Amgen and Wyeth Statement on FDA Announcement About Tumor Necrosis Factor (TNF) Blockers

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THOUSAND OAKS, Calif. and COLLEGEVILLE, Pa., Aug. 4 /PRNewswire-FirstCall/ -- Amgen (Nasdaq: AMGN) and Wyeth Pharmaceuticals, a division of Wyeth (NYSE: WYE), issued a statement in response to the Food and Drug Administration (FDA) announcement regarding the results of a safety review of Tumor Necrosis Factor (TNF) blockers [marketed as Remicade (infliximab), Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab pegol) and Simponi (golimumab)]. This safety review was the subject of an FDA Early Communication in June 2008 pertaining to cases of malignancy in pediatric patients exposed to a TNF blocker. As a result of this review, the FDA has required strengthened warnings about the occurrence of lymphoma and other cancers in children and young adults using these medicines.

AMGEN AND WYETH STATEMENT:

Amgen and Wyeth believe that ENBREL continues to offer a favorable benefit-risk relationship for patients with the diseases for which it is indicated to treat, including moderate to severe Juvenile Idiopathic Arthritis (JIA). JIA can be a serious and potentially debilitating condition. Amgen will work with the FDA to update the U.S. Prescribing Information, and Medication Guide for ENBREL as described in the FDA communication which can be read at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm175803.htm. In addition, Amgen and Wyeth will communicate the revised product labeling to both physicians and patients.

ENBREL was first approved for JIA in the U.S. in 1999. It is estimated through postmarketing data that approximately 13,847 pediatric patients have been treated with ENBREL globally through February 2009, accounting for approximately 44,600 patient-years of exposure. Postmarketing cases of malignancies have been reported in pediatric patients treated with ENBREL.

Amgen and Wyeth are committed to patient safety and support the continued evaluation of the potential risks and benefits of TNF blockers for patients who are prescribed these therapies. Both companies maintain ongoing safety surveillance programs worldwide to review all data sources available to them, and work with regulatory agencies to update the label as appropriate based on emerging information. As always, physicians and patients or their caregivers should carefully evaluate the benefits and risks of ENBREL.

ABOUT JUVENILE IDIOPATHIC ARTHRITIS

ENBREL was first approved for juvenile idiopathic arthritis (JIA), formerly called juvenile rheumatoid arthritis, in 1999, and this is the only FDA-approved use for ENBREL in the pediatric population. 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 has been studied in JIA for up to nine years in controlled and open-label portions of a clinical study.

JIA is a systemic inflammatory disease that strikes children before age 16 and can cause painful joint swelling, deformity and stunted growth. According to the Arthritis Foundation, JIA can impair a child's ability to take part in physical activities, make daily activities such as schoolwork more difficult, and affect a child's physical appearance. Parents and siblings may be impacted by the psychological and financial stress of chronic illness in a family member.

ABOUT ENBREL

ENBREL is a soluble form of a fully human tumor necrosis factor (TNF) receptor. ENBREL was first approved in 1998 for adult moderate to severe rheumatoid arthritis and has more than 17 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 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 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 while on ENBREL.

Before starting ENBREL, tell your doctor if you:

-- 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.
-- 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 (anakinra)
-- Have or develop a serious nervous disorder, seizures, any numbness or tingling, or a disease that affects your nervous system such as multiple sclerosis
-- Are scheduled to have surgery
-- 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

After starting ENBREL, call your doctor right away if you have any sign of infection, including a fever, cough, flu-like symptoms, or have any open sores on your body. ENBREL can make you more likely to get infections or make any infection you have worse.

Possible side effects of ENBREL

Serious side effects include: serious infections including TB; nervous system problems, such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes; rare reports of serious blood problems (some fatal); heart failure, including new heart failure or worsening of heart failure you already have; allergic reactions; immune reactions, including a lupus-like syndrome and lymphoma (a type of cancer). People with rheumatoid arthritis and psoriasis may have a higher chance for getting lymphoma.

Common side effects include: Injection site reaction, upper respiratory infections (including sinus infection), and headaches.

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 see 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.

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 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.

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 Aug. 4, 2009, 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 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.

Wyeth Forward-Looking Statement

The statements in this press release that are not historical facts are forward-looking statements based on current expectations of future events and 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 the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialization of our products, including with respect to our 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; data generated on our 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." 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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