



Data Presented at Two Global Medical Congresses Reinforce Benefit of Enbrel® (etanercept) for Patients with Chronic Inflammatory Conditions

Tuesday, May 24, 2011 - 10:33pm

New Interim Results from the PRESERVE Study Evaluate ENBREL Therapy in Patients with Moderately Active Rheumatoid Arthritis
Analysis of Ankylosing Spondylitis Trials Suggests Nocturnal Back Pain is Predictive of Fatigue, and ENBREL was Shown to Reduce These Symptoms
PRISTINE Trial Data Explore Effects of ENBREL on Cardiometabolic Biomarkers in Subjects with Moderate-to-Severe Plaque Psoriasis

"With its first approval for RA in 1998, ENBREL has 2.5 million patient-years of collective clinical experience, and we continue to gain important knowledge about these conditions and the potential benefits of treating patients with certain chronic inflammatory diseases."

(BUSINESS WIRE)--Amgen (Nasdaq: AMGN) and Pfizer Inc. (NYSE: PFE) today announced new results from multiple studies of ENBREL, further expanding the body of evidence supporting the efficacy and safety profile of ENBREL, the most prescribed biologic by rheumatologists in the United States (U.S.). Eighteen abstracts across four indications, including moderate-to-severe rheumatoid arthritis (RA), ankylosing spondylitis (AS), moderate-to-severe plaque psoriasis (PsO), and psoriatic arthritis (PsA), will be published at two global medical congresses, the European League Against Rheumatism (EULAR) and World Congress of Dermatology (WCD), this week.

“The breadth of data being presented at these congresses underscores our ongoing commitment to the rigorous study of these conditions where treatment has been shown to improve patient outcomes,” said Yvonne Greenstreet, senior vice president and head of the Medicines Development Group for Pfizer’s Specialty Care Business Unit. “With its first approval for RA in 1998, ENBREL has 2.5 million patient-years of collective clinical experience, and we continue to gain important knowledge about these conditions and the potential benefits of treating patients with certain chronic inflammatory diseases.”

Selected abstracts of interest include:

Rheumatoid Arthritis

Impact of Etanercept-Methotrexate (MTX) Therapy on Disease Activity and Radiographic Progression in Moderately Active Rheumatoid Arthritis: Interim Results of the PRESERVE Trial

Persistent inflammation and associated joint damage may play a critical role in causing impairment in joint function in RA. Previous studies exploring treatment with biologics focused primarily on patients with severe disease. The radiographic data are an exploratory endpoint and represent results from Period 1 of a 2-period study from the initial open-label portion of the PRESERVE trial examining patients with moderately active rheumatoid arthritis.

The results demonstrated that treatment with ENBREL added to MTX reduced radiographic progression in 82 percent (modified Total Sharp Score [mTSS] change ≤ 0.5) of these patients, all of whom had an inadequate response to MTX alone. Results also showed that 86 percent of patients achieved Disease Activity Score (DAS) 28 low disease activity and 67 percent achieved DAS28 clinical remission with continuous treatment with ENBREL plus MTX.

Improvement in Patient-Reported Outcomes with Etanercept-Methotrexate (MTX) Therapy in Moderately Active Rheumatoid Arthritis: Interim Results of the PRESERVE Trial

Patients with RA often experience impairment in physical function, health-related quality of life (HR-QOL) and productivity at work. Patient-reported outcomes from the initial open-label portion of the PRESERVE trial examining patients with moderate rheumatoid arthritis showed clinically important improvements in measures of physical function, disease activity, pain, fatigue, HR-QOL and work productivity after 36 weeks of ENBREL added to MTX.

Ankylosing Spondylitis

Association Between Nocturnal Back Pain and Fatigue in Ankylosing Spondylitis and Improvements in Both Patient-Reported Outcomes with Etanercept Therapy

Nocturnal back pain in AS patients is a strong predictor of fatigue. In an exploratory pooled analysis, data combined from four clinical trials of AS patients were analyzed and found that nocturnal back pain was a significant predictor of fatigue and showed that ENBREL provided reductions in nocturnal back pain and fatigue.

Psoriatic Arthritis

Psoriasis Patients with Psoriatic Arthritis and Axial Involvement Have a Higher Disease Burden than Those without Axial Involvement but Similar Treatment Outcomes: Results from PRESTA Trial

Patients who have PsO and PsA with axial disease (disease involvement in the spine) have a higher burden of disease than those without axial disease (patients who have disease in the peripheral joints only). Data from an exploratory analysis of the PRESTA trial examining patients with moderate-to-severe PsO and PsA found that patients presenting with and without axial disease showed benefit from treatment with ENBREL compared with baseline.

Psoriasis

Effects of Etanercept on Cardiometabolic Biomarkers in Subjects with Moderate-to-Severe Plaque Psoriasis: The PRISTINE Trial

Psoriasis patients may have an increased incidence of co-morbid conditions, such as diabetes and cardiovascular disease. Data from this exploratory endpoint from the PRISTINE trial studying patients with moderate-to-severe plaque psoriasis found at week 12, ENBREL 50mg once or twice weekly did not negatively impact various biomarkers of cardiometabolic disease like apolipoprotein B/apolipoprotein A1 ratio, hsCRP, and NT-proBNP. The clinical significance of these findings needs to be studied further, but the results are important for consideration as the medical community continues to explore the potentially broader effects of inflammatory disease in the body.

About Rheumatoid Arthritis

Rheumatoid arthritis affects approximately 0.6 to 0.9 percent of the adult population worldwide and can start at any age, but usually occurs between 40 and 70 years. RA can

cause pain, stiffness, swelling and limitation in the motion and function of multiple joints. In RA, joint damage can significantly worsen over time, especially if left untreated. Joint damage may impair function, and potentially disable some patients.

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.

About Psoriatic Arthritis

Psoriatic arthritis is an auto-immune disease that causes pain, stiffness and swelling in and around the joints. In addition, psoriatic arthritis patients may experience skin lesions similar to those seen in plaque psoriasis.

Approximately 600,000 Americans have psoriatic arthritis. In fact, up to 30 percent of people diagnosed with plaque psoriasis may actually have psoriatic arthritis.

About Ankylosing Spondylitis

Ankylosing spondylitis is a debilitating condition that may affect two to three times as many men as women, and typically presents in patients during the second and third decades of life. AS typically causes inflammation, stiffness and pain in the spine (known as axial disease), but can also affect the peripheral joints. As a result of the disease, patients with symptomatic AS can lose productivity owing to work disability and unemployment, and may have substantial use of healthcare resources and an overall reduced quality of life.

ABOUT ENBREL

ENBREL is a fully human soluble tumor necrosis factor (TNF) receptor antagonist. ENBREL was first approved in 1998 for moderate to severe rheumatoid arthritis and was approved in 2004 to treat adult chronic moderate to severe plaque psoriasis. ENBREL has more than 18 years (with more than 12 years of post-marketing experience in RA) and 2.5 million patient-years of collective clinical experience.

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.

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.

ENBREL in the EU is approved for the following indications:

Rheumatoid arthritis: ENBREL in combination with methotrexate is indicated for the treatment of moderate to severe active rheumatoid arthritis in adults when the response to disease-modifying antirheumatic drugs, including methotrexate (unless contraindicated), has been inadequate. ENBREL can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. ENBREL is also indicated in the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. ENBREL, alone or in combination with methotrexate, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function. Polyarticular juvenile idiopathic arthritis: Treatment of active polyarticular juvenile idiopathic arthritis (JIA) in children and adolescents aged 4 to 17 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. ENBREL has not been studied in children aged less than 4 years. Psoriatic arthritis: Treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug therapy has been inadequate. ENBREL has been shown to improve physical function in patients with psoriatic arthritis, and to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease. Ankylosing spondylitis: Treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy. Plaque psoriasis: Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are

intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA. The European Commission recently approved a new 50mg ENBREL once-weekly dosage regimen as an alternative to the currently approved 25mg ENBREL twice-weekly regimen for the treatment of patients with moderate-to-severe plaque psoriasis. Pediatric plaque psoriasis: Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 8 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

For full information about ENBREL go to: [\files\pressrelease_assets\pdf\WC500027364.pdf](#)

Important Safety Information

Serious infections, including sepsis and tuberculosis, have been reported with the use of ENBREL. Some of these infections have been fatal. These infections were due to bacteria, mycobacteria, fungi, and viruses. Opportunistic infections have also been reported. Patients who develop a new infection while undergoing treatment with ENBREL should be monitored closely. Administration of ENBREL should be discontinued if a patient develops a serious infection.

Caution should be exercised when considering the use of ENBREL in patients with a history of recurring or chronic infections or underlying conditions which may predispose patients to infections. Treatment with ENBREL should not be initiated in patients with sepsis or risk of sepsis, or in patients with serious active infections.

Before initiation of therapy with ENBREL, any patient at increased risk for tuberculosis (TB) should be evaluated for active or latent infection. Prophylaxis of latent TB infection should be initiated prior to therapy with ENBREL. Physicians should monitor patients receiving ENBREL for signs and symptoms of active TB, including patients who tested negative for latent tuberculosis infection. Applicable local guidelines should be consulted.

Reports of malignancies affecting various sites have been received in the postmarketing period. In clinical trials of TNF antagonists, more cases of lymphoma were seen among patients receiving a TNF antagonist compared to control patients. However, there is an increased background lymphoma risk in RA patients with long-standing, highly active, inflammatory disease. Combining the results of controlled portions of clinical trials of ENBREL, more cases of melanoma and non-melanoma skin cancer were seen in patients receiving ENBREL compared with control patients, particularly in patients with psoriasis. A possible risk for the development of lymphomas or other malignancies in patients treated with an anti-TNF agent cannot be excluded.

Do not start ENBREL in patients with hypersensitivity to ENBREL or its components. Allergic reactions associated with ENBREL administration have been reported. If any serious allergic or anaphylactic reaction occurs, discontinue administration of ENBREL immediately.

There have been rare reports of CNS demyelinating disorders in patients treated with ENBREL.

Rare cases of pancytopenia, and very rare cases of aplastic anemia, some fatal, have been reported in patients treated with ENBREL. Exercise caution in patients who have a previous history of blood dyscrasias. Advise patients to seek immediate medical attention if they develop signs or symptoms of blood dyscrasias or infection. If blood dyscrasias are confirmed, discontinue ENBREL.

Reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of this virus who are receiving anti-TNF agents, including ENBREL, has been reported. Patients at risk for HBV infection should be evaluated for prior evidence of the virus before initiating anti-TNF therapy. Although a causal relationship has not been established for ENBREL, caution should be exercised when administering ENBREL for patients identified as carriers for HBV.

There have been reports of worsening of hepatitis C in patients receiving ENBREL, although a causal relationship with ENBREL has not been established.

Physicians should use caution when using ENBREL in patients who also have moderate to severe alcoholic hepatitis.

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 May 25, 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 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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