



October 28, 2013

## **NEW TWO-YEAR RESULTS SHOW SIMPONI® ARIA™ (GOLIMUMAB) FOR INFUSION INHIBITED RADIOGRAPHIC PROGRESSION IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS**

### ***Nearly 70 Percent of Patients Receiving SIMPONI ARIA at Two Years Demonstrated ACR 20 Response***

**SAN DIEGO, October 28, 2013** - New two-year results of a Phase 3 study sponsored by Janssen Research & Development, LLC (Janssen) showed that SIMPONI® ARIA™ (golimumab) for infusion in combination with methotrexate inhibited radiographic progression in patients with moderately to severely active rheumatoid arthritis (RA) at week 24, and continued to inhibit radiographic progression through weeks 52 and 100. Analysis of study patients' X-rays showed significant inhibition of the progression of structural damage at week 24 in patients receiving SIMPONI ARIA plus methotrexate compared with patients receiving placebo plus methotrexate. The continued inhibition of structural damage progression was seen in patients randomized to SIMPONI ARIA through weeks 52 and 100, and inhibition of structural damage progression was observed in patients receiving placebo who crossed over to SIMPONI ARIA at weeks 16 or 24. Treatment with SIMPONI ARIA plus methotrexate also led to improvements in disease activity with nearly 60 percent of patients achieving at least a 20 percent improvement in the American College of Rheumatology (ACR 20) score at week 14, the study's primary endpoint, and 68 percent achieving that response at week 100. These data were presented during an oral presentation at the 2013 Annual Meeting of the American College of Rheumatology (ACR).

In July, Janssen received U.S. Food and Drug Administration (FDA) approval of SIMPONI ARIA for the treatment of adults with moderately to severely active RA in combination with methotrexate. SIMPONI ARIA is the only fully human anti-TNF-alpha infusible therapy.

"Data from this Phase 3 study demonstrates the long-term radiographic and clinical results of intravenous golimumab in combination with methotrexate for patients with moderately to severely active RA," said Rene Westhovens, M.D., Ph.D., Professor at the Department of Rheumatology, KU Leuven, Belgium, and study investigator. "These new findings are encouraging for rheumatologists and their patients who are battling this chronic and potentially disabling disease as they provide additional information about treatment with intravenous golimumab in managing RA through two years."

In 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), patients were randomized to receive SIMPONI ARIA 2 mg/kg or placebo, via a 30-minute infusion, at weeks 0, 4 and then every 8 weeks plus weekly methotrexate. Non-responders (< 10% improvement from baseline in swollen and tender joint count) to placebo plus methotrexate at week 16 were crossed over to receive SIMPONI ARIA plus methotrexate, and all remaining patients receiving placebo plus methotrexate crossed over at week 24. Eighty-two percent of patients (486/592) continued through week 112 (12 weeks post the last infusion at week 100). Radiographic progression was 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 ( $\pm$  standard deviation) in total vdH-S score of 0.03 ( $\pm$ 1.90) from baseline, compared with a mean change of 1.09 ( $\pm$  3.19) in the placebo plus methotrexate group ( $P < 0.001$ ). At week 52, patients who received SIMPONI ARIA plus methotrexate for the entire 52 weeks had a mean change of 0.13 ( $\pm$  3.11) from baseline, compared with a mean change of 1.22 ( $\pm$  3.98) in patients who crossed over from placebo plus methotrexate to SIMPONI ARIA plus methotrexate at either week 16 or 24 during the trial ( $P < 0.001$ ). At week 100, patients who received SIMPONI ARIA plus methotrexate for the entire 100 weeks had a mean change of 0.74 ( $\pm$  6.32) from baseline, compared with a mean change of 2.10 ( $\pm$  7.42) in patients who crossed over from placebo plus methotrexate to SIMPONI ARIA plus methotrexate ( $p=0.005$ ) at either week 16 or 24, supporting long-term inhibition of structural damage progression in patients receiving SIMPONI ARIA.

Significant proportions of patients receiving SIMPONI ARIA plus methotrexate also demonstrated improvements in signs and symptoms compared with patients receiving placebo according to ACR responses, Disease Activity Score (DAS) 28 C-reactive protein (CRP) and Health Assessment Questionnaire (HAQ) disability scores at weeks 14 and 24. Clinical improvements were reported through week 100 with ACR 20/50/70 responses among all SIMPONI ARIA plus methotrexate patients of 68 percent, 44 percent and 23 percent, respectively. DAS28-CRP moderate/good response at week 100 was achieved by 82 percent of patients. The median improvement from baseline in HAQ score was 0.5 at week 100, with 67 percent of SIMPONI ARIA plus methotrexate patients improving in HAQ  $\geq$ 0.25 from baseline.

Through week 112, adverse events (AEs) and serious AEs occurred in 79 percent and 18 percent, respectively, of SIMPONI ARIA-treated patients, compared with 49 percent and two percent at week 24. Serious infections occurred in six percent of patients; malignancies occurred in one percent of patients; serious opportunistic infections occurred in 0.3 percent of patients; and tuberculosis occurred in 0.5 percent of patients through week 112. Six deaths were reported, which included one placebo plus methotrexate patient and five SIMPONI ARIA plus methotrexate patients (pneumonia/MI, dehydration, abdominal TB, and two unknown). Through week 112, the proportion of infusions with infusion reactions was 0.4 percent and the proportion of patients with infusion reactions was 3.9 percent (versus 1.1 percent and 3.5 percent, respectively, at week 24).

### **About GO-FURTHER**

The GO-FURTHER trial is a Phase 3, international multicenter, double-blind, placebo-controlled study including 592 adults with moderately to severely active RA designed to compare ACR 20 response at week 14 in patients receiving a SIMPONI ARIA infusion plus methotrexate versus patients receiving placebo infusions plus methotrexate. The trial included patients diagnosed with active RA who had at least six tender and six swollen joints and who had been receiving background methotrexate for at least three months. Patients were randomized 2:1 to receive a 30 (+/- 10) minute I.V. infusion of SIMPONI ARIA 2 mg/kg or placebo at weeks 0, 4, and then every 8 weeks on the background of stable weekly methotrexate doses. The primary endpoint of the study was ACR 20 at week 14. At week 16, patients receiving placebo plus methotrexate with less than 10 percent improvement in combined swollen and tender joint counts were entered into early escape to receive SIMPONI ARIA 2 mg/kg plus methotrexate at week 16 and week 20. All patients receiving placebo plus methotrexate crossed over to SIMPONI ARIA plus methotrexate at week 24. Radiographs of the hands and feet were taken at baseline, week 24 (or week 16 for early escape participants), week 52 and week 100, and were scored using the modified vdH-S score.

### **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<sup>1</sup>. It is estimated that 1.3 million Americans<sup>2</sup> and more than 23.7 million people worldwide<sup>3</sup> 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 with the medicine methotrexate. The SIMPONI ARIA dose regimen is 2 mg/kg given as an intravenous infusion at weeks 0 and 4, then every 8 weeks thereafter. More information about SIMPONI ARIA is available at [www.SimponiARIA.com](http://www.SimponiARIA.com).

Please see SIMPONI ARIA U.S. full [Prescribing Information](#) and [Medication Guide](#).

Janssen Biotech, Inc. discovered and developed SIMPONI ARIA and markets the product in the U.S.

### **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
- 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 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 your 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 sclerosis 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 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® 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 face, 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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

**About Janssen Research & Development, LLC and Janssen Biotech, Inc.**

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people with serious diseases throughout the world. Beyond its innovative medicines, Janssen is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates and healthcare professionals have access to the latest treatment information, support services and quality care.

[Janssen Research & Development, LLC](#) and [Janssen Biotech, Inc.](#) are two of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit [www.janssen.com](http://www.janssen.com) for more information. Follow us on Twitter at [www.twitter.com/JanssenUS](https://www.twitter.com/JanssenUS).

**Media Contact:**

Megan Farina  
Office: 215-325-6861  
Mobile: 610-724-1079

Brian Kenney  
Office: 215-628-7010  
Mobile: 215-620-0111

**Investor Contacts:**

Louise Mehrotra  
Johnson & Johnson  
Office: 732-524-6491

Stan Panasewicz  
Johnson & Johnson  
Office: 732-524-2524

---

<sup>1</sup>Arthritis Foundation. What is rheumatoid arthritis? <http://www.arthritis.org/types-what-is-rheumatoid-arthritis.php>. Accessed September 18, 2013.

<sup>2</sup>Arthritis Foundation. Who gets rheumatoid arthritis? <http://www.arthritis.org/who-gets-rheumatoid-arthritis.php>. Accessed September 18, 2013.

<sup>3</sup>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](http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf). Accessed September 18, 2013.