News Release

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U.S. FDA APPROVES UPDATE OF SIMPONI ARIA® (GOLIMUMAB FOR INFUSION) LABEL TO INCLUDE IMPROVEMENT IN BOTH PHYSICAL AND EMOTIONAL MEASURES OF HEALTH WHEN TREATING MODERATELY TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS

SIMPONI ARIA® shown to provide improvements across all eight measures of physical and emotional well-being reported by patients through the Medical Outcomes Study Short Form-36 questionnaire

Horsham, PA, September 2, 2015 – Janssen Biotech, Inc. announced today the approval of a U.S. Food and Drug Administration (FDA) Supplemental Biologics License Application (sBLA) for SIMPONI ARIA® (golimumab for infusion) for the treatment of moderately to severely active rheumatoid arthritis (RA) to include measures of physical and mental health reported by patients through the Medical Outcomes Study Short Form-36 questionnaire (SF-36). According to the revised label, SIMPONI ARIA®, when administered in combination with methotrexate (MTX), improved patients' physical and emotional well-being as measured by the SF-36 assessment. SIMPONI ARIA® received U.S. FDA approval in July 2013 for the treatment of moderately to severely active RA and is the only intravenous anti-tumor necrosis factor (TNF)-alpha administered as a 30-minute infusion.

"Traditional assessments of RA treatments measure joint function and pain, but we as clinicians know that there is much more to this disease. Measuring physical, mental and social function can provide a more comprehensive view of how RA treatment impacts patient lives," said Dr. Jeffrey Curtis, MD MS MPH, University of Alabama at Birmingham, Division of Clinical Immunology and Rheumatology. "According to results from the SF-36 assessment, patients receiving SIMPONI ARIA® and methotrexate showed marked improvement in general health status measures of physical and mental well-being."

The SF-36 collects data from patients to help assess health status across a range of physical and mental categories. Collected as part of the pivotal GO-FURTHER trial, results showed that patients receiving SIMPONI ARIA® plus MTX demonstrated greater improvement from baseline compared with placebo and MTX in all areas of SF-36 at weeks 12, 16 and 24: physical

component summary (PCS) scores, mental component summary (MCS) scores, and in all eight domains of the survey – physical function, role limitations due to physical problems, bodily pain, general health perception, vitality, social function, role limitations due to emotional problems, and general mental health.

"The SF-36 is a general health assessment that allows people receiving treatment for RA to share the physical and mental impact of the disease in their own words," said Pauline McNulty, Vice President, Patient Reported Outcomes, J&J Pharmaceutical Services, LLC. "In today's healthcare environment, patient-reported outcomes are more important than ever as they enable healthcare providers to engage patients in making decisions that impact their health-related quality of life."

The eight-scale SF-36 profile of functional health and well-being assesses:

Physical Composite Scores (PCS)

- Physical functioning (including vigorous and moderate activities)
- Role-physical (limitations due to physical problems)
- Bodily pain (intensity level and degree it interferes with functioning)
- General health (perceptions of overall health)

Mental Composite Scores (MCS)

- Vitality (energy levels and fatigue)
- Social functioning (extent and frequency health interferes with social activities)
- Role-emotional (limitations due to emotional problems)
- Mental health (general positive and negative feelings)

The SIMPONI ARIA® dose regimen is 2 mg/kg given as an intravenous infusion every 8 weeks after two starter doses at weeks 0 and 4. The infusion is given over a 30-minute period. Phase 3 studies are ongoing to seek approval for additional indications for SIMPONI ARIA®.

About GO-FURTHER

GO-FURTHER is a Phase 3, randomized, multicenter, double-blind, placebo-controlled trial including 592 adults with RA who were randomly assigned to receive IV placebo (n=197) or SIMPONI ARIA 2 mg/kg (n=395) infusions at week 0, week 4, week 12 and week 20. All patients continued stable oral methotrexate (15–25 mg/wk). Randomization was stratified according to screening C-reactive protein (CRP) level (< or ≥ 1.5 mg/dl; upper limit of normal: 1.0 mg/dl). At Week 16, patients in the placebo + MTX group who had less than 10 percent improvement in tender and swollen joint counts entered blinded early escape and crossed over to receive SIMPONI ARIA® 2 mg/kg at weeks 16 and 20. Patients randomized to SIMPONI ARIA® 2 mg/kg + MTX received placebo infusions at Week 16 to maintain the blind but did not undergo dose increase or changes in dosing frequency. Data collected through week 24 are included in the current release.

Patient-reported outcome assessments included Health Assessment Questionnaire-Disability Index (HAQ-DI; physical function), Medical Outcomes Study Short Form-36 questionnaire, EQ-5D assessment of current health state, Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) questionnaire, and disease effect on productivity [10-cm visual analog scale (VAS)].

Specific to the Medical Outcomes Study Short Form-36 questionnaire (SF-36), physical and mental component summary (PCS and MCS) scores as well as 8 individual domain scores of the SF-36 were reported, with higher scores indicating better Health-Related Quality of Life (HRQOL).

Significantly greater improvements in all 8 individual SF-36 subscores and both the SF-36 PCS and MCS scores ($p < 0.001$) accompanied SIMPONI ARIA® + MTX therapy.

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 of the joints, and in some cases, joint destruction and disability. An estimated 1.5 million Americans[i] have the condition, which affects nearly three times as many women as men. While the cause of RA is unknown, many cases are believed to result from genetic and environmental factors. There is no medical cure for RA, but there are several medications available to help alleviate symptoms.

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 RA with the medicine methotrexate. More information about SIMPONI ARIA® is available 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
- 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. Hepatosplenic T-cell lymphoma, a rare and fatal lymphoma, has occurred mostly in teenage or young adult males with Crohn's disease or ulcerative colitis who were taking a TNF blocker with azathioprine or 6-mercaptopurine. 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 or treatment with a weakened bacteria (such as BCG for bladder cancer).

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, 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 healthcare 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 dedicated to addressing and solving some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, 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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[i] World Health Organization. The Global Burden of Disease: 2004 Update. p32. Available at: http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf. Accessed August 3, 2015.