Enbrel is First Biologic Recommended by FDA Panel for Approval to Treat Ankylosing Spondylitis

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THOUSAND OAKS, Calif., and COLLEGEVILLE, Pa., June 24, 2003 - Amgen (NASDAQ: AMGN) and Wyeth Pharmaceuticals, a division of Wyeth (NYSE: WYE), today announced that ENBRELÆÊ (etanercept) is the first biologic recommended for approval by the Arthritis Advisory Committee of the U.S. Food and Drug Administration (FDA) for the treatment of ankylosing spondylitis (AS).

"We are pleased with the committee's unanimous positive vote and will work closely with the FDA to bring ENBREL to ankylosing spondylitis patients, who until now, have had limited options in the treatment of the disease," said Dr. Beth Seidenberg, Amgen's senior vice president of development. "ENBREL has shown significant reduction in pain, as well as improvement in spinal mobility and physical function."

Currently there are few FDA-approved treatments other than non-steroidal anti-inflammatory agents and steroids to treat AS. Ankylosing spondylitis, which affects about 350,000 people in the United States, belongs to a family of spine-related inflammatory diseases (spondyloarthropathies).

"The panel's recommendation brings physicians and patients closer to a new option in the treatment of AS," said Dr. Victoria Kusiak, vice president of global medical affairs and North American medical director of Wyeth Pharmaceuticals. "We look forward to the opportunity to extend the benefits and impact of ENBREL, beyond rheumatoid arthritis, juvenile rheumatoid arthritis, and psoriatic arthritis patients, to patients who have gone for so long with few aggressive options to significantly reduce the painful symptoms of their disease."

In pivotal Phase 3 studies, patients treated with ENBREL experienced significant and rapid reduction in pain and morning stiffness, and improvement in spinal mobility and physical function.

"The results of these pivotal studies with ENBREL were very encouraging, with some patients responding after as early as two weeks of treatment and reaching maximum relief within the first two months," said primary investigator Dr. John Davis, assistant professor of medicine at the University of California-San Francisco and associate director of the Department of Medicine Clinical Trials Center.

"The committee's recommendation for approval of ENBREL underscores the importance of identifying new treatments to help those with ankylosing spondylitis," said Jane Bruckel, RN, executive director of the Spondylitis Association of America. "We support efforts to develop treatments for this disease, since spondylitis can dramatically affect people's lives."

A supplemental biologics license application (sBLA) is under review by the FDA for the use of ENBREL in treating AS. If approved for use in AS, ENBREL will be the first TNF receptor therapy available to treat the disease.

ABOUT ANKYLOSING SPONDYLITIS

Ankylosing spondylitis is a painful, chronic and progressive inflammatory disease affecting the spine and the joints and ligaments that normally allow a person's back to move and flex. Over time, new bone can develop and replace the elastic tissue of ligaments or tendons. Eventually, a patient's vertebrae can fuse together, causing complete loss of motion and a stooped-over posture.

The disease frequently begins in the lower back or pelvis and, with time, may progress into the upper spine, chest and neck. Ankylosing spondylitis may also involve other joints, such as the hips, shoulders, knees, and ankles.

ABOUT ENBREL

ENBREL is the only fully human anti-TNF receptor approved for use to reduce the signs and symptoms and inhibit the progression of structural damage in patients with moderately to severely active RA, and to reduce the signs and symptoms of active arthritis in patients with psoriatic arthritis. ENBREL is the only biologic therapy approved to treat newly diagnosed RA patients, and can be used alone. It is also 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 disease-modifying medicines.

Physicians have become familiar with the benefits and proven long-term tolerability profile of ENBREL. It has been used to treat over 180,000 patients worldwide across all indications since becoming commercially available five years ago.

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 psoriatic arthritis and RA. The binding of ENBREL to TNF renders the bound TNF biologically inactive, resulting in significant reduction in inflammatory activity.

Individual results may vary. In medical studies, ENBREL worked for about two out of three adults with RA, three of four children with JRA, and about 50 percent of patients with psoriatic arthritis.

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 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**

• 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**

• The incidence of cancer 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%) and depression/personality disorder (1%)

Amgen and Wyeth Pharmaceuticals, a division of Wyeth, market ENBREL in North America. Other Wyeth affiliates market 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 (NASDAQ: AMGN) 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 (NYSE: WYE) 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 nonprescription 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.

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