

**JANSSEN BIOTECH ISSUES STATEMENT ON NOR-SWITCH STUDY RESULTS
PRESENTED AT UNITED EUROPEAN GASTROENTEROLOGY WEEK (UEGW) MEETING**

“The NOR-SWITCH study results highlight the need for additional clinical research on biosimilars. These findings are consistent with Janssen’s concern about switching patients who are stable on therapy,” said Andrew Greenspan, MD, vice president of medical affairs at Janssen Biotech, Inc. “The study pooled the results in patients with inflammatory arthritis, psoriasis, and inflammatory bowel disease—which are very different diseases. In patients with Crohn’s disease, the largest sub-group in the study, there was a higher rate of disease worsening in patients who switched from REMICADE® to the biosimilar: 36.5% had disease worsening versus 21.2% who continued on REMICADE.”

Despite the findings in the subgroups favoring either REMICADE or the biosimilar, overall study results showed patients who switched from REMICADE to the infliximab biosimilar didn’t do any worse than those who continued on REMICADE.

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About REMICADE®

REMICADE® was the first anti-TNF-alpha treatment approved in the United States in August 1998 and the first TNF inhibitor to be approved in three different therapeutic areas: gastroenterology, rheumatology and dermatology. REMICADE® has demonstrated broad clinical utility with indications in Crohn's disease, rheumatoid arthritis (RA), ankylosing spondylitis, psoriatic arthritis, ulcerative colitis (UC), pediatric Crohn's disease, psoriasis, and pediatric UC. The safety and efficacy of REMICADE® have been well established in clinical trials over the past 22 years and through commercial experience with more than 2.4 million patients treated worldwide.

In the U.S., REMICADE® is approved for the following indications:

- Reducing signs and symptoms, inhibiting the progression of structural damage and improving physical function in patients with moderately to severely active RA, when administered in combination with methotrexate.
- Reducing signs and symptoms in patients with active ankylosing spondylitis.

- Reducing signs and symptoms and inducing and maintaining clinical remission in adult and pediatric patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.
- Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.
- Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in patients with moderately to severely active UC who have had an inadequate response to conventional therapy.
- Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage and improving physical function in patients with psoriatic arthritis.
- Treatment of adult patients with chronic severe plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

REMICADE® is unique among available anti-TNF-alpha biologic therapies. It is the only anti-TNF-alpha biologic administered directly by caregivers in the clinic or office setting.

REMICADE® is a two-hour infusion administered every 6 or 8 weeks (indication-dependent), 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 as maintenance therapy.

Janssen Biotech, Inc. discovered and developed REMICADE® and markets the product in the United States. The Janssen Pharmaceutical Companies market REMICADE® in Canada, Central and South America, the Middle East, Africa, and Asia Pacific.

In Japan, Indonesia, and Taiwan, Janssen Biotech, Inc. licenses distribution rights to REMICADE® to Mitsubishi Tanabe Pharma Corporation. In Europe, Russia and Turkey, Janssen Biotech, Inc. licenses distribution rights to REMICADE® to Schering-Plough (Ireland) Company, a subsidiary of Merck & Co, Inc.

Important Safety Information

Only a doctor can recommend a course of treatment after checking a patient's health condition. REMICADE® (infliximab) can cause serious side effects such as lowering your ability to fight infections. There are reports of serious infections caused by viruses, fungi or bacteria that have spread throughout the body, including tuberculosis (TB) and histoplasmosis. Some of these infections have been fatal. Your doctor should monitor you closely for signs and symptoms of TB during treatment with REMICADE®.

Unusual cancers have been reported in children and teenage patients taking TNF-blocker medicines. A rare form of fatal lymphoma has occurred mostly in teenage or young adult males with Crohn's disease or ulcerative colitis who were taking REMICADE® and azathioprine or 6-mercaptopurine. For children and adults taking TNF blockers, including REMICADE®, the chances of getting lymphoma or other cancers may increase.

Patients should discuss any concerns about their health and medical care with their doctor.

Patients should let their doctors know if they have or ever had any of the following:

- Tuberculosis (TB) or have been near someone who has TB. Your doctor will check you for TB with a skin test. If you have latent (inactive) TB, you will begin TB treatment before you start REMICADE®.
- Lived in a region where certain fungal infections like histoplasmosis or coccidioidomycosis are common.
- Infections that keep coming back, have diabetes or an immune system problem.
- Any type of cancer or a risk factor for developing cancer, for example, chronic obstructive pulmonary disease (COPD) or had phototherapy for psoriasis.
- Heart failure or any heart condition. Many people with heart failure should not take REMICADE®.
- Hepatitis B virus (HBV) infection or think you may be a carrier of HBV.
- Nervous system disorders (like multiple sclerosis or Guillain-Barre syndrome). Also tell your doctor about any medications you are taking, including vaccines or Kineret (anakinra), Orencia (abatacept) and Actemra (tocilizumab) and if you are pregnant, plan to become pregnant or are nursing. Adults and children should not receive a live vaccine while taking REMICADE®.

The following serious (sometimes fatal) side effects have been reported in people taking REMICADE®. Patients should tell their doctors right away if you have any of the signs listed below:

- Infections (like TB, blood infections, pneumonia) – fever, tiredness, cough, flu, or warm, red or painful skin or any open sores. REMICADE® can make you more likely to get an infection or make any infection that you have worse.
- Lymphoma, or any other cancers in adults and children.
- Heart failure – new or worsening symptoms, such as shortness of breath, swelling of your ankles or feet, or sudden weight gain.
- Reactivation of HBV – feeling unwell, poor appetite, tiredness, fever, skin rash and/or joint pain.
- Liver injury – jaundice (yellow skin and eyes), dark brown urine, right-sided abdominal pain, fever, or severe tiredness.
- Blood disorders – fever that doesn't go away, bruising, bleeding or severe paleness.
- Nervous system disorders – numbness, weakness, tingling, changes in your vision or seizures.
- Allergic reactions during or after the infusion – hives, difficulty breathing, chest pain, high or low blood pressure, swelling of face and hands, and fever or chills.
- Lupus-like syndrome – chest discomfort or pain that does not go away, shortness of breath, joint pain, rash on the cheeks or arms that gets worse in the sun. The more common side effects with REMICADE® are respiratory infections (that may include sinus infections and sore throat), headache, rash, coughing and stomach pain.
- Psoriasis – new or worsening psoriasis such as red scaly patches or raised bumps on the skin that are filled with pus.

Please read important information about REMICADE®, including full U.S. prescribing information and Medication Guide, at www.remicade.com.

About Janssen Biotech, Inc.

Janssen Biotech, Inc. redefines the standard of care in immunology, oncology, urology and nephrology. Built upon a rich **legacy of innovative firsts**, Janssen Biotech has delivered on the promise of new treatments and ways to improve the health of individuals with serious disease. Beyond its innovative medicines, Janssen Biotech is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates and health care professionals have access to the latest treatment information, support services and quality care. For more information on Janssen Biotech, Inc. or its products, visit www.janssen.com.

Janssen Biotech is one of the Janssen Pharmaceutical Companies which are dedicated to addressing and solving some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we work together to bring innovative ideas, products, services and solutions to people throughout the world. Follow us on **Twitter** at www.twitter.com/JanssenUS.

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