

# Amgen and Pfizer Highlight Data to be Presented at American College of Rheumatology Meeting

Monday, November 12, 2012 - 12:29am

"Moderate to severe rheumatoid arthritis (RA) places a significant burden on patients, and we are pleased that ENBREL remains the number one most prescribed biologic among rheumatologists to help reduce pain and help stop the progression of joint damage in these patients,"

Amgen (NASDAQ:AMGN) and Pfizer (NYSE:PFE) today announced that results from several Enbrel® (etanercept) studies will be presented at the American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) 2012 Annual Meeting in Washington, D.C. from Nov. 10-14, 2012.

"Moderate to severe rheumatoid arthritis (RA) places a significant burden on patients, and we are pleased that ENBREL remains the number one most prescribed biologic among rheumatologists to help reduce pain and help stop the progression of joint damage in these patients," said Sean E. Harper, M.D., executive vice president of Research and Development at Amgen. "Physicians have been prescribing ENBREL for 14 years, and the data being presented at ACR demonstrate our ongoing commitment to the study of RA and the meaningful impact ENBREL has on patients."

Abstracts are available on the ACR website at [www.rheumatology.org](http://www.rheumatology.org).

## SELECTED ABSTRACTS OF INTEREST INCLUDE:

### Oral Presentations

- Induction of Remission in Patients with up to 12 Months of Moderate-to-Severe Rheumatoid Arthritis Symptoms Treated with Etanercept Plus Methotrexate Over 52 Weeks  
Lead Author: Paul Emery, Department of Rheumatology, Leeds General Infirmary, Leeds, United Kingdom  
Abstract No. 2549  
Tuesday, Nov. 13, 5:30 p.m. – 5:45 p.m. EST

### Poster Presentations

- Impact of Etanercept-Methotrexate Therapy on Patient-Reported Outcomes in Rheumatoid Arthritis Patients with up to 12 Months of Symptoms  
Lead Author: Paul Emery, Department of Rheumatology, Leeds General Infirmary, Leeds, United Kingdom  
Abstract No. 368

Sunday, Nov. 11, 9:00 a.m. – 6:00 p.m. EST

- Structural Damage is Reduced by Early Achievement of Clinical Remission  
Lead Author: Paul Emery, Department of Rheumatology, Leeds General Infirmary, Leeds, United Kingdom

Abstract No. 1011

Monday, Nov. 12, 9:00 a.m. – 6:00 p.m. EST

- Relationship Between Clinical Response and Radiographic Outcomes in Patients with Moderate Rheumatoid Arthritis  
Lead Author: Josef S. Smolen, Division of Rheumatology, Department of Internal Medicine III, Medical University of Vienna, Vienna, Austria

Abstract No. 2133

Tuesday, Nov. 13, 9:00 a.m. – 6:00 p.m. EST

- Factors that Impact Work Productivity in the PRESERVE Trial: A Randomized Controlled Trial of Combination Etanercept-Methotrexate Therapy in Patients with Moderately Active Rheumatoid Arthritis  
Lead Author: Vibeke Strand, Division of Immunology/Rheumatology, Stanford University School of Medicine, Palo Alto, California, United States

Abstract No. 1827

Tuesday, Nov. 13, 9:00 a.m. – 6:00 p.m. EST

## About Rheumatoid Arthritis

RA is a chronic inflammatory disease that affects approximately one percent of the adult population worldwide and can start at any age, but usually occurs between 40 and 70 years of age. RA can cause pain, stiffness, swelling and limited 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 ENBREL

ENBREL is a soluble form of a fully human tumor necrosis factor (TNF) receptor with efficacy and safety evaluated in clinical studies over the past 19 years. ENBREL was first approved in the U.S. 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 polyarticular juvenile idiopathic arthritis) in 1999. In 2004, ENBREL was approved in the U.S. to treat adult patients with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Prescription ENBREL is taken 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, HIV, or a weak immune system
- 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, have lived in, or traveled to 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 these infections are common in the areas you've been to, ask your doctor
- Have or have had hepatitis B
- Have or have had heart failure
- Develop symptoms such as persistent fever, bruising, bleeding, or paleness while taking ENBREL
- Use the medicine Kineret<sup>®</sup> (anakinra), Orencia<sup>®</sup> (abatacept), or Cytoxan<sup>®</sup> (cyclophosphamide)
- Are taking anti-diabetic medicines
- Have, have had, 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: New infections or worsening of infections you already have; 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.

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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

Please see Prescribing Information and Medication Guide at [www.ENBREL.com](http://www.ENBREL.com).

#### About Amgen

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, 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 vital medicines, visit [www.amgen.com](http://www.amgen.com). Follow us on [www.twitter.com/amgen](https://www.twitter.com/amgen).

#### About Pfizer Inc.

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 healthcare 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 healthcare 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](http://www.pfizer.com).

#### Amgen Forward Looking Statements

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 Nov. 12, 2012, 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 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.

#### Pfizer Disclosure Notice

The information contained in this release is as of November 12, 2012. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information that involves substantial risks and uncertainties about Enbrel, including data relating to Enbrel and the potential implications of such data. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; competitive developments; and the other risks and uncertainties set forth in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and in its reports on Form 10-Q and Form 8-K.

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