



## **News Release**

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## **SIMPONI ARIA® (golimumab) Approved by the U.S. Food and Drug Administration for Active Polyarticular Juvenile Idiopathic Arthritis and Extension of Its Active Psoriatic Arthritis Indication in Patients 2 Years of Age and Older**

*SIMPONI ARIA is the first and only fully human anti-tumor necrosis factor (TNF)-alpha biologic agent administered by intravenous (IV) infusion approved for pediatric use in both active polyarticular juvenile idiopathic arthritis (pJIA) and active psoriatic arthritis (PsA)*

*Phase 3 GO-VIVA clinical trial adds to the growing body of evidence for SIMPONI ARIA*

*SIMPONI ARIA is a 30-minute IV infusion administered by a health care professional once every eight weeks after starter doses at weeks 0 and 4*

**HORSHAM, PA, September 30, 2020** – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the U.S. Food and Drug Administration (FDA) has approved SIMPONI ARIA® (golimumab) for patients 2 years of age and older for the treatment of active pJIA and has extended the PsA

indication for this same patient population.

“This latest FDA approval of SIMPONI ARIA for pediatric use in active pJIA and active PsA not only brings a new option to young patients living with these diseases but also adds to the growing body of evidence for this treatment,” said Mathai Mammen, M.D., Ph.D., Global Head, Janssen Research & Development, Johnson & Johnson. “For more than 20 years, we at Janssen have been committed to researching anti-TNF biologic agents for immune-mediated diseases and are encouraged to expand treatment options for these patients.”

### **About pJIA and PsA**

JIA is a group of disorders characterized by arthritis persisting for at least six weeks before the age of 16 years.<sup>i</sup> Approximately 300,000 children suffer from some form of JIA in the United States.<sup>ii</sup> The polyarticular form of JIA is most common and is characterized by inflammation in more than four joints and resembles adult rheumatoid arthritis (RA).<sup>iii</sup> PsA in pediatric patients is one of the rarest subtypes of JIA and is characterized by both joint inflammation and skin lesions associated with psoriasis resembling adult PsA.<sup>iv,v</sup> Given the heterogeneity of these diseases, additional treatment options are needed for these conditions.

“For far too long, children with pJIA or PsA have had limited treatment options,” said Seth D. Ginsberg, Co-Founder and President of the Global Healthy Living Foundation and CreakyJoints. “This approval represents an important step forward for these children and their families.”

### **Data Supporting Approval**

The approval was based on results from the GO-VIVA Phase 3 clinical trial, an open-label study in children with JIA with active polyarthritis ages 2 to 17 years who had active arthritis in five or more joints, despite receiving treatment with methotrexate for at least two months. Trial results demonstrated that pharmacokinetic (PK) exposure of SIMPONI ARIA was consistent with that of two pivotal Phase 3 clinical trials of SIMPONI ARIA in adult patients with moderately to

severely active RA and active PsA.

Efficacy was assessed as supportive endpoints through Week 52. The efficacy was generally consistent with responses in adult patients with RA. The adverse reactions observed in GO-VIVA were consistent with the established safety profile of SIMPONI ARIA in adult patients with RA and PsA.

“Due to the limited availability of pediatric patients for inclusion in clinical trials, it can be challenging to build clinical studies for this young patient population,” said Daniel J. Lovell, the Joseph E. Levinson Professor of Pediatric Rheumatology at Cincinnati Children’s Hospital Medical Center. “Given these challenges, I am pleased to see Janssen advance the approval of a new treatment option for pediatric patients with pJIA and PsA – an important milestone in the treatment of these complex, heterogeneous diseases.”

### **Access to SIMPONI ARIA**

Janssen strives to work closely with payers, providers and pharmacy benefit managers in an effort to help ensure SIMPONI ARIA is broadly accessible to appropriate patients.

Janssen [CarePath](#) offers a comprehensive support program that helps patients get started on SIMPONI ARIA and stay on track. Janssen CarePath provides information on insurance coverage, potential out-of-pocket costs and treatment support, and identifies options that may help make treatment more affordable, including the Janssen CarePath Savings Program for commercially insured patients who are eligible.

### **About the GO-VIVA Clinical Trial**

GO-VIVA is a Phase 3, open-label, single arm, multicenter study conducted across nine countries with treatment received by 127 patients with JIA with active polyarthritis, despite current treatment with methotrexate. GO-VIVA was conducted as a post-marketing requirement under the Pediatric Research Equity Act (PREA)

following the initial approval of SIMPONI ARIA for adults with moderately to severely active RA in 2013.

GO-VIVA was designed to evaluate the dosing of SIMPONI ARIA in children that is required to achieve drug levels and exposures that are similar to those that were shown to be safe and effective in adults with moderately to severely active RA, since active pJIA, active PsA in pediatric patients, and adult RA show similarities in disease.

### **About SIMPONI ARIA (golimumab)**

In addition to the treatment of children ages 2 years and older with active pJIA or active PsA, SIMPONI ARIA is approved in the U.S. for the treatment of adults with moderately to severely active RA, active PsA and active ankylosing spondylitis (AS). SIMPONI ARIA is currently approved for one or more of these indications in 24 countries.

SIMPONI ARIA is a fully human anti-TNF-alpha monoclonal antibody that targets both soluble and transmembrane bioactive forms of human TNF-alpha, a protein that when overproduced in the body due to chronic inflammatory diseases can cause inflammation.

For adults with RA, PsA, and AS, the SIMPONI ARIA weight-based dosage regimen is 2 mg/kg given as an IV infusion over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter. SIMPONI ARIA is given with methotrexate for the treatment of RA.

For pediatric patients with pJIA and PsA, the SIMPONI ARIA body surface area (BSA)-based dosage regimen is 80 mg/m<sup>2</sup> given as an IV infusion over 30 minutes at weeks 0 and 4, and every 8 weeks thereafter.

More information about SIMPONI ARIA is available at [www.SimponiARIA.com](http://www.SimponiARIA.com).

Janssen Biotech, Inc. discovered and developed SIMPONI ARIA.

## **What is SIMPONI ARIA® (golimumab)?**

SIMPONI ARIA® is a prescription medicine used to treat:

- Moderate to severe rheumatoid arthritis (RA) in adults, used in combination with methotrexate
- Active psoriatic arthritis (PsA) in people 2 years of age and older
- Active ankylosing spondylitis (AS) in adults
- Active polyarticular juvenile idiopathic arthritis (pJIA) in people 2 years of age and older

## **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

Your doctor will examine you for TB and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with

medicine for TB before you begin treatment with SIMPONI ARIA<sup>®</sup> and during treatment with SIMPONI ARIA<sup>®</sup>. Even if your TB test is negative, your doctor should carefully monitor you for TB infections while you are taking SIMPONI ARIA<sup>®</sup>. People who had a negative TB skin test before receiving SIMPONI ARIA<sup>®</sup> have developed active TB. Tell your doctor if you have any of the following symptoms while taking or after taking SIMPONI ARIA<sup>®</sup>:

- cough that does not go away
- low grade fever
- weight loss
- loss of body fat and muscle (wasting)

## **CANCER**

**Unusual cancers have been reported in children and teenage patients taking Tumor Necrosis Factor (TNF)-blocker medicines.** For children and adults receiving TNF blockers, including SIMPONI ARIA<sup>®</sup>, 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<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup> (abatacept), KINERET<sup>®</sup> (anakinra), ACTEMRA<sup>®</sup> (tocilizumab), RITUXAN<sup>®</sup> (rituximab), or another TNF blocker, or if you are scheduled to or recently received a vaccine. People receiving SIMPONI ARIA<sup>®</sup> 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<sup>®</sup>. Some of these cases have been fatal. Your doctor should do blood tests before and after you start treatment with SIMPONI ARIA<sup>®</sup>. 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
- dark urine
- skin or eyes look yellow
- little or no appetite
- vomiting
- muscle aches
- clay-colored bowel movements
- fever
- 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, or 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, are breastfeeding, or plan to breastfeed, 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, abnormal liver tests, decreased blood cells that fight 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 the Janssen Pharmaceutical Companies of Johnson & Johnson**

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at [www.janssen.com](http://www.janssen.com). Follow us at [www.twitter.com/JanssenGlobal](https://www.twitter.com/JanssenGlobal) or [www.twitter.com/JanssenUS](https://www.twitter.com/JanssenUS). Janssen Research & Development, LLC and Janssen Biotech, Inc. are 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 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, any of the other Janssen Pharmaceutical Companies 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; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; 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 December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.*

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<sup>i</sup> Mayo Clinic. Juvenile idiopathic arthritis. Overview. Accessed September 29, 2020. Available at <https://www.mayoclinic.org/diseases-conditions/juvenile-idiopathic-arthritis/symptoms-causes/syc-20374082>.

<sup>ii</sup> National Institutes of Health. U.S. National Library of Medicine. Genetics Home Reference. Juvenile idiopathic arthritis. Frequency. Accessed September 29, 2020. Available at <https://ghr.nlm.nih.gov/condition/juvenile->

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[idiopathic-arthritis#](#).

<sup>iii</sup> National Institutes of Health. U.S. National Library of Medicine. Genetics Home Reference. Juvenile idiopathic arthritis. Description. Accessed September 29, 2020. Available at <https://ghr.nlm.nih.gov/condition/juvenile-idiopathic-arthritis#>.

<sup>iv</sup> Ravelli A, Martini A. Juvenile idiopathic arthritis. *Lancet*. 2007;369(9563):767-778.

<sup>v</sup> Stoll ML, Punaro M. Psoriatic juvenile idiopathic arthritis: a tale of two subgroups. *Curr Opin Rheumatol*. 2011;23(5):437-443.