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some patients have died from these infections. Your doctor should test you for TB before you take ENBREL and monitor you closely for TB before, during, and after ENBREL treatment, even if you have tested negative for TB.

There have been some cases of unusual cancers reported in children and teenage patients who started using tumor necrosis factor (TNF) blockers before 18 years of age. Also, for children, teenagers, and adults taking TNF blockers, including ENBREL, the chances of getting lymphoma or other cancers may increase. Patients with RA or psoriasis may be more likely to get lymphoma.

Before starting ENBREL, tell your doctor if you:

- Have any existing medical conditions
- Are taking any medicines, including herbals
- Think you have, are being treated for, have signs of, or are prone to infection. You should not start taking ENBREL if you have any kind of infection, unless your doctor says it is okay
- Have any open cuts or sores
- Have diabetes or an immune system problem
- Have TB or have been in close contact with someone who has had TB
- Were born in, lived in, or traveled to countries where there is more risk for getting TB. Ask your doctor if you are not sure
- Live or have lived in certain parts of the country (such as, the Ohio and Mississippi River valleys, or the Southwest) where there is a greater risk for certain kinds of fungal infections, such as histoplasmosis. These infections may develop or become more severe if you take ENBREL. If you don't know if histoplasmosis or other fungal infections are common in the areas where you live or have lived, ask your doctor
- Have or have had hepatitis B
- Have heart failure
- Develop symptoms such as persistent fever, bruising, bleeding, or paleness while taking ENBREL
- Use the medicine Kineret(R) (anakinra), Orenciaa (abatacept), or Cytoxan(R) (cyclophosphamide)
- Are taking anti-diabetic medicines
- Have or develop a serious nervous disorder, seizures, any numbness or tingling, or a disease that affects your nervous system such as multiple sclerosis or Guillain-Barre syndrome
- Are scheduled to have surgery
- Have recently received or are scheduled for any vaccines. All vaccines should be brought up-to-date before starting ENBREL. Patients taking ENBREL should not receive live vaccines.
- Are allergic to rubber or latex
- Are pregnant, planning to become pregnant, or breastfeeding
- Have been around someone with chicken pox

What are the possible side effects of ENBREL?

ENBREL can cause serious side effects including: **Infections**, including serious infections like TB; **hepatitis B** can become active if you already have had it; **nervous system problems**, such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes; **blood problems** (some fatal); new or worsening **heart failure**; new or worsening **psoriasis**; **allergic reactions**; **autoimmune reactions**, including a lupus-like syndrome and autoimmune hepatitis.

Common side effects include: Injection site reactions, upper respiratory infections (sinus infections), 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.

These are not all the side effects with ENBREL. Tell your doctor about any side effect that bothers you or does not go away.

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 see Prescribing Information and Medication Guide at www.enbrel.com.

About Amgen and Pfizer

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, bone disease, 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.

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.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 Feb. 4, 2011 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 healthcare 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 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 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 theinvestigational use(s) discussed in this news release, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for theseuses. Only the FDA can determine whether the products are safe and effective for these uses. Healthcareprofessionals shouldrefer to and rely upon the FDA-approved labeling for the products, and not the information discussed in this news release.

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