



## **REMICADE® (Infliximab) Granted Priority Review by FDA for Use in Maintaining Fistula Closure in Patients With Fistulizing Crohn's Disease**

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MALVERN, Pa., Jan 7, 2003 /PRNewswire via COMTEX/ -- Centocor, Inc. today announced that REMICADE® (infliximab) has been designated for priority review by the U.S. Food and Drug Administration for use in maintaining fistula closure in patients with fistulizing Crohn's disease (CD). Up to 30 percent of the estimated half-million Americans with CD suffer from fistulas -- openings that burrow through the bowel wall into nearby organs or through the surface of the skin.

The FDA grants priority review status to products that are considered to be a potential significant therapeutic advance over existing therapies. Centocor submitted a supplemental biologics application (sBLA) to the FDA based on 54-week data from the ACCENT II trial.

ACCENT II involved 306 patients with fistulizing CD at 45 sites in North America, Europe and Israel. The objective of the study was to determine the safety and efficacy of REMICADE in maintaining fistula closure when administered every eight weeks.

REMICADE is the first and only biologic approved to reduce signs and symptoms and induce and maintain clinical remission in patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. It is also indicated as a short-term treatment for reducing the number of draining enterocutaneous fistulas in patients with fistulizing Crohn's disease.

"We are extremely pleased that the FDA has designated REMICADE for priority review," said Jerome A. Boscia, M.D., Vice President, Clinical Research & Development. "This designation recognizes the significant unmet medical need facing thousands of Americans currently living with Crohn's disease."

CD is a chronic inflammatory bowel disorder that commonly affects the lower part of the small intestine and the large intestine and typically begins in late childhood or early adulthood. The disease causes inflammation of the gastrointestinal tract, typically resulting in symptoms such as diarrhea, fever, abdominal pain and weight loss.

REMICADE is a monoclonal antibody that specifically targets and irreversibly binds to tumor necrosis factor alpha (TNF-alpha) on the cell membrane and in the blood. Overproduction of TNF-alpha is believed to play a role in CD and rheumatoid arthritis (RA) in addition to a wide range of Immune-Mediated Inflammatory Disorders (I.M.I.D.) in which REMICADE is currently being studied.

#### About REMICADE

REMICADE, in combination with methotrexate, is indicated to reduce signs and symptoms, inhibit progression of joint damage, and improve physical function in patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to methotrexate alone.

REMICADE is also approved to reduce signs and symptoms and induce and maintain clinical remission in patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. It is also approved for use as a short-term treatment for reducing the number of draining enterocutaneous fistulas in patients with fistulizing Crohn's disease.

#### Important Information

Many people with heart failure should not take REMICADE; so, prior to treatment, patients should discuss any heart condition with their doctor. Patients should tell their doctor right away if they develop new or worsening symptoms of heart failure (such as shortness of breath or swelling of their feet).

There are reports of serious infections, including tuberculosis (TB) and sepsis. Some of these infections have been fatal. Patients should tell their doctor if they have had recent or past exposure to people with TB. Their doctor will evaluate them for TB and perform a skin test. If a patient has latent (inactive) TB, his or her doctor should begin TB treatment before starting REMICADE. If a patient is prone to or has a history of infections, currently has one, or develops one while taking REMICADE,

he or she should tell his or her doctor right away. Patients should also tell their doctor if they have lived in a region where histoplasmosis is common, or if they have or have had a disease that affects the nervous system, or if they experience any numbness, tingling, or visual disturbances.

There are also reports of serious infusion reactions with hives, difficulty breathing, and low blood pressure. In clinical studies, some people experienced the following common side effects: upper respiratory infections, headache, nausea, cough, sinusitis or mild reactions to the infusion such as rash or itchy skin. Please read important information about REMICADE, including full prescribing information, at <http://www.remicade.com>.

#### About Centocor

Centocor is a leading biopharmaceutical company that creates, acquires and markets cost-effective therapies that yield long-term benefits for patients and the healthcare community. The company is dedicated to the research and development of treatments for a wide range of Immune-Mediated Inflammatory Disorders (I.M.I.D.), such as arthritis, inflammatory skin diseases and cancer. Centocor's products, developed primarily through monoclonal antibody technology, help physicians deliver innovative treatments to improve human health and restore patients' quality of life. Centocor is a wholly owned subsidiary of Johnson & Johnson, the worldwide manufacturer of healthcare products.

Centocor has exclusive marketing rights to REMICADE in the United States. Schering-Plough Corporation (NYSE: SGP) has rights to market REMICADE in all other countries throughout the world, except in Japan and parts of the Far East where Tanabe Seiyaku, Ltd. will market the product.

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