

FOR IMMEDIATE RELEASE**CONTACT:**

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**FDA APPROVES REMICADE FOR PATIENTS WITH ANKYLOSING SPONDYLITIS, A
DEBILITATING INFLAMMATORY CONDITION OF THE SPINE**

Label Also Updated to Include Important Safety Information

MALVERN, PA, December 20, 2004 – Centocor, Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved REMICADE[®] (infliximab) for the treatment of ankylosing spondylitis (AS). REMICADE is now indicated for reducing signs and symptoms in active AS, a painful, progressive inflammatory condition of the spine that can result in fusion of the spinal vertebrae and structural damage to hips and other joints, which can lead to limited function and disability. This approval is the second for REMICADE in the U.S. in the past three months. REMICADE, in combination with methotrexate, was recently approved for use as first-line therapy for patients with moderately to severely active rheumatoid arthritis. These approvals continue to demonstrate the clinical benefit of REMICADE across rheumatic diseases.

“The approval of REMICADE is a significant treatment development for patients suffering with AS,” said Jerome A. Boscia, M.D., Senior Vice President, Clinical Research and Development, Centocor, Inc. “Not only did patients in the trial experience rapid and sustained improvement in symptoms, including pain, stiffness and fatigue, they also experienced improvement in function and spinal mobility.”

REMICADE was first approved for the treatment of AS in the European Union (EU), making it the first biologic to receive approval from a major regulatory authority for this use. REMICADE is currently approved for the treatment of AS in 58 countries, including the U.S.

Centocor also announced today that the existing Warning on Risk of Infections was updated to describe pneumonia and a Warning on Hepatotoxicity was added to the label for REMICADE. This update describes rare post-marketing reports of severe hepatic reactions, including acute liver failure, jaundice, hepatitis and cholestasis and provides recommendations for physician evaluation and treatment discontinuation, where appropriate, as well as information for patients (see prescribing information at www.remicade.com and Important Information below). These labeling changes are effective immediately and in agreement with the FDA, will be communicated to the medical community via a Dear Health Care Professional Letter this week.

Since August 24, 1998, when REMICADE was approved in the U.S., approximately 576,000 patients have been treated with REMICADE worldwide. Approximately three patients in controlled clinical trials and 35 patients in the voluntary post-marketing surveillance reported events considered to be severe hepatic reactions. A causal relationship between REMICADE and these events has not been established.

“Centocor firmly believes that a cautious and conservative approach should always be employed as it relates to issues regarding patient safety, said Thomas F. Schaible, Ph.D., Vice President, Medical

Affairs, "Centocor continues to actively support a number of post-marketing patient registries evaluating the long-term safety of Remicade and work closely with the FDA to ensure patients and physicians have the most up-to-date safety information possible."

About ASSERT

ASSERT was a randomized Phase III placebo-controlled, double blind, 33-center trial conducted in North America and Europe. The trial included 279 patients; 201 patients were treated with REMICADE, and 78 patients were given placebo infusions. Patients were given REMICADE monotherapy 5 mg/kg infusions at weeks 0, 2 and 6, followed by infusions every six weeks. Patients were followed through 102 weeks, and further analyses will evaluate structural damage. The primary endpoint of the ASSERT trial was the proportion of patients demonstrating a 20 percent or greater improvement in signs and symptoms at 24 weeks as measured by Assessment in Ankylosing Spondylitis Response Criteria (ASAS 20). Patients were assessed at baseline and at 24 weeks by standard AS performance scores.

The approval for AS in the U.S. is based primarily on the 24-week results of the ASSERT (Ankylosing Spondylitis Study for the Evaluation of Recombinant Infliximab Therapy) trial, which demonstrated that AS patients treated with REMICADE achieved significant improvement in signs and symptoms associated with their disease, including reduced spinal pain and increased physical function. In the REMICADE group, 60 percent of patients achieved ASAS 20 (Assessment in Ankylosing Spondylitis Response Criteria, a composite score that includes spinal pain, inflammation and functionality) compared with 18 percent of patients in the placebo group ($p < 0.001$). Clinical benefit was observed in patients receiving REMICADE as early as week 2 and was maintained over the 24-week study period. In the REMICADE group, minimal disease activity (defined as a value of < 20 on a scale of 0-100mm in each of the four ASAS response parameters) was achieved in 22 percent of patients compared with 1 percent in the placebo group ($p < 0.001$). Patients receiving REMICADE also showed significant improvements in individual measurements of disease activity, function and mobility, as well as improvements in chest expansion, and patient global assessment.

The most commonly reported adverse events were upper respiratory tract infections, which occurred at a rate of 15 percent in the placebo group, compared with 14 percent in the infliximab group. Serious adverse events were reported in 4 percent of REMICADE-treated patients compared with 3 percent of patients receiving placebo. ALT elevations > 3 times the upper limit of normal were also observed in 12 (6 percent) REMICADE-treated patients compared with none in placebo-treated patients. Please read the important information below.

About Ankylosing Spondylitis

AS is a painful and progressive form of spinal arthritis that usually affects people under the age of 35 years. It typically begins in the late teens and early twenties and in severe cases can result in fusing of the spinal vertebrae and cause structural damage to hips and other joints. Often misdiagnosed as "just back pain" or undifferentiated arthritis, AS is a systemic inflammatory disease that in addition to its effect on the spine, can affect internal organs, peripheral joints and vision. The Spondylitis Association of America estimates that between 350,000 and one million people in the U.S. suffer from AS.

About REMICADE

REMICADE is the global market leader among anti-tumor necrosis factor alpha (TNF- α) therapies and the only agent approved for the treatment of both RA and Crohn's disease in North America, the EU and Japan. In the EU, REMICADE is indicated for the treatment of ankylosing spondylitis in patients who have severe axial symptoms, elevated serological markers of inflammatory activity and who have responded inadequately to conventional therapy.

In September, the European Commission gave approval for expanded labeling for REMICADE (infliximab), in combination with methotrexate, for the treatment of active and progressive psoriatic arthritis (PsA) in patients who have responded inadequately to disease modifying anti-rheumatic drugs.

In the U.S., REMICADE, in combination with methotrexate, is indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). REMICADE is the only biologic indicated for the treatment of patients with moderately-to-severely active Crohn's disease (CD) who have had an inadequate response to conventional therapy. REMICADE is also indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in patients with fistulizing CD.

REMICADE is unique among available anti-TNF biologic therapies. Unlike self-administered therapies that require patients to inject themselves frequently, REMICADE is the only anti-TNF biologic administered directly by caregivers in the clinic or office setting. In RA and CD, REMICADE is a two-hour infusion administered every eight weeks, following a standard induction regimen that requires treatment at weeks 0, 2 and 6. As a result, REMICADE patients may require as few as six treatments each year. In AS, REMICADE is a two-hour infusion (5 mg/kg) administered every 6 weeks, following a standard induction regimen that requires treatment at weeks 0, 2, and 6. The safety and efficacy of REMICADE have been well established in clinical trials over the past 12 years and through commercial experience with over a half a million patients treated worldwide.

Important Information

Many people with heart failure should not take REMICADE; so prior to treatment you should discuss any heart condition with your doctor. Tell your doctor right away if you develop new or worsening symptoms of heart failure (such as shortness of breath or swelling of your ankles or feet).

There are reports of serious infections, including tuberculosis (TB), sepsis and pneumonia. Some of these infections have been fatal. Tell your doctor if you have had recent or past exposure to people with TB. Your doctor will evaluate you for TB and perform a skin test. If you have latent (inactive) TB, your doctor should begin TB treatment before you start REMICADE. REMICADE can lower your ability to fight infections, so if you are prone to or have a history of infections, or develop any signs of an infection such as fever, fatigue, cough, or the flu while taking REMICADE, tell your doctor right away. Also tell your doctor if you have lived in a region where histoplasmosis or coccidioidomycosis is common.

There have been rare cases where people taking REMICADE have developed severe liver problems. Signs that you could be having a problem include: jaundice (skin and eyes turning yellow), dark brown-colored urine, right-sided abdominal pain, fever, and severe fatigue (tiredness). You should contact your doctor immediately if you develop any of these symptoms. Blood disorders have been reported, some fatal. Tell your doctor if you develop possible signs of blood disorders such as persistent fever, bruising, bleeding, or paleness while taking REMICADE. Nervous system disorders have also been reported. Tell your doctor if you have or have had a disease that affects the nervous system, or if you experience any numbness, weakness, tingling, or visual disturbances while taking REMICADE.

Reports of lymphoma (a type of cancer) in patients on REMICADE and other TNF blockers are rare but occur more often than in the general population. Tell your doctor if you have or have had cancer. Serious infusion reactions have been reported with REMICADE, including hives, difficulty breathing, and low blood pressure. Reactions have occurred during or after infusions. In clinical studies, some people experienced the following common side effects: respiratory infections (that may include sinus infections and sore throat), coughing, and stomach pain or mild reactions to infusion such as rash or

itchy skin. Please read important information about REMICADE, including full prescribing information, at 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 diseases including cancer, infectious diseases, cardiovascular and metabolic diseases and Immune-Mediated Inflammatory Disorders (I.M.I.D.), such as arthritis and inflammatory skin diseases. 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 discovered REMICADE and has exclusive marketing rights to the product in the United States. Schering-Plough Corporation has rights to market REMICADE in all countries outside of the United States, except in Japan and parts of the Far East where Tanabe Seiyaku, Ltd. markets the product.

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