FDA Approves ENBREL to Treat Psoriasis; New Convenient Treatment Provides Rapid and Significant Relief of Symptoms

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THOUSAND OAKS, Calif. & COLLEGEVILLE, Pa., Apr 30, 2004 -- Amgen Inc. (Nasdaq:AMGN) and Wyeth Pharmaceuticals, a division of Wyeth (NYSE:WYE), today announced that ENBREL(R) (etanercept) has been approved by the U.S. Food and Drug Administration (FDA) 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. The psoriasis indication marks the fifth disease for which ENBREL has received an FDA approval in just over five years.

Psoriasis is a chronic immune disorder in which certain immune cells become overactive and release proteins called cytokines. Tumor necrosis factor (TNF) is one of those cytokines that helps regulate the body's immune response to infection and inflammation. In patients with psoriasis, TNF causes inflammation, which can lead to the formation of painful, often disfiguring psoriasis plaques. As an anti-TNF therapy, ENBREL binds to the over-produced TNF and renders it biologically inactive, which can result in a significant reduction in inflammation.

"Both physicians and patients have expressed a desire for new options to treat psoriasis. ENBREL rapidly cleared psoriasis in many patients and was generally well-tolerated in two large clinical trials," said Laura Hamill, vice president and general manager of Amgen's Inflammation Business Unit. "This approval in psoriasis, coupled with our previous indication in psoriatic arthritis, reinforces our commitment to dermatology and our core aspiration of providing treatments that can dramatically improve people's lives."

The approval was based on data from two Phase 3 studies totaling more than 1,200 adults with plaque psoriasis who were treated with ENBREL for up to 12 months. ENBREL was approved with a step-down dosing regimen of 50 mg administered twice-weekly for three months, followed by a maintenance dose of 50 mg weekly thereafter. ENBREL demonstrated rapid and significant clearing in many patients at this recommended dosing regimen. Patients who are treated with ENBREL require no routine laboratory monitoring specific to ENBREL therapy other than standard medical oversight.

"Dermatologists are already familiar with ENBREL because it is the only approved treatment for psoriatic arthritis. The product is now poised to emerge as a real-world treatment option for psoriasis that can help satisfy the needs of community dermatologists and their patients," explained Gary L. Stiles, M.D., executive vice president and chief medical officer of Wyeth Pharmaceuticals. "Dermatologists have prescribed ENBREL because of its extensive clinical experience and its established safety profile -- ENBREL has 12 years of collective clinical experience in a variety of indications and has been used in more than 234,000 patients worldwide across indications."

"My psoriasis was devastating -- I suffered with the disease for many years. I was in so much pain that I stopped being physically active and gained over 100 pounds," said ENBREL patient, Matt J. "Some of the traditional treatments I'd tried in the past were time consuming, inconvenient and almost worse than the disease itself. Taking ENBREL has been very easy and my skin has cleared and has stayed clear. As a result, I'm not worried about the pain that I once felt from my psoriasis and I'm more outgoing and physically active."

Study Results

In a Phase 3 study, nearly half (46 percent) of patients receiving 50 mg twice-weekly of ENBREL achieved the primary endpoint of a 75 percent or greater improvement in the Psoriasis Area Severity Index (also known as PASI 75) at three months. These patients were "stepped down" to half the dose and then continued treatment for an additional three months. At six months, the percentage of patients achieving a PASI 75 response was maintained following dose reduction.

"Psoriasis can be a chronic, disabling disease requiring continuous treatment. ENBREL was shown to provide rapid and significant relief of psoriasis in many patients," said Alice Gottlieb, M.D., Ph.D., director of the Clinical Research Center at the University of Medicine and Dentistry of the New Jersey-Robert Wood Johnson Medical School. "Additionally, in one clinical trial, patients who stopped treatment did so without experiencing disease flare or rebound. The trial also demonstrated, that upon retreatment with ENBREL the overall response rates were similar to those seen after initial treatment."

ENBREL was generally well-tolerated in both Phase 3 studies. Adverse events were similar to those reported in previous clinical trials in other indications. The most common adverse events in the ENBREL group when compared to placebo were injection site reactions.

ABOUT PSORIASIS

An estimated 4.5 million people in the United States suffer from psoriasis and 1.5 million have moderate to severe plaque psoriasis. The disease is characterized by chronic inflammation of the skin. This inflammation helps drive the formation of red, itchy skin plaques that are often painful and disfiguring. Tumor necrosis factor (TNF) is found at increased levels in psoriatic plaques and plays a critical role in their formation and continued existence.

ABOUT ENBREL

ENBREL is the only fully human TNF receptor approved to reduce signs and symptoms, improve physical function, and inhibit the progression of structural damage in patients with moderately to severely active rheumatoid arthritis (RA), and to reduce the signs and symptoms and inhibit the progression of structural damage of active arthritis in patients with psoriatic arthritis. ENBREL is the only biologic therapy approved for first-line treatment of RA patients, and can be used alone or in combination with methotrexate. It is approved to reduce the signs and symptoms of moderately to severely active polyarticular-course juvenile rheumatoid arthritis (JRA) in patients who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs). It is also the first biologic approved to treat the signs and symptoms in patients with active ankylosing spondylitis (AS). 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.

ENBREL has been used by more than 234,000 patients worldwide across indications.

ENBREL acts by binding TNF, one of the dominant inflammatory cytokines or regulatory proteins that play an important role in both normal immune function and the cascade of reactions that causes the inflammatory process of RA, JRA, psoriasis, psoriatic arthritis and AS. The binding of ENBREL to TNF renders the bound TNF biologically inactive, resulting in significant reduction in inflammatory activity.

Since the product was first introduced, the following have been reported in patients using ENBREL:

- Serious Infections
- Many occurred in people prone to infection, such as those with advanced or poorly controlled diabetes
- Some serious infections were fatal
- Rare cases of tuberculosis
- What to do/Not to do
- Do not start ENBREL if you have an infection or are allergic to ENBREL or its components.
- Tell your doctor if you are prone to infection.
- Stop ENBREL if a serious infection occurs.
- Contact your doctor if you have questions about ENBREL or develop an infection.
- Tell your doctor if you have ever been treated for heart failure.
- Serious nervous system disorders such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes
- Tell your doctor if you have ever had any of these disorders or if you develop them after starting ENBREL.
- Rare reports of serious blood disorders (some fatal)
- Contact your doctor immediately if you develop symptoms such as persistent fever, bruising, bleeding, or paleness.
- In medical studies of all TNF-inhibitors, a higher rate of lymphoma (a type of cancer) was seen compared to the general population, however, the risk of lymphoma may be up to several fold higher in RA and psoriasis patients. The role of TNF-inhibitors in the development of lymphoma is unknown.
- The incidence of other cancers has not increased with extended exposure to ENBREL and is similar to the expected rate.
- ENBREL can also cause injection site reactions.
- In a medical study of patients with JRA, infections, headaches, 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 rarely, including serious infections (2 percent) and depression/personality disorder (1 percent).

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. Additional information about ENBREL, including full Prescribing Information, can be found on the Web site sponsored by the companies at www.enbrel.com or by calling toll free 888-4ENBREL (888-436-2735).

Amgen is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology.

Wyeth Pharmaceuticals, a division of Wyeth, has leading products in the areas of women's health care, cardiovascular disease, central nervous system, inflammation, hemophilia, oncology and vaccines. 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.

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in Amgen's Form 10-K for the year ended December 31, 2003, and in Amgen's periodic reports on Form 10-Q and Form 8-K. Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Amgen's results may be affected by its ability to successfully market both new and existing products domestically and internationally, sales growth of recently launched products, difficulties or delays in manufacturing its products, and regulatory developments (domestic or foreign) involving current and future products and manufacturing facilities.

In addition, sales of Amgen's products are affected by reimbursement policies imposed by third party payors, including governments, private insurance plans and managed care providers, and may be affected by domestic and international trends toward managed care and healthcare cost containment as well as possible U.S. legislation affecting pharmaceutical pricing and reimbursement. Government regulations and reimbursement policies may affect the development, usage and pricing of Amgen's products. Furthermore, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen or others could identify side effects or manufacturing problems with its products after they are on the market.

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. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product.

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. Further, some raw materials, medical devices and component parts for Amgen's products are supplied by sole third party suppliers.

The statements in this press release that are not historical facts are forward-looking statements based on current expectations of future events that involve risks and uncertainties including, without limitation, risks associated with the inherent uncertainty of pharmaceutical research, product development, manufacturing, and commercialization, and economic conditions, including interest and currency exchange rate fluctuations, the impact of competitive or generic products, product liability and other types of lawsuits, the impact of legislative and regulatory compliance and obtaining approvals, and patents, and other risks and uncertainties, including those detailed from time to time in Wyeth's periodic reports, including quarterly reports on Form 10-Q and the Annual Report on Form 10-K, filed with the Securities and Exchange Commission.

Actual results may vary materially from the forward-looking statements. Wyeth assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

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