Innovative Medicine

JANSSEN RECEIVES TWO U.S. FDA APPROVALS FOR SIMPONI ARIA® (GOLIMUMAB) FOR THE TREATMENT OF ADULTS WITH ACTIVE PSORIATIC ARTHRITIS OR ACTIVE ANKYLOSING SPONDYLITIS

SIMPONI ARIA® is the Only Fully-Human Anti-TNF-alpha Infused Therapy Now Approved for Psoriatic Arthritis, Ankylosing Spondylitis and Rheumatoid Arthritis

October 20, 2017

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Horsham, Pa., October 20, 2017 — Janssen Biotech, Inc., announced today that the U.S. Food and Drug Administration (FDA) has approved SIMPONI ARIA® (golimumab), the only fully-human anti-tumor necrosis factor (TNF)-alpha therapy administered via a 30-minute infusion, for the treatment of adults with active psoriatic arthritis (PsA) or active ankylosing spondylitis (AS). Today's approvals follow the first FDA approval of SIMPONI ARIA® in 2013 for the treatment of

Janssen Biotech, Inc.
Exhibit 2056
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psoriatic arthritis (PsA) or active ankylosing spondylitis (AS). Today's approvals follow the first FDA approval of SIMPONI ARIA® in 2013 for the treatment of moderately to severely active rheumatoid arthritis (RA). The PsA and AS approvals are supported by comprehensive clinical development programs that demonstrated the significant efficacy of SIMPONI ARIA® over placebo, while offering a consistent safety profile across all indications. In the study for the treatment of active PsA, patients experienced improvement in joint symptoms and inhibition of structural damage. In the study for treatment of active AS, results showed improvement in measures of disease activity.

"There is a need for new treatment options for patients with psoriatic arthritis. The results of the Phase 3 study of intravenous (IV) golimumab in patients with psoriatic arthritis demonstrated significant and clinically important efficacy across various domains including the inhibition of structural damage," said Arthur Kavanaugh, M.D., Professor of Medicine, University of California San Diego, and Chair of the GO-VIBRANT steering committee. "The approval of IV golimumab for the treatment of active psoriatic arthritis brings an important new treatment option to patients, especially those who prefer IV administration, and offers one with a 30-minute infusion time."

The approvals of SIMPONI ARIA® for PsA and AS are based on two large-scale, pivotal Phase 3 studies involving more than 600 patients. In both studies, the primary endpoints were met, with a higher proportion of patients demonstrating significant improvement in the signs and symptoms of PsA and AS in the groups receiving treatment with SIMPONI ARIA® compared with those receiving placebo. In the GO-VIBRANT (PsA) study, 75 percent of patients receiving SIMPONI ARIA®, compared with 22 percent of patients receiving placebo ($P < 0.001$), achieved at least a 20 percent improvement in the American College of Rheumatology (ACR20) response at week 14. Treatment with SIMPONI ARIA® resulted in the inhibition of the progression of structural joint damage and improvement in physical function associated with PsA at week 24. In the GO-ALIVE (AS) study, 73 percent of patients receiving SIMPONI ARIA®, compared with 26 percent of patients receiving placebo ($P < 0.001$), achieved at least a 20 percent improvement in the Assessment of Spondyloarthritis International Society criteria (ASAS20) at week 16. ACR20 and ASAS20 are standard measures used to assess clinical improvement in PsA and AS, respectively.

"Ankylosing spondylitis is a disease that adversely affects quality of life and the choices for treating this disabling condition are limited; The approval of IV golimumab for the treatment of active ankylosing spondylitis provides a welcomed new option," said Atul Deodhar, M.D., Professor of Medicine at the Oregon Health & Science University in Portland, and Chair of the GO-ALIVE steering committee. "The GO-ALIVE Phase 3 study demonstrated the efficacy of IV golimumab in reducing the signs and symptoms of disease, as well as improving

steering committee. "The GO-ALIVE Phase 3 study demonstrated the efficacy of IV golimumab in reducing the signs and symptoms of disease, as well as improving physical function and quality of life in patients."

"Over the past 20+ years, Janssen has been pioneers in addressing the unmet needs of patients living with rheumatologic diseases like psoriatic arthritis and ankylosing spondylitis," said Andrew Greenspan, M.D., Vice President of Medical Affairs at Janssen Scientific Affairs, LLC. "SIMPONI ARIA® has been helping patients with rheumatoid arthritis since its approval in 2013. With today's FDA approvals, we are pleased to extend the benefits of SIMPONI ARIA® to adult patients living with active psoriatic arthritis or active ankylosing spondylitis. We know having all three indications is valuable to rheumatologists and for patients who prefer to have their treatment administered by their healthcare provider."

Janssen will work with payers, providers and pharmacy benefit managers to ensure SIMPONI ARIA® is broadly accessible for patients and that the cost for payers is competitive with currently available biologic therapies for PsA and AS. The Janssen CarePath Savings Program offers an affordability option for SIMPONI ARIA®, where eligible commercial patients pay just $5 for each infusion for SIMPONI ARIA® medication costs. See full details and eligibility requirements here.

About GO-VIBRANT

The Phase 3, multicenter, randomized, double-blind, placebo-controlled GO-VIBRANT study was designed to evaluate the efficacy and safety of SIMPONI ARIA® in biologic-naïve adult patients with active PsA. Patients (n=480) were randomized one-to-one to receive SIMPONI ARIA® 2 mg/kg at weeks 0 and 4, and then every 8 weeks thereafter or placebo at weeks 0, 4, 12 and 20 with crossover to SIMPONI ARIA® at week 24. Patients who were on stable doses of methotrexate (MTX) were allowed to enroll in the study and remained on MTX during the double-blind phase. The primary endpoint was ACR20 response at week 14. Multiplicity-controlled endpoints at week 14 or 24 included ACR50, ACR70, at least a 75 percent improvement in the Psoriasis Area Severity Index (PASI 75) and change from baseline in Health Assessment Questionnaire Disability Index (HAQ-DI), enthesitis, dactylitis, van der Heijde Sharps (vdH-S) and Short Form (SF)-36 Physical Component (PC)/Mental Component (MC) scores. The study continued through 60 weeks.

About GO-ALIVE

The Phase 3, multicenter, randomized, double-blind, placebo-controlled GO-ALIVE study was designed to evaluate the efficacy and safety of SIMPONI ARIA® in adult patients with active AS. Patients (n=208) were randomized one-to-one to receive SIMPONI ARIA® 2 mg/kg at weeks 0 and 4, and then every 8 weeks thereafter or placebo at weeks 0, 4 and 12, with crossover to SIMPONI ARIA® at week 16. The primary endpoint was ASAS20 response at week 16. Multiplicity-controlled

placebo at weeks 0, 4 and 12, with crossover to SIMPONI ARIA® at week 16. The primary endpoint was ASAS20 response at week 16. Multiplicity-controlled endpoints at week 16 included ASAS40, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI50), Bath Ankylosing Spondylitis Functional Index (BASFI), ASAS partial remission, Bath Ankylosing Spondylitis Metrology Index (BASMI), Ankylosing Spondylitis Quality of Life (ASQoL), and SF-36 PC/MC scores. The study continued through 60 weeks.

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, immune-mediated inflammatory disease characterized by both joint inflammation and the skin lesions associated with psoriasis.[1],[2] It is estimated that at least one million Americans are living with PsA, and up to 30 percent of patients living with psoriasis can develop PsA.[3] 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.[1] Though the exact cause of PsA is unknown, genes, the immune system and environmental factors are all believed to play a role in the onset of the disease.[1]

About Ankylosing Spondylitis

Ankylosing spondylitis (AS) is a chronic, immune-mediated disease of the axial skeleton, affecting the sacroiliac joints and the spine. AS frequently also causes enthesitis, which is 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 spondyloarthritis.[4] It is estimated that 700,000 people in the U.S. are living with AS.[5] Peripheral joint involvement (in particular, hips and shoulders) can occur. Other organs can also be involved, including the eyes (uveitis), heart and aorta, and lungs. The disease affects men more often than women and typically manifests in early adulthood.[6] In contrast to mechanical low back pain, low back pain and stiffness with AS worsen after a period of rest or upon waking up in the morning and improve after exercise, a hot bath or a shower.[6]

About SIMPONI ARIA® (golimumab) infusion

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 MTX, active PsA or active AS. SIMPONI ARIA® is approved in 22 countries, including the U.S.

More information about SIMPONI ARIA® is available at www.SimponiARIA.com.

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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 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

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

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/JanssenUS or 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 product development. 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. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in product research and development, including the uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for new products or new indications; 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 January 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including in the section captioned "Cautionary Note Regarding Forward-Looking Statements," 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. Neither Janssen Biotech, Inc. 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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References

[1] National Center for Biotechnology Information, U.S. National Library of Medicine. Managing Patients with Psoriatic Disease: The Diagnosis and Pharmacologic Treatment of Psoriatic Arthritis in Patients with Psoriasis. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3958815/. Accessed October 2017.

[2] Mayo Clinic. Psoriatic Arthritis. http://www.mayoclinic.org/diseases-conditions/psoriatic-arthritis/home/ovc-20233896. Accessed October 2017.

[3] National Center for Biotechnology Information, U.S. National Library of Medicine. Rachakonda, Schupp and Armstrong. Psoriasis prevalence among adults in the United States. https://www.ncbi.nlm.nih.gov/pubmed/24388724. Accessed October 2017

[4] Arthritis Foundation. Arthritis By The Numbers: Book of Trusted Fact and Figures. http://www.arthritis.org/Documents/Sections/About-Arthritis/arthritis-facts-stats-figures.pdf. Accessed October 2017.

[5] National Center for Biotechnology Information, U.S. National Library of Medicine. Reveille. Epidemiology of Spondyloarthritis in North America. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3063892/. Accessed October 2017.

[6] Mayo Clinic. Ankylosing Spondylitis. http://www.mayoclinic.org/diseases-conditions/ankylosing-spondylitis/basics/definition/con-20019766?p=1. Accessed

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3063892/. Accessed October 2017.

[6] Mayo Clinic. Ankylosing Spondylitis. http://www.mayoclinic.org/diseases-conditions/ankylosing-spondylitis/basics/definition/con-20019766?p=1. Accessed October 2017.

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