

New Phase 3 Data Show SIMPONI ARIA® (golimumab) Significantly Improved Signs and Symptoms in Patients with Active Ankylosing Spondylitis

Patients with Painful Inflammatory Spinal Arthritis Showed Marked Improvements
in Multiple Study Endpoints Following Treatment with SIMPONI ARIA®



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Janssen Research & Development, LLC →

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WASHINGTON, Nov. 14, 2016 /PRNewswire/ -- Janssen Research & Development, LLC (Janssen) announced today new findings from a pivotal Phase 3 study showing the efficacy and safety profile of the intravenously administered anti-tumor necrosis factor (TNF)-alpha therapy SIMPONI ARIA® (golimumab) in the treatment of active ankylosing spondylitis (AS). Data from the GO-ALIVE study showed that 73.3 percent of patients with active ankylosing spondylitis receiving SIMPONI ARIA® 2 mg/kg achieved the study's primary endpoint of at least a 20 percent improvement in the Assessment in Ankylosing Spondylitis criteria (ASAS20) at week 16, compared with 26.2 percent of patients receiving placebo ($P \leq 0.001$). Data from GO-ALIVE, which will be part of an upcoming submission to the U.S. Food and Drug Administration (FDA) seeking approval of SIMPONI ARIA® for the treatment of active ankylosing spondylitis, are being presented for the first time at the 2016 ACR/ARHP Annual Meeting. In July 2013, SIMPONI ARIA® received U.S. FDA approval as a 30-minute infusion for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate.



"Anti-TNF therapy remains the mainstay in the treatment of ankylosing spondylitis, a complex chronic inflammatory disease involving the spine, peripheral joints and multiple other organ systems," said Atul Deodhar, M.D., MRCP, FACP, FACR, Professor of Medicine, Oregon Health & Science University and lead study author.* "The results reported from the GO-ALIVE study demonstrate significant improvement in signs and symptoms and physical function in patients with active ankylosing spondylitis receiving SIMPONI ARIA®, and these are important findings for patients living with this progressive, debilitating immune disease."

In addition to meeting the primary endpoint of ASAS20 at week 16, all statistically-controlled secondary endpoints in the GO-ALIVE study were also met with statistical significance in comparisons of SIMPONI ARIA® versus placebo at week 16 ($P < 0.05$). Major secondary endpoints evaluated at week 16 were ASAS40, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI 50) score, an indicator of a major clinical response, and change in Bath Ankylosing Spondylitis Functional Index (BASFI) score, which measures improvements in physical function.

- 47.6 percent of patients receiving SIMPONI ARIA® achieved an ASAS40 response compared with 8.7 percent of patients receiving placebo ($P < 0.001$).
- 41.0 percent of SIMPONI ARIA® patients achieved a BASDAI 50 response compared with 14.6 percent of placebo patients ($P < 0.001$).
- Mean change from baseline in BASFI was -2.4 for the SIMPONI ARIA® group compared with -0.5 for the placebo group ($P < 0.001$).

Additional assessments in GO-ALIVE were ASAS partial remission, change from baseline in Bath Ankylosing Spondylitis Metrology Index (BASMI), change in baseline measures of physical and mental health reported by patients through the Medical Outcomes Study Short Form-36 questionnaire (SF-36), and Ankylosing Spondylitis Quality of Life (ASQoL) patient-reported outcomes. Each of these demonstrated statistically significant superiority of SIMPONI ARIA® compared with placebo.

Through week 16, 32.4 percent of patients receiving SIMPONI ARIA® and 23.3 percent of patients receiving placebo had one or more adverse events (AEs). The most common type of AE was infection, 11.4 percent reported in the SIMPONI ARIA® group and 7.8 percent reported in the placebo group. At week 16, patients initially treated with placebo began to receive SIMPONI ARIA®. Through week 28, 34.8 percent of SIMPONI ARIA®-treated patients experienced one or more AEs, and nasopharyngitis was the most common AE reported (5.4 percent) and serious AEs reported in the SIMPONI ARIA® group included one case of

pancreatitis and one case of pneumonia. There were no opportunistic infections, malignancies, or deaths through week 28. Infusion reactions were low (1.5 percent) among SIMPONI ARIA®-treated patients, with three patients reporting four reactions, none of which was serious or severe.

"We are very encouraged by these robust results, which show the potential of SIMPONI ARIA® in the treatment of ankylosing spondylitis, an immune-mediated disease that can severely impact the lives of patients," said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. "With the data from the GO-ALIVE Phase 3 study, we look forward to pursuing FDA approval of SIMPONI ARIA® for the treatment of active ankylosing spondylitis."

About GO-ALIVE

GO-ALIVE is a Phase 3, multicenter, randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of IV golimumab (SIMPONI ARIA®) in adult patients with active ankylosing spondylitis. Patients had a diagnosis of definite AS per modified New York criteria, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) greater than or equal to four, total back pain visual analogue scale greater than or equal to four, and C-reactive protein greater than or equal to 0.3 mg/dL. Up to 20 percent of patients could have had prior anti-TNF-alpha treatment with agents other than SIMPONI® (golimumab) and up to 10 percent of patients could have complete ankylosis of the spine. Patients (n=208) were randomized one-to-one to receive SIMPONI ARIA® 2 mg/kg at weeks 0, 4, and every 8 weeks or placebo at week 0, 4, and 12, with crossover to SIMPONI ARIA® at week 16. The study will continue through 52 weeks.

About Ankylosing Spondylitis

Ankylosing spondylitis is a chronic, immune-mediated disease that causes enthesitis, or inflammation where ligaments and muscles attach to bones, most commonly those within the spine. It is the primary disease in a group of arthritis-related diseases known as spondylitis, spondyloarthropathy or spondyloarthritis.¹ The disease affects men more often than women and typically manifests in early adulthood.² In contrast to mechanical low back pain, low back pain and stiffness with ankylosing spondylitis worsen after a period of rest or upon waking up in the morning and improve after exercise, a hot bath or a shower.¹

About SIMPONI ARIA® (golimumab) infusion

SIMPONI ARIA® is an infusible, fully human anti-TNF-alpha 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® 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.

Janssen Biotech, Inc. discovered and developed SIMPONI ARIA®.

Important Safety Information

SERIOUS INFECTIONS

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, sweats, 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

CANCER

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.

USE WITH OTHER DRUGS

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).

HEPATITIS B INFECTION

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

Heart failure can occur or get worse in people who use TNF blockers, including SIMPONI ARIA®. If you develop new or worsening heart failure with SIMPONI ARIA®, you may need treatment in a hospital, and it may result in death. 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.

NERVOUS SYSTEM PROBLEMS

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.

IMMUNE SYSTEM PROBLEMS

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.

LIVER PROBLEMS

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.

BLOOD PROBLEMS

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.

ALLERGIC REACTIONS

Allergic reactions can happen in people who use TNF-blocker medicines, including SIMPONI ARIA®. 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.

OTHER CONSIDERATIONS TO TELL YOUR DOCTOR

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.

COMMON SIDE EFFECTS

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 the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com. Follow us on Twitter at <https://twitter.com/JanssenGlobal>.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995, regarding the development and potential benefits of SIMPONI ARIA®. 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 known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC and Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; competition, including technological advances, new products and patents attained by competitors; challenges to patents; manufacturing difficulties or delays; product efficacy or safety concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2016, including in Exhibit 99 thereto, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

*Compensated as chair of the GO-ALIVE steering committee.

References

1. Arthritis Foundation. Ankylosing Spondylitis. Available at <http://www.arthritis.org/about-arthritis/types/ankylosing-spondylitis>. Accessed October 2016.
2. Mayo Clinic. Ankylosing Spondylitis. Available at <http://www.mayoclinic.org/diseases-conditions/ankylosing-spondylitis/basics/definition/con-20019766?p=1>. Accessed October 2016.

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