



## Amgen and Wyeth Statement on the FDA Safety Announcement Regarding Tumor Necrosis Factor (TNF) Blockers

September 4, 2008

THOUSAND OAKS, Calif. & COLLEGEVILLE, Pa.--(BUSINESS WIRE)--Sept. 4, 2008--Amgen (NASDAQ: AMGN) and Wyeth Pharmaceuticals, a division of Wyeth (NYSE: WYE), issued a statement in response to the Food and Drug Administration (FDA) safety announcement regarding opportunistic fungal infections in patients treated with Tumor Necrosis Factor (TNF) blockers (marketed as Remicade(R) (infliximab), Enbrel(R) (etanercept), Humira(R) (adalimumab) and Cimzia(R) (certolizumab pegol)).

### AMGEN AND WYETH STATEMENT:

The FDA has reviewed reports of histoplasmosis and other opportunistic fungal infections in patients treated with TNF-blockers. Although the increased risk for infections is currently included in the U.S. Prescribing Information for ENBREL, the FDA stated that specific language around histoplasmosis and other opportunistic fungal infections is necessary to help ensure the early diagnosis and treatment of these uncommon and often undiagnosed conditions in patients on TNF-blocking therapy.

Using its new authority under the Food and Drug Administration Amendments Act of 2007 (FDAAA), the FDA has requested that the WARNINGS and PRECAUTIONS section of the U.S. Prescribing Information and Medication Guide for ENBREL be strengthened to include the risk of developing opportunistic fungal infections, which will be consistent with labeling changes requested for other medicines in the TNF-blocker class. Amgen will work with the Agency to finalize and communicate revised product labeling for ENBREL to both physicians and patients.

The FDA stated that patients taking TNF-blockers who develop a fungal infection may be advised by their health care professional to stop the TNF-blocker until they recover from the infection. The FDA has concluded that histoplasmosis and other invasive fungal infections in individuals taking TNF blockers are not consistently recognized and may go untreated, potentially leading to deaths that may have been prevented had appropriate treatment been administered. According to the FDA safety announcement, this action "will help health care professionals be more vigilant in watching for these adverse events, and is necessary to ensure that the benefits of these drugs outweigh the risks."

The full FDA safety announcement is available at [http://www.fda.gov/cder/drug/InfoSheets/HCP/TNF\\_blockersHCP.htm](http://www.fda.gov/cder/drug/InfoSheets/HCP/TNF_blockersHCP.htm).

Amgen and Wyeth are committed to the safety of patients. Both companies maintain ongoing safety surveillance programs worldwide to analyze and evaluate safety reports from controlled and open-label clinical trials and patient registries, as well as reports received from health care professionals and patients. Both companies work with regulatory agencies to update the label periodically as appropriate based on emerging information.

### ABOUT HISTOPLASMOSIS

Histoplasmosis is a non-contagious infectious disease caused by a fungus, most often affecting the lungs. Its symptoms vary greatly and include a general ill feeling, a dry or nonproductive cough, chest pains, fever, chills, headache, muscle aches, and loss of appetite. The vast majority of those infected have no symptoms, or experience mild flu-like symptoms that do not require medical attention. Disseminated histoplasmosis can affect multiple organs, and can be fatal if untreated. Histoplasmosis is seen more frequently in the central and eastern portions of the U.S., particularly in areas bordering the Ohio River Valley, as well as the areas surrounding the lower Mississippi River.

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

Please visit [www.enbrel.com](http://www.enbrel.com) or call 1-888-4ENBREL to request additional information, including the U.S. Prescribing Information and Medication Guide.

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, 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](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, nutritionals 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 Sept. 4, 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 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 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 that 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, without limitation, the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialization of our products and 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; emerging data on our products and pipeline 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" in our Annual Report on Form 10-K for the year ended December 31, 2007, which was filed with the Securities and Exchange Commission on February 29, 2008. 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.

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