News Release

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Janssen Announces Submission of Two Applications to U.S. FDA Seeking Approval of SIMPONI ARIA® (golimumab) for the Treatment of Polyarticular Juvenile Idiopathic Arthritis and Juvenile Psoriatic Arthritis

Submissions demonstrate Janssen's commitment to developing new options for young patients

HORSHAM, PA, April 24, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the submission of two supplemental Biologics License Applications (sBLA) to the U.S. Food and Drug Administration (FDA) seeking approval of SIMPONI ARIA® (golimumab) for the treatment of polyarticular juvenile idiopathic arthritis (pJIA) and juvenile psoriatic arthritis (jPsA), in patients two years of age and older in combination with methotrexate. If approved for these indications, SIMPONI ARIA would be the first anti-tumor necrosis factor (TNF)-alpha biologic agent administered by intravenous infusion available for the treatment of these juvenile arthritides.

Juvenile Idiopathic Arthritis (JIA) is a group of disorders characterized by arthritis

persisting for at least six weeks before the age of 16 years.[i] Approximately 300,000 children suffer from some form of JIA in the United States.[ii] The polyarticular form of JIA is most common and is characterized by inflammation in more than four joints and resembles adult rheumatoid arthritis (RA).[iii] Juvenile psoriatic arthritis (PsA) is one of the rarest subtypes of JIA and is characterized by both joint inflammation and skin lesions associated with psoriasis resembling adult PsA.[iv,v]

"All forms of JIA can be debilitating for children who live with the disease, and their parents and physicians often have a difficult time establishing a treatment plan given the limited options currently available for pediatric patients," said Alyssa Johnsen, M.D., Ph.D., Vice President and Rheumatology Disease Area Leader, Janssen Research & Development, LLC. "At Janssen, we are focused on addressing unmet needs for all patients and are especially pleased to be taking these positive steps that could make a new treatment option available for these young patients."

The submissions are based on results from the GO-VIVA Phase 3 clinical trial, which was an open-label study conducted to assess the pharmacokinetics, safety and efficacy of SIMPONI ARIA in children with pJIA ages two to 17 years who had active arthritis in five or more joints, despite receiving treatment with methotrexate for at least two months. The trial also included patients with jPsA.

GO-VIVA was designed to extrapolate data from a pivotal Phase 3 clinical development program for SIMPONI ARIA. Data extrapolation is the process of estimating future trends or effects based on previous observations. With limited pediatric patients available for clinical trial inclusion, researchers can extrapolate data from adult patient trials to determine the potential efficacy and tolerability of a treatment for the pediatric population.

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 active pJIA, despite current treatment with methotrexate. GO-VIVA is included 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.

The purpose of the study was to evaluate the pharmacokinetics safety and efficacy of SIMPONI ARIA in pJIA in pediatric patients aged two to 17 years. The pharmacokinetic and efficacy data in pJIA patients were compared to adult RA patients from the SIMPONI ARIA Phase 3 GO-FURTHER trial and the pharmacokinetics and efficacy results in jPsA patients were compared to adult PsA patients from the Phase 3 GO-VIBRANT trial.

About Juvenile Idiopathic Arthritis

JIA is a group of disorders characterized by arthritis persisting for at least six weeks before the age of 16 years.[i] Approximately 300,000 children in the U.S. suffer from some form of JIA.[ii]

The polyarticular form of JIA causes inflammation in more than four joints and can be rheumatoid factor-positive or negative, with rheumatoid factor-positive polyarticular arthritis closely resembling adult RA.[iii] About 25 percent of children with JIA have the polyarticular form.[vi] Polyarticular JIA poses challenges given the number of joints involved in the condition and the refractory nature of the disease which can increase the risk of joint damage.[vi] Weight-bearing joints and the jaw can be affected, although the disease more commonly affects the small joints of the fingers and hands.[vii]

Juvenile PsA is one of the rarest subtypes of JIA with an estimated 2 to 11 percent of JIA patients affected by the disease.[iv,v] Juvenile patients experience many of the same PsA symptoms as adults, including pain, stiffness and swelling in and around the joints.[iii]

About SIMPONI ARIA® (golimumab) infusion

SIMPONI ARIA is the only fully human anti-TNF-alpha therapy administered via a 30-minute infusion approved for the treatment of adults with moderately to severely active RA, active PsA or active AS.

SIMPONI ARIA® is a 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. By binding with and blocking TNF-alpha, SIMPONI ARIA® helps control inflammation. SIMPONI ARIA® is approved as a 30-minute infusion for the treatment of adult patients with moderately to severely active RA used in combination with methotrexate, active PsA or active AS. SIMPONI ARIA® is approved in 24 countries, including the U.S.

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, sweat, or chills
- muscle aches
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- cough
- shortness of breath
- blood in phlegm
- weight loss
- 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® and during treatment with SIMPONI ARIA®. Even if your TB testis negative, your doctor should carefully monitor you for TB infections while you are taking SIMPONI ARIA®. People who had a negative TB skin test before receiving SIMPONI ARIA® have developed active TB. Tell your doctor if you have any of the following symptoms while taking or after taking SIMPONI ARIA®:

- 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®, 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
- 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, 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, 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. Follow us at www.twitter.com/JanssenGlobal or 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, 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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