



Amgen Submits Data To FDA Supporting Once-Weekly Dosing Of Enbrel

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FOR IMMEDIATE RELEASE

THOUSAND OAKS, Calif., Dec. 23, 2002 – Amgen (NASDAQ: AMGN)

today announced that it has submitted a supplemental Biologics License Application (sBLA) with the U.S. Food and Drug Administration (FDA) supporting once-weekly dosing of ENBREL® (etanercept).

“This is another important milestone in the development of ENBREL,” said Dr. Beth Seidenberg, Amgen's senior vice president of development. “Not only does ENBREL have the broadest range of indications to treat rheumatic diseases, but this latest application may offer patients dosing flexibility.”

The filing is based on results from a Phase 3 study demonstrating that patients treated with 50 mg of ENBREL once weekly achieved similar efficacy, tolerability and pharmacokinetics when compared to patients receiving 25 mg of ENBREL twice weekly.

ABOUT ENBREL

ENBREL is the only fully human anti-TNF receptor approved for use to reduce the signs and symptoms of active arthritis in patients with psoriatic arthritis, and to reduce the signs and symptoms and inhibit the structural damage in patients with moderately to severely active rheumatoid arthritis (RA). 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 129,000 patients since became commercially available four years ago, making it one of the fastest-growing prescription products ever launched.

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.

Important Treatment Considerations

SINCE THE PRODUCT WAS FIRST INTRODUCED, SERIOUS INFECTIONS, SOME INVOLVING DEATH, HAVE BEEN REPORTED IN PATIENTS USING ENBREL. MANY OF THESE INFECTIONS OCCURRED IN PATIENTS WHO WERE PRONE TO INFECTIONS, SUCH AS THOSE WITH ADVANCED OR POORLY CONTROLLED DIABETES. RARE CASES OF TUBERCULOSIS HAVE ALSO BEEN REPORTED. ENBREL SHOULD BE DISCONTINUED IN PATIENTS WITH SERIOUS INFECTIONS. DO NOT START ENBREL IF YOU HAVE AN INFECTION OF ANY TYPE OR IF YOU HAVE AN ALLERGY TO ENBREL OR ITS COMPONENTS. ENBREL SHOULD BE USED WITH CAUTION IN PATIENTS PRONE TO INFECTION. CONTACT YOUR PHYSICIAN IF YOU HAVE ANY QUESTIONS ABOUT ENBREL OR INFECTIONS.

There have been reports of 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.

There have also been rare reports of serious blood disorders, some involving death.

Contact your doctor immediately if you develop symptoms such as persistent fever, bruising, bleeding, or paleness. It is unclear if ENBREL has caused these nervous system or blood disorders. If your doctor confirms serious blood problems, you may need to stop using ENBREL.

The most frequent adverse events in placebo-controlled RA clinical trials involving 349 adults were injection site reactions (ISR) (37%), infections (35%), and headache (17%).

Only the rate of ISR was higher than that of placebo. The most frequent adverse events in a methotrexate-controlled clinical trial of 415 adults with early-stage RA were infections (64%), ISR (34%), and headache (24%). Of these, only the rate of ISR was higher than that of methotrexate. Patients have been observed in clinical trials for over 3 years. The incidence of malignancies has not increased with extended exposure to ENBREL and is similar to the projected background rate.

Adverse events in the psoriatic arthritis trial were similar to those reported in RA clinical trials. In a study of 69 patients with JRA, infections (62%), headache (19%), abdominal pain (19%), vomiting (13%), and nausea (9%) occurred more frequently than in adults. The types of infections reported in JRA patients were generally mild and consistent with those commonly seen in children. Serious adverse reactions reported rarely were chicken pox (3%), gastroenteritis (3%), serious infection (2%), depression/personality disorder (1%), skin ulcer (1%), inflammation in parts of the upper digestive tract (1%), and diabetes (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 is a global biotechnology company that discovers, develops, manufactures and markets important human therapeutics based on advances in cellular and molecular biology.

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CONTACT: Amgen

Rebecca Hamm (media)
805/447-3872
Cary Rosansky (investors)
805/447-4634

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