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Janssen Submits Application To FDA Requesting Approval Of SIMPONI® Intravenous Formulation For Treatment Of Moderately To Severely Active Rheumatoid Arthritis

HORSHAM, Pa., Sept. 18, 2012 /PRNewswire/ -- Janssen Biotech, Inc. announced today the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) requesting approval of an investigational intravenous formulation of the anti-tumor necrosis factor (TNF)-alpha SIMPONI® (golimumab) for the treatment of adults with moderately to severely active rheumatoid arthritis (RA). An estimated 1.5 million Americans are living with RA,[1] a chronic autoimmune disease that causes pain, stiffness and inflammation in the joints, and may lead to irreversible joint damage.

"We are pleased to present the FDA with an application supporting the efficacy and safety of an intravenous formulation of SIMPONI seeking its approval for the treatment of moderately to severely active rheumatoid arthritis," said Jerome A. Boscia, M.D., Vice President, Head of Immunology Development, Janssen Research & Development, LLC. "Upon approval, an intravenous formulation of SIMPONI would offer rheumatologists and people affected by this chronic, immune-mediated inflammatory disease an important new treatment option, in addition to the currently available subcutaneous formulation of SIMPONI."

The BLA is supported by findings from the Phase 3 Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, an Anti-TNF-alpha Monoclonal Antibody, Administered Intravenously, in Subjects with Active Rheumatoid Arthritis Despite Methotrexate Therapy (GO-FURTHER) trial, which evaluated the safety and efficacy of intravenously administered SIMPONI, in combination with methotrexate, via a 30-minute infusion at weeks 0, 4 and then every eight weeks compared with placebo in 592 adults. Study participants had been diagnosed with active RA, defined as having at least six tender and six swollen joints, and had been receiving background methotrexate for at least three months. The primary endpoint of GO-FURTHER is the proportion of patients demonstrating 20 percent improvement in arthritis signs and symptoms (ACR 20) at week 14. Secondary endpoints include a 50 percent improvement in arthritis signs and symptoms (ACR50) at week 24, improvements in disease activity and physical function, as measured by the European League Against Rheumatism (EULAR)/Disease Activity Score (DAS) 28-C-reactive protein (CRP) and Health Assessment Questionnaire (HAQ), and inhibition of structural damage, as measured by X-ray.

Week 24 signs and symptoms, physical function and safety results from the Janssen R&D-sponsored study were [presented](#) at the 2012 EULAR Annual Congress and the study appeared in the June 2012 [Annals of the Rheumatic Diseases](#). Long-term data, including signs and symptoms, structural damage and safety analyses, will be submitted for presentation at a medical congress in the future.

An application requesting approval of an intravenous formulation of SIMPONI for the treatment of moderately to severely active RA is currently under review in the European Union (EU).

About Rheumatoid Arthritis

[Rheumatoid arthritis](#) is a chronic, systemic inflammatory condition that is often characterized by symptoms that include pain, stiffness and inflammation, and in some cases, joint destruction and disability. It is estimated that 1.5 million Americans[1] and more than 23.5 million people worldwide[2] are affected by the condition, for which there is no cure.

About SIMPONI Subcutaneous Formulation

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 approved in 57 countries for adult rheumatologic indications, including the United States where SIMPONI received FDA approval in April 2009 for the treatment of moderately to severely active rheumatoid arthritis (RA) with the medicine methotrexate, active psoriatic arthritis alone or with the medicine methotrexate and active ankylosing spondylitis. SIMPONI is available either through the SmartJect® autoinjector or a prefilled syringe as a subcutaneously administered injection. For more information about SIMPONI, visit www.SIMPONI.com.

Applications seeking approval for SIMPONI as a subcutaneously administered anti-TNF-alpha therapy have been [submitted](#) in the EU and U.S. seeking approval for the treatment of adult patients with moderately to severely active ulcerative colitis.

SIMPONI is also being investigated in Phase 3 studies as a subcutaneously administered treatment for active polyarticular

juvenile idiopathic arthritis (JIA).

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.

The U.S. full prescribing information for SIMPONI can be accessed at the following link:
<http://www.simoni.com/sites/default/files/pdf/prescribing-information.pdf>.

For further information about SIMPONI outside of the United States, please consult the relevant official product information applicable to that country location

Important Safety Information About SIMPONI Subcutaneous Formulation

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 <http://www.fda.gov/Safety/MedWatch>, or call 1-800-FDA-1088.

The U.S. full prescribing information for SIMPONI[®] can be accessed at the following link: <http://www.simponi.com/sites/default/files/pdf/prescribing-information.pdf>.

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.

Janssen Biotech is one of the Janssen Pharmaceutical Companies of Johnson & Johnson 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.

About Janssen Research & Development, LLC

At Janssen Research & Development, LLC, we are united and energized by one mission—to discover and develop innovative medicines that ease patients' suffering, and solve the most important unmet medical needs of our time. As one of the Janssen Pharmaceutical Companies of Johnson & Johnson, our strategy is to identify the biggest unmet medical needs and match them with the best science, internal or external, to find solutions for patients worldwide. We leverage our world-class discovery and development expertise, and operational excellence, to bring innovative, effective treatments in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. For more information on Janssen R&D, visit <http://www.janssenrmd.com>.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. The reader is cautioned not to rely on these forward-looking statements. 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., Janssen Research & Development, LLC 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, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the health care 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 1, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Janssen Biotech, Inc., Janssen Research & Development, LLC and Johnson & Johnson do not undertake to update any forward-looking statements as a result of new information or future events or developments.)

References:

[1] Centers for Disease Control and Prevention. Arthritis-Related Statistics.

http://www.cdc.gov/arthritis/data_statistics/arthritis_related_stats.htm. Accessed September 17, 2012.

[2] World Health Organization. The global burden of disease: 2004 update. Geneva: WHO Press, 2008.

http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf. Accessed September 17, 2012.

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