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SIMPONI® ARIA™ (golimumab) For Infusion Receives FDA Approval For Treatment Of Moderately To Severely Active Rheumatoid Arthritis

First Anti-TNF Infusion Therapy Approved in More Than a Decade for Patients Living with Moderately to Severely Active Rheumatoid Arthritis

Horsham, PA, July 18, 2013 - Janssen Biotech, Inc. announced today the U.S. Food and Drug Administration (FDA) approval of SIMPONI® ARIA™ (golimumab) for infusion for the treatment of adults with moderately to severely active rheumatoid arthriti (RA) in combination with methotrexate. SIMPONI ARIA, the only fully-human anti-tumor necrosis factor (TNF)-alpha infusible therapy, has been shown to significantly improve signs and symptoms and physical function, and inhibit the progression of structural damage. The SIMPONI ARIA dose regimen is 2 mg/kg given as an intravenous infusion at weeks 0 and 4, then every 8 weeks thereafter. The infusion is given over a 30-minute period, providing a short infusion time for patients. Approximately 1.3 million people in the United States are living with RA,[i] 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.[ii]

"Phase 3 data showed treatment with SIMPONI ARIA plus methotrexate significantly improved signs and symptoms and physical function at week 24, and inhibited the progression of structural damage in patients with moderate to severe RA at week 24 and 52," said Sergio Schwartzman*, MD, Director, Inflammatory Arthritis Center, Hospital for Special Surgery, Associate Professor, Weill Cornell Medical College, and advisory board member. "The approval of SIMPONI ARIA offers rheumatologists a new anti-TNF infusible treatment for patients who demonstrate an inadequate response to methotrexate; having treatment options remains critical for us to continue to meet the needs of our patients."

The approval is supported by findings from the Phase 3 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 592 patients diagnosed with moderately to severely active RA who had at least six tender and six swollen joints at screening and baseline, had elevated C-reactive protein (CRP) levels at screening and who had been receiving background methotrexate for at least three months. Results from the trial revealed 59 percent (n = 231/395) of patients receiving treatment with SIMPONI ARIA plus methotrexate versus 25 percent of patients receiving placebo plus methotrexate (n = 49/197) (a difference with 95 percent CI 25.9, 41.4) experienced significant improvements in signs and symptoms at week 14, as demonstrated by at least 20 percent improvement in American College of Rheumatology criteria (ACR 20), the study's primary endpoint. A higher proportion of patients receiving SIMPONI ARIA plus methotrexate achieved at least a 50 percent improvement in ACR criteria (ACR 50) compared with patients receiving placebo plus methotrexate at week 14 (30 percent versus 9 percent, respectively, a difference with 95 percent CI 15.3, 27.2). Significant improvements in ACR 20 were observed as early as week 2, after a single SIMPONI ARIA infusion, as 33 percent of patients achieved an ACR 20 response versus 12 percent of patients receiving placebo. Radiographic progression of the hands and feet were assessed by the change from baseline in van der Heijde-Sharp (vdH-S) scores, an X-ray measure of joint destruction, including joint erosion and joint space narrowing in which higher scores indicate greater structural damage. At week 24, patients receiving SIMPONI ARIA plus methotrexate had a mean change in total vdH-S score of 0.03 from baseline, compared with a mean change of 1.09 in the placebo plus methotrexate group (P<0.001). At week 52, the mean change in total vdH-S score from baseline was 0.13 in SIMPONI ARIA treated patients versus 1.20 in placebo patients who crossed over to SIMPONI ARIA at either week 16 or 24.

"SIMPONI ARIA demonstrated a compelling efficacy profile in the treatment of moderately to severely active rheumatoid arthritis in the GO-FURTHER study," said Jerome A. Boscia, M.D., Vice President, Head of Immunology Development, Janssen Research & Development, LLC. "The approval of SIMPONI ARIA represents our commitment to bringing forward new therapeutic options for patients living with immunological diseases, including potentially disabling diseases like rheumatoid arthritis."

"As leaders in rheumatology, we're proud to expand our treatment portfolio by making an anti-TNF infusible medicine like SIMPONI ARIA available to patients," said Rob Bazemore, President, Janssen Biotech, Inc. "Treatment with SIMPONI ARIA provides a different infusion experience; patients can now receive this form of treatment administration with an anti-TNF therapy via a short infusion time of 30 minutes with a dosing regimen of every 8 weeks."

About GO-FURTHER

The GO-FURTHER trial is a Phase 3, international multicenter, double-blind, placebo-controlled study including 592 adults with RA designed to compare ACR 20 response at week 14 in patients receiving an I.V. golimumab infusion plus methotrexate compared with patients receiving placebo infusions plus methotrexate. The trial included patients diagnosed with moderately to severely active RA who had at least six tender and six swollen joints at screening and baseline, had elevated CRP levels at

screening and who had been receiving background methotrexate for at least 3 months. Patients were randomized 2:1 to receive a 30 (+/- 10) minute I.V. infusion of golimumab 2 mg/kg or placebo at weeks 0, 4, and then every 8 weeks; in both treatment arms, methotrexate was taken. The primary endpoint of the study was the proportion of ACR 20 responders at week 14. At week 16, patients receiving placebo with less than 10 percent improvement in combined swollen and tender joint counts from baseline qualified for early escape and received I.V. golimumab 2 mg/kg infusions at week 16 and week 20 and every 8 weeks subsequent; patients receiving golimumab who qualified for early escape remained on their golimumab therapy. All patients receiving placebo crossed over to I.V. golimumab at week 24. Radiographs of the hands and feet were taken at baseline, week 24 (week 16 for early escape participants regardless of whether they had been randomized to placebo or golimumab) and week 52, and were scored using the van der Heijde-Sharp (vdH-S) score.

Through week 24, adverse events (AEs) occurred in 53 percent of patients receiving I.V. golimumab and 49 percent of patients receiving placebo, and serious AEs were reported in more I.V. golimumab-treated patients (4 percent) than placebo-treated patients (2 percent). In the controlled phase of the trial through Week 24, infections were observed in 27 percent of SIMPONI ARIA-treated patients compared with 24 percent of placebo-treated patients, and serious infections were observed in 0.9 percent of SIMPONI ARIA-treated patients and 0.0 percent of placebo-treated patients. One case of tuberculosis and one death, a myocardial infarction secondary to community-acquired pneumonia, were reported in the I.V. golimumab group. In addition, one death was reported among placebo-treated patients through week 24. Through week 24, the proportions of infusions with infusion reactions were 1.1 percent and 0.2 percent, respectively.

For more information regarding the safety profile for SIMPONI ARIA, please see "Important Safety Information" below.

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) 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[2]. It is estimated that 1.3 million Americans[1] and more than 23.5 million people worldwide[iii] are affected by the condition, for which there is no cure.

About SIMPONI® ARIA™ (golimumab) for infusion

SIMPONI ARIA is an infusible, fully human anti-TNF monoclonal antibody that targets both soluble and transmembrane bioactive forms of 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. By binding with and blocking TNF-alpha, SIMPONI ARIA helps control inflammation. SIMPONI ARIA also helps to inhibit the progression of further joint damage. SIMPONI ARIA is approved for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) with the medicine methotrexate. More information about SIMPONI ARIA will be available soon at **www.SimponiARIA.com**.

Please see SIMPONI ARIA U.S. full **Prescribing Information** and **Medication Guide**.

Janssen Biotech, Inc. discovered and developed SIMPONI ARIA.

Important Safety Information

SIMPONI® ARIA™ (golimumab) is a prescription medicine. SIMPONI ARIA™ 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® ARIA™ and will closely 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 receive SIMPONI® ARIA™ 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 vburning 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 receiving TNF blockers, including SIMPONI® ARIA™, 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.

Some people treated with SIMPONI® ARIA™ developed skin cancer. Tell your doctor if any changes in the appearance of you skin or growths on your skin occur during or after your treatment with SIMPONI® ARIA™. Your doctor should periodically examine your skin, especially if you have a history of skin cancer.

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 receiving SIMPONI® ARIA™ should not receive live vaccines.

Reactivation of hepatitis B virus has been reported in patients who are carriers of this virus and are receiving TNF-blocker medicines, such as SIMPONI® ARIA™. Some of these cases have been fatal. Your doctor should do blood tests before and after you start treatment with SIMPONI® ARIA™. 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
- clay-colored bowel movements
- dark urine
- fevers
- skin or eyes look yellow
- little or no appetite
- vomiting
- muscle aches
- chills
- stomach discomfort
- skin rash

Heart failure can occur or get worse in people who use TNF blockers, including SIMPONI® ARIA™. 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, swelling of your lower legs or feet, or sudden weight gain.

Rarely, people using TNF blockers, including SIMPONI® ARIA™, can have nervous system problems such as multiple sclerosi or Guillain-Barré 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® ARIA™. Contact your doctor immediate 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® ARIA™. 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.

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

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 or legs.

Tell your doctor if you have psoriasis.

Tell your doctor if you are pregnant, planning to become pregnant or are breastfeeding or have a baby and received SIMPONI® ARIA™ 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.

The most common side effects of SIMPONI® ARIA™ include: upper respiratory infection, viral infections, bronchitis, high blood pressure, and rash.

Please read the full Prescribing Information and Medication Guide for SIMPONI® ARIA™ 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, 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.

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.

**Dr. Schwartzman was not associated with the SIMPONI® ARIATM clinical trials and was not compensated for any media work. He has been a paid consultant to Janssen Biotech, Inc.*

References

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[ii] Arthritis Foundation. What is rheumatoid arthritis? Available at: http://www.arthritis.org/types-what-is-rheumatoid-arthritis.php. Accessed April 22, 2013.

[iii] World Health Organization. The global burden of disease: 2004 update. Geneva: WHO Press, 2008. Available at: http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf. Accessed November 10, 2012.

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