# News Release


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## JANSSEN SUBMITS TWO APPLICATIONS TO FDA SEEKING APPROVAL OF SIMPONI ARIA® (GOLIMUMAB) FOR THE TREATMENT OF ACTIVE PSORIATIC ARTHRITIS AND ACTIVE ANKYLOSING SPONDYLITIS

**Horsham, PA, December 22, 2016** — Janssen Biotech, Inc. (Janssen) announced today the submission of two Supplemental Biologics License Applications (sBLAs) to the U.S. Food and Drug Administration (FDA) seeking approval of SIMPONI ARIA® (golimumab) for the treatment of adults living with active psoriatic arthritis and the treatment of adults living with active ankylosing spondylitis. SIMPONI ARIA® is a fully-human anti-tumor necrosis factor (TNF)-alpha therapy that is currently approved as a 30-minute intravenous infusion for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate. Psoriatic arthritis and ankylosing spondylitis are chronic, systemic inflammatory conditions that combined affect more than two million Americans.[1-3]

“At Janssen, we are committed to addressing the unmet medical needs of patients living with psoriatic arthritis and ankylosing spondylitis through the discovery and development of innovative therapeutics,” said Newman Yeilding, M.D, Head of Immunology Development, Janssen Research & Development, LLC. “We understand the need for additional treatment options for patients and their healthcare providers and hope to make SIMPONI ARIA® available for those in need.”

Data from two separate Phase 3 studies evaluating the efficacy and safety of SIMPONI ARIA® 2 mg/kg given as an intravenous infusion every eight weeks after two starter doses at weeks 0 and 4 in the treatment of adults living with active psoriatic arthritis (GO-VIBRANT) and active ankylosing spondylitis (GO-ALIVE) served as the basis for the submissions. Results from the GO-ALIVE study were presented at the 2016 ACR/ARHP Annual Meeting and results from the GO-VIBRANT study are planned for presentation at an upcoming scientific congress.

### 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.

For more information, please see SIMPONI ARIA® U.S. full Prescribing Information and Medication Guide, available at 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, 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

**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 Psoriatic Arthritis**
Psoriatic arthritis is a chronic immune-mediated inflammatory disease characterized by both joint inflammation and the skin lesions associated with psoriasis.[4] An estimated one to two million Americans—and more than 12 million people worldwide—have psoriatic arthritis.[1,2,5] While estimates of the prevalence of psoriatic arthritis among people living with psoriasis vary, up to 30 percent may develop inflammatory arthritis.[6] The disease causes pain, stiffness and swelling in and around the joints and commonly appears between the ages of 30 and 50, but can develop at any time.[7] Though the exact cause of psoriatic arthritis is unknown, genes, the immune system and environmental factors are all believed to play a role in the onset of the disease.[7]

**About Ankylosing Spondylitis**
Ankylosing spondylitis is a chronic, immune-mediated disease of the axial skeleton, affecting the sacroiliac joints and the spine. Ankylosing spondylitis frequently also 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.[8] Peripheral joint involvement (in particular, hips and shoulders) can occur. Other organs can also be involved including eyes (uveitis), heart and aorta, and lungs. The disease affects men more often than women and typically manifests in early adulthood.[9] 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.[9]

**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 at Twitter.com/JanssenGlobal.

Janssen Biotech, Inc. and Janssen Research & Development, LLC are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

**Cautions Concerning Forward-Looking Statements**
*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development including potential approval of new indications for 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 Biotech, Inc., Janssen Research & Development, LLC and/or 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.*

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