



## FDA Issues Complete Response Letter to Janssen Biotech, Inc. for SIMPONI® Supplemental Biologics License Application

HORSHAM, Pa., Sept. 9, 2011 /PRNewswire/ -- Janssen Biotech, Inc. announced today that the U.S. Food and Drug Administration (FDA) issued a Complete Response letter for the SIMPONI® (golimumab) supplemental Biologics License Application (sBLA) seeking an expanded label in the treatment of active psoriatic arthritis. The application, filed in November 2010, included data from a Phase 3 trial evaluating the effect of SIMPONI® in inhibiting the progression of structural damage and maintaining improvement in signs and symptoms and physical function in the treatment of patients with active psoriatic arthritis.

Janssen Biotech, Inc. intends to request an end-of-review meeting with the FDA to thoroughly understand the details of the Complete Response letter and discuss what future steps may be necessary to achieve the intended approval.

"We believe the data from the SIMPONI® Phase 3 study support the proposed label expansion in the treatment of active psoriatic arthritis," said Jerome A. Boscia, M.D., Vice President, Head of Immunology Development, Centocor Research & Development division of Johnson & Johnson Pharmaceutical Research & Development, L.L.C. "We look forward to meeting with the agency to identify a path forward."

In 2009, SIMPONI® received approvals in the United States, Europe and Canada for the treatment of moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate, active psoriatic arthritis, and active ankylosing spondylitis as a once-monthly subcutaneously administered anti-tumor necrosis factor (TNF)-alpha treatment.

In May 2011, the European Commission approved a new indication for SIMPONI® in the treatment of active and progressive psoriatic arthritis to reduce the rate of progression of peripheral joint damage as measured by X-ray in psoriatic arthritis patients with polyarticular symmetrical subtypes of the disease. This information was added to the existing therapeutic indication for the use of SIMPONI, alone or in combination with methotrexate, for the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate.

### About SIMPONI®

SIMPONI® is a human monoclonal antibody that targets and neutralizes excess TNF-alpha, a protein that when overproduced in the body due to chronic inflammatory diseases can cause inflammation and damage to bones, cartilage and tissue. SIMPONI® is available either through the SIMPONI® SmartJect® autoinjector or a prefilled syringe. For more information about SIMPONI®, visit [www.SIMPONI.com](http://www.SIMPONI.com).

Janssen Biotech, Inc. discovered and developed SIMPONI® and markets the product in the United States. Janssen pharmaceutical companies market SIMPONI® 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 SIMPONI® to Mitsubishi Tanabe Pharma Corporation and has retained co-marketing rights in those countries. In Europe, Russia and Turkey, Janssen Biotech, Inc. licenses distribution rights to SIMPONI® to Schering-Plough (Ireland) Company, a subsidiary of Merck & Co, Inc.

### Important Safety Information

**SIMPONI® (golimumab) is a prescription medicine. SIMPONI® can lower your ability to fight infections. There are reports of serious infections caused by bacteria, fungi, or viruses that have spread throughout the body, including tuberculosis (TB) and histoplasmosis. Some of these infections have been fatal. Your doctor will test you for TB before starting SIMPONI® and will monitor you for signs of TB during treatment. Tell your doctor if you have been in close contact with people with TB. Tell your doctor if you have been in a region (such as the Ohio and Mississippi River Valleys and the Southwest) where certain fungal infections like histoplasmosis or coccidioidomycosis are common.**

You should not start SIMPONI® if you have any kind of infection. Tell your doctor if you are prone to or have a history of infections or have diabetes, HIV or a weak immune system. You should also tell your doctor if you are currently being treated for an infection or if you have or develop any signs of an infection such as:

- fever, sweat, or chills

- muscle aches
- cough
- shortness of breath
- blood in phlegm
- weight loss
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- burning when you urinate or urinate more than normal
- feel very tired

**Unusual cancers have been reported in children and teenage patients taking TNF-blocker medicines.** For children and adults taking TNF blockers, including SIMPONI®, the chances for getting lymphoma or other cancers may increase. You should tell your doctor if you have had or develop lymphoma or other cancers.

Tell your doctor about all the medications you take including ORENCIA (abatacept), KINERET (anakinra), ACTEMRA (tocilizumab), RITUXAN (rituximab), or another TNF blocker, or if you are scheduled to or recently received a vaccine. People taking SIMPONI® should not receive live vaccines.

Reactivation of hepatitis B virus has been reported in patients who are carriers of this virus and are taking TNF-blocker medicines, such as SIMPONI®. Some of these cases have been fatal. Your doctor should do blood tests before and after you start treatment with SIMPONI®. Tell your doctor if you know or think you may be a carrier of hepatitis B virus or if you experience signs of hepatitis B infection, such as:

- feel very tired
- dark urine
- skin or eyes look yellow
- little or no appetite
- vomiting
- muscle aches
- clay-colored bowel movements
- fevers
- chills
- stomach discomfort
- skin rash

Heart failure can occur or get worse in people who use TNF blockers, including SIMPONI®. Your doctor will closely monitor you if you have heart failure. Tell your doctor right away if you get new or worsening symptoms of heart failure like shortness of breath or swelling of your lower legs or feet.

Rarely, people using TNF blockers, including SIMPONI®, can have nervous system problems such as multiple sclerosis or Guillain-Barre syndrome. Tell your doctor right away if you have symptoms like vision changes, weakness in your arms or legs, or numbness or tingling in any part of your body.

Serious liver problems can happen in people using TNF blockers, including SIMPONI®. Contact your doctor immediately if you develop symptoms such as feeling very tired, skin or eyes look yellow, poor appetite or vomiting, or pain on the right side of your stomach.

Low blood counts have been seen with people using TNF blockers, including SIMPONI®. If this occurs, your body may not make enough blood cells to help fight infections or help stop bleeding. Your doctor will check your blood counts before and during treatment. Tell your doctor if you have signs such as fever, bruising, bleeding easily, or paleness.

Rarely, people using TNF blockers have developed lupus-like symptoms. Tell your doctor if you have any symptoms such as a rash on your cheeks or other parts of the body, sensitivity to the sun, new joint or muscle pain, becoming very tired, chest pain or shortness of breath, swelling of the feet, ankles, and/or legs.

New or worse psoriasis symptoms may occur. Tell your doctor if you develop red scaly patches or raised bumps that are filled with pus.

Tell your doctor if you are pregnant, planning to become pregnant or are breastfeeding or have a baby and were using SIMPONI® during pregnancy. Tell your baby's doctor before your baby receives any vaccine because of an increased risk of infection for up to 6 months after birth.

Tell your doctor if you are allergic to rubber or latex. The needle cover contains dry natural rubber.

Tell your doctor if you have any symptoms of an allergic reaction while taking SIMPONI® such as hives, swollen face, breathing trouble, chest pain. Some reactions can be serious and life-threatening.

Common side effects of SIMPONI® include: upper respiratory tract infection, reaction at site of injection, and viral infections.

**Please read the Medication Guide for SIMPONI® and discuss any questions you have with your doctor.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

### **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.janssenbiotech.com](http://www.janssenbiotech.com).

Janssen Biotech is one of the Janssen Pharmaceutical Companies of Johnson & Johnson 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](https://www.twitter.com/JanssenUS).

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Biotech, Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; trends toward health care cost containment; and increased scrutiny of the healthcare industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 2, 2011. Copies of this Form 10-K, as well as subsequent filings, are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. Neither Janssen Biotech, Inc. nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)

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