News Release

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Janssen Highlights Data from Rheumatology Portfolio During the American College of Rheumatology Convergence 2020 Virtual Scientific Program

Thirty-five abstracts with clinical trial data to be presented, featuring findings across psoriatic arthritis (PsA), rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE)

Sixteen abstracts focus on TREMFYA® (guselkumab) in adults with active PsA, including 52-week safety and efficacy data, spinal disease-related endpoints, as well as analyses that highlight patient-reported outcome measures including fatigue

SPRING HOUSE, PENNSYLVANIA, November 5, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the latest research from its expanding rheumatology portfolio will be presented at the American College of Rheumatology (ACR) Convergence 2020 Virtual Scientific Program (#ACR20) from November 5 – 9.

"The extensive data presented at this year's ACR virtual meeting reinforce the breadth and depth of Janssen's rheumatology portfolio, underscoring our long standing commitment to understanding rheumatic disease and advancing new treatments for people living with these chronic conditions," said Andrew Greenspan, M.D., Vice President, Immunology Medical Affairs, Janssen Scientific Affairs, LLC. "Among the many highlights at this year's conference, we're pleased to build on the growing body of clinical evidence for TREMFYA in PsA and look forward to presenting 52-week safety and efficacy data, efficacy in spinal disease-related endpoints and improvement in the patient-reported outcome measure FACIT-Fatigue."

A focus for this year's meeting is to demonstrate the extensive clinical evidence for TREMFYA® (guselkumab), the first approved selective IL-23 inhibitor for adult patients with active PsA. TREMFYA is the first and only treatment approved for active psoriatic arthritis to have improvement in fatigue as measured by the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) Scale included in the U.S. Prescribing Information.

Key data to be presented span DISCOVER-1 and -2 abstracts centered around efficacy and safety through one year, a deeper look at fatigue as well as spinal disease-related endpoints. Additional details on these abstracts can be found below. All presentation times are Eastern Standard Time (EST).

- *An oral presentation (#0506) about the efficacy and safety of TREMFYA through week 52 in biologic-naïve patients with active psoriatic arthritis, from the pivotal DISCOVER-2 Phase 3 clinical trial. This oral presentation is scheduled for Friday, Nov. 6 from 3:30-3:40 p.m.*
- *An oral presentation (#2025) discussing the efficacy of TREMFYA on axial-related endpoints in patients with active PsA who have imaging-confirmed sacroiliitis at 52 weeks (DISCOVER-1 and -2). This oral presentation is scheduled for Monday, Nov. 9 from 11:20-11:30 a.m.*

- *Poster presentations outlining additional analyses from both DISCOVER-1 and-2 on the impact of TREMFYA on fatigue reduction over 52 weeks (#0347), pooled safety results through one year (#0349) and the sustained reduction in acute phase proteins and Th17 effector cytokines in PsA (#0367). These posters are all scheduled for presentation on Friday, Nov. 6 from 9-11 a.m.*

Other presentations feature new research across the portfolio of Janssen medications including SIMPONI ARIA® (golimumab), STELARA® (ustekinumab) and REMICADE® (infliximab).

A complete list of data presentations is provided in the table below. Abstracts can be accessed on the ACR 2020 Annual Meeting website at: https://acrabstracts.org/.

ABSTRACT NO.	TITLE	DATE/TIME (EST)
TREMFYA® (guselkumab)		
Poster #0332	Guselkumab Improved Work Productivity and Daily Activity in Patients With Psoriatic Arthritis: Results From a Phase 3 Trial	Friday, Nov. 6, 9-11 a.m.
Poster #0334	Comparative Efficacy of Guselkumab in Patients with Psoriatic Arthritis: Results from Systematic Literature Review and Network Meta-Analysis	Friday, Nov. 6, 9-11 a.m.
Poster #0347	In Two Phase-3 Trials, Guselkumab Reduced Fatigue over 52 Weeks in Patients with Psoriatic Arthritis and Demonstrated Independent Treatment Effects on Fatigue After Adjustment for Clinical Response (ACR20)	Friday, Nov.6, 9-11 a.m.
Poster #0349	Pooled Safety Results of Two Phase-3 Trials of Guselkumab in Patients with Psoriatic Arthritis Through 1 Year	Friday, Nov. 6, 9-11 a.m.
Poster #0355	Collagen Turnover Markers are Associated with Active Psoriatic Arthritis and Decrease with Guselkumab Treatment in a Phase-3 Clinical Trial	Friday, Nov. 6, 9-11 a.m.
Poster #0362	Patients with Psoriatic Arthritis Treated with Guselkumab Achieved Psoriasis-Related Symptom-Free State and Had No Skin	Friday, Nov. 6, 9-11 a.m.

	Condition Impact on Their Health-Related Quality of Life	
Poster #0367	Guselkumab Induces Sustained Reduction in Acute Phase Proteins and Th17 Effector Cytokines in Active Psoriatic Arthritis in 2 Phase-3 Clinical Studies (DISCOVER-1 and DISCOVER-2)	Friday, Nov. 6, 9-11 a.m.
Poster #0370	Guselkumab-Treated Patients Achieved Clinically Meaningful Improvement in Systemic Symptoms as Measured with PROMIS Instrument: Results from Phase-3 Trial DISCOVER-1	Friday, Nov. 6, 9-11 a.m.
Oral #0506	Efficacy and Safety of Guselkumab, a Monoclonal Antibody Specific to the p19-Subunit of Interleukin-23, Through Week 52 of a Phase 3, Randomized, Double-blind, Placebo-controlled Study Conducted in Biologic-naïve Patients with Active Psoriatic Arthritis	Friday, Nov. 6, 3:30-3:40 p.m.
Poster #0888	Guselkumab Efficacy and Safety in TNF-Inhibitor-Experienced and TNF-Inhibitor-Naïve Patients With Active PsA: 1-Year Results of a Phase 3, Randomized, Controlled Study	Saturday, Nov. 7, 9-11 a.m.
Poster #0891	Four-year efficacy and safety of guselkumab in psoriasis patients with and without psoriatic arthritis: a pooled analysis from VOYAGE 1 and VOYAGE 2	Saturday, Nov. 7, 9-11 a.m.
Poster #0895	Effects of Guselkumab, a Monoclonal Antibody That Specifically Binds to the p19-Subunit of Interleukin-23, on Dactylitis and Enthesitis in Patients with Active Psoriatic Arthritis: Pooled Results through Week 24 from Two Phase 3 studies	Saturday, Nov. 7, 9-11 a.m.
Poster #0908	Guselkumab Efficacy in Adult Patients With Active Psoriatic Arthritis by Baseline Demographic and Disease Characteristics: Pooled Results of Two Phase 3, Randomized, Placebo-Controlled Studies	Saturday, Nov. 7, 9-11 a.m.
Poster #1344	Guselkumab, an IL-23 Inhibitor That Specifically Binds to the IL23p19-Subunit, for Active Psoriatic Arthritis: One Year Results of a Phase 3, Randomized, Double-blind, Placebo-controlled Study of Patients who Were Biologic-Naïve or TNFα Inhibitor-Experienced	Sunday, Nov. 8, 9-11 a.m.
Poster #1349	Guselkumab Provides Domain-Specific and Comprehensive Efficacy As Assessed Using	Sunday, Nov. 8, 9-11 a.m.

	Composite Endpoints in Patients with Active Psoriatic Arthritis	
Oral #2025	Efficacy of Guselkumab, a Monoclonal Antibody that Specifically Binds to the p19 Subunit of IL-23, on Axial-Related Endpoints in Patients with Active PsA with Imaging-Confirmed Sacroiliitis: Week-52 Results from Two Phase 3, Randomized, Double-blind, Placebo-controlled Studies	Monday, Nov. 9, 11:20-11:30 a.m.
Psoriatic Arthritis (PsA) Data		
Poster #0325	The Impact of PsA Disease Control Status on Patient Treatment Satisfaction: Real-world Survey in US and Europe	Friday, Nov. 6, 9-11 a.m.
Poster #0326	Flares Among Patients with Psoriatic Arthritis (PsA) - Frequency and Impact on Patient Outcomes: Real-world Survey in the US and Europe	Friday, Nov. 6, 9-11 a.m.
Poster #0327	Skin involvement in psoriatic arthritis (PsA) - The incremental impact of psoriasis on quality of life, disability and work productivity: Real-world survey in US and Europe	Friday, Nov. 6, 9-11 a.m.
Poster #0328	Healthcare Utilization and Costs among Patients with Psoriatic Arthritis and Psoriasis in the United States – A Retrospective Study of Claims Data from 2009 to 2020	Friday, Nov. 6, 9-11 a.m.
Poster #0331	Work Absenteeism and Disability Associated with Psoriatic Arthritis and Psoriasis in the United States – A Retrospective Study of Claims Data from 2009 to 2020	Friday, Nov. 6, 9-11 a.m.
Poster #0336	Anxiety and Depression in Psoriatic Arthritis (PsA) - Prevalence and Impact on Patient Reported Outcomes: Real-World Survey in the US and Europe	Friday, Nov. 6, 9-11 a.m.
Poster #0359	Clinical Characteristics of Psoriatic Arthritis Patients with Physician-Reported Axial Disease by HLA-B27 Status: An Analysis from the Corrona Psoriatic Arthritis/ Spondyloarthritis Registry	Friday, Nov. 6, 9-11 a.m.
Poster #1314	Fatigue in Psoriatic Arthritis (PsA): Prevalence in Patients from the US and Europe, and Impact on Quality of Life and Work Productivity	Sunday, Nov. 8, 9-11 a.m.
SIMPONI ARIA® (golimumab)		
Poster #0809	Comparative Effectiveness of IV Golimumab versus Dose Escalated Infliximab in a Real World Population of Rheumatoid Arthritis	Saturday, Nov. 7, 9-11 a.m.

	Patients: 52-Week Data from the AWARE Study	
Poster #1210	Patient-Reported Outcomes Measurement Information System (PROMIS) Assessment of Response to Treatment with Golimumab IV or Infliximab in Rheumatoid Arthritis Patients: Results from a Phase 4 Study	Sunday, Nov. 8, 9-11 a.m.
STELARA® (ustekinumab)		
Poster #0351	Ustekinumab-Treated Patients with Psoriatic Arthritis in a Real-world Study: Similar Clinical Responses and Treatment Persistence Over One Year in Elderly and Younger Patients	Friday, Nov. 6, 9-11 a.m.
Poster #1826	Maintenance of Efficacy and Safety and Reduction of BILAG Flares with Ustekinumab, an Interleukin-12/23 Inhibitor, in Patients with Active Systemic Lupus Erythematosus (SLE): 2-Year Results of a Phase 2, Randomized Placebo-Controlled, Crossover Study	Monday, Nov. 9, 9-11 a.m.
Poster #1831	Biomarkers Linked to Anti-IFN-I and Ustekinumab Suggest Distinct Mechanisms of Action in Systemic Lupus Erythematosus	Monday, Nov. 9, 9-11 a.m.
Systemic Lupus Erythematosus (SLE)		
Poster #0244	What Are the Early versus Late Predictors for Systemic Lupus Erythematosus (SLE) Diagnosis?	Friday, Nov. 6, 9-11 a.m.
Poster #0254	LLDAS (Low Lupus Disease Activity State) and Remission Prevent Damage Accrual in Systemic Lupus Erythematosus (SLE) Patients in a Primarily Mestizo Cohort	Friday, Nov. 6, 9-11 a.m.
Poster #0268	Impact of Flares on Healthcare Resource Usage and PROs in Systemic Lupus Erythematosus Patients	Friday, Nov. 6, 9-11 a.m.
Poster #1272	Impact of Remission and Low Disease Activity Status on Hospitalizations among SLE Patients from the GLADEL Latin American Cohort	Sunday, Nov. 8, 9-11 a.m.
Poster #1282	The impact of High Disease Activity as Measured by SLEDAI and Drug Burden on Healthcare Utilization, Quality of Life and Work Productivity in Systemic Lupus Erythematosus Patients	Sunday, Nov. 8, 9-11 a.m.
Poster #1834	Biomarker Analysis of IFN-I Modulation in JNJ-839 First-in-Human Study for Systemic Lupus Erythematosus	Monday, Nov. 9, 9-11 a.m.

About Psoriatic Arthritis (PsA)

Psoriatic arthritis affects about 1.5 million Americans.[1] Studies show that up to 30 percent of the more than eight million Americans living with psoriasis will also develop PsA.[2] There is currently no cure for the disease and, despite available treatments, many people living with PsA are still searching for more options that can help alleviate their symptoms and provide some relief.

Psoriatic arthritis is a chronic, progressive, immune-mediated disease characterized by joint inflammation, enthesitis (inflammation where the bone, tendon and ligament meet), dactylitis (severe inflammation of the digits of the hands and feet), axial disease (pain in the axial skeleton, primarily in the spine, hips and shoulders) and the skin lesions associated with psoriasis.[3] The disease commonly appears between the ages of 30 and 50 but can develop at any time.[4] 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.[4] Without early recognition, diagnosis and treatment, the disease can continue to progress.[4]

About Rheumatoid Arthritis (RA)

Rheumatoid arthritis is a chronic, systemic inflammatory condition that is often characterized by symptoms that include pain, stiffness and inflammation of the joints, which can lead to joint destruction and disability.[5] An estimated 1.5 million Americans have the condition, which affects nearly three times as many women as men.[6] While the cause of RA is unknown, many cases are believed to result from genetic and environmental factors.[5] There is no medical cure for RA, but there are numerous medications available to help alleviate symptoms and prevent joint destruction.

About Systemic Lupus Erythematosus (SLE)

Lupus is a chronic, inflammatory autoimmune disease that can affect many different body systems, including joints, skin, heart, lungs, kidneys and brain.[7] SLE can range from mild to severe and is characterized by inflammation of any organ

system and complex auto-antibody production (antibodies directed against normal human tissue).[8] The disease most often affects women and disproportionately affects women of African American, Hispanic, Asian and Native American descent compared to Caucasian women.[9] Incidence rates in the United States are estimated at 5.6 cases per 100,000. Lupus is estimated to affect at least 5 million people worldwide.[10]

About the DISCOVER Development Program

DISCOVER-1 and DISCOVER-2 are Phase 3 randomized, double-blind, placebo-controlled studies that evaluated the safety and efficacy of TREMFYA in 1,120 adult patients with active PsA who had inadequate response to standard therapies. In DISCOVER-1, approximately 31 percent of patients had been previously treated with up to two anti-TNF-alpha agents whereas in DISCOVER2 all patients were naïve to biologic therapy. Approximately 58 percent of patients from both studies had concomitant methotrexate (MTX) use.

The DISCOVER-1 study showed that in patients who received TREMFYA 100 mg every 8 weeks after two starter doses, 52 percent achieved an ACR20 response versus 22 percent treated with placebo ($p < 0.0001$), with a comparable response irrespective of prior TNF exposure. In DISCOVER-2, 64 percent of patients who received TREMFYA every 8 weeks achieved an ACR20 response, versus 33 percent treated with placebo ($p < 0.0001$).

TREMFYA was also shown to relieve patients' pain in their soft tissue and inflammation in their fingers and toes. In a pre-specified pooled analysis of DISCOVER-1 and -2 at week 24, treatment with TREMFYA every 8 weeks resolved enthesitis in 50 percent of patients, versus 29 percent in patients receiving placebo ($p=0.0301$). In another pre-specified pooled analysis at week 24, treatment with TREMFYA every 8 weeks also resolved dactylitis in 59 percent of patients, versus 42 percent receiving placebo ($p=0.0301$).

Beyond its impact on improving symptoms of PsA in joints, among patients with psoriatic skin involvement, TREMFYA also resulted in an improvement in the skin manifestations of psoriasis in patients with PsA.

About TREMFYA® (guselkumab)

Developed by Janssen, TREMFYA is the first approved human monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor. TREMFYA is approved in the U.S., Canada, the European Union, Japan and a number of other countries worldwide for the treatment of adult patients with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet [UV] light). It is approved as a prescription medicine in the U.S., Canada, Japan and Brazil for the treatment of adult patients with active PsA, and the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending its expanded use for the treatment of adult patients with active PsA in the European Union (EU).[11] A final decision from the European Commission (EC) regarding PsA indication expansion is expected later this year. IL-23 is an important driver of the pathogenesis of inflammatory diseases such as psoriasis and PsA.[12]

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to TREMFYA.

TREMFYA® (guselkumab) Important Safety Information

What is the most important information I should know about TREMFYA®?

TREMFYA® is a prescription medicine that may cause serious side effects, including:

- **Serious Allergic Reactions**. Stop using TREMFYA® and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:
    - fainting, dizziness, feeling lightheaded (low blood pressure)
    - swelling of your face, eyelids, lips, mouth, tongue or throat
    - trouble breathing or throat tightness

    - chest tightness
    - skin rash, hives
    - itching

- **Infections**. TREMFYA® may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with TREMFYA® and may treat you for TB before you begin treatment with TREMFYA® if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with TREMFYA®.

Tell your healthcare provider right away if you have an infection or have symptoms of an infection, including:

- fever, sweats, or chills
- muscle aches
- weight loss
- cough
- warm, red, or painful skin or sores on your body different from your psoriasis
- diarrhea or stomach pain
- shortness of breath
- blood in your phlegm (mucus)
- burning when you urinate or urinating more often than normal

Do not take TREMFYA® if you have had a serious allergic reaction to guselkumab or any of the ingredients in TREMFYA®.

Before using TREMFYA®, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section **"What is the most important information I should know about TREMFYA®?"**
- have an infection that does not go away or that keeps coming back.
- have TB or have been in close contact with someone with TB.

- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with TREMFYA®.
- are pregnant or plan to become pregnant. It is not known if TREMFYA® can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TREMFYA® passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of TREMFYA®?

TREMFYA may cause serious side effects. See "What is the most important information I should know about TREMFYA®?"

The most common side effects of TREMFYA® include: upper respiratory infections, headache, injection site reactions, joint pain (arthralgia), diarrhea, stomach flu (gastroenteritis), fungal skin infections and herpes simplex infections.

These are not all the possible side effects of TREMFYA®. Call your doctor for medical advice about side effects.

Use TREMFYA® exactly as your healthcare provider tells you to use it.

Please read the full Prescribing Information, including Medication Guide for TREMFYA®, and discuss any questions that 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 SIMPONI ARIA® (golimumab)

SIMPONI ARIA is approved for the treatment of adults with moderately to severely active RA, adults with active ankylosing spondylitis (AS), patients 2 years of age

and older with active PsA, and pediatric patients 2 years of age and older with polyarticular juvenile idiopathic arthritis (pJIA). SIMPONI ARIA is currently approved in 24 countries, including the U.S.

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 intravenous 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 BSA-based dosage regimen is 80 mg/m2 given as an intravenous 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.

Janssen Biotech, Inc. discovered and developed SIMPONI ARIA.

SIMPONI ARIA® (golimumab) 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® and during treatment with SIMPONI ARIA®. Even if your TB test is 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, 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, or call 1-800-FDA-1088.

About STELARA® (ustekinumab)

STELARA (ustekinumab), a human IL-12 and IL-23 antagonist, is approved in the United States for the treatment of: 1) adults and children six years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy; 2) adult patients (18 years or older) with active psoriatic arthritis, used alone or in combination with methotrexate (MTX); 3) adult patients (18 years and older) with moderately to severely active Crohn's disease; 4) adult patients (18 years and older) with moderately to severely active ulcerative colitis.

STELARA® (ustekinumab) IMPORTANT SAFETY INFORMATION

STELARA® is a prescription medicine that affects your immune system. STELARA® can increase your chance of having serious side effects including:

Serious Infections

STELARA® may lower your ability to fight infections and may increase your risk of infections. While taking STELARA®, some people have serious infections, which may require hospitalization, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses.

- Your doctor should check you for TB before starting STELARA® and watch you closely for signs and symptoms of TB during treatment with STELARA®.
- If your doctor feels that you are at risk for TB, you may be treated for TB before and during treatment with STELARA®.

You should not start taking STELARA® if you have any kind of infection unless your doctor says it is okay.

Before starting STELARA®, tell your doctor if you:

- think you have an infection or have symptoms 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 often than normal
    - feel very tired
- are being treated for an infection.
- get a lot of infections or have infections that keep coming back.
- have TB, or have been in close contact with someone with TB.

After starting STELARA®, call your doctor right away if you have any symptoms of an infection (see above). STELARA® can make you more likely to get infections or make an infection that you have worse. People who have a genetic problem where the body does not make any of the proteins interleukin 12 (IL-12)

and interleukin 23 (IL-23) are at a higher risk for certain serious infections that can spread throughout the body and cause death. People who take STELARA® may also be more likely to get these infections.

Cancers

STELARA® may decrease the activity of your immune system and increase your risk for certain types of cancer. Tell your doctor if you have ever had any type of cancer. Some people who had risk factors for skin cancer developed certain types of skin cancers while receiving STELARA®. Tell your doctor if you have any new skin growths.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS)

RPLS is a rare condition that affects the brain and can cause death. The cause of RPLS is not known. If RPLS is found early and treated, most people recover. Tell your doctor right away if you have any new or worsening medical problems including: headache, seizures, confusion, and vision problems.

Serious Allergic Reactions

Serious allergic reactions can occur. Stop using STELARA® and get medical help right away if you have any symptoms of a serious allergic reaction such as: feeling faint, swelling of your face, eyelids, tongue, or throat, chest tightness, or skin rash.

Lung Inflammation

Cases of lung inflammation have happened in some people who receive STELARA® and may be serious. These lung problems may need to be treated in a hospital. Tell your doctor right away if you develop shortness of breath or a cough that doesn't go away during treatment with STELARA®.

Before receiving STELARA, tell your doctor about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed above for serious infections, cancers, or RPLS.
- ever had an allergic reaction to STELARA® or any of its ingredients. Ask your doctor if you are not sure.
- are allergic to latex. The needle cover on the prefilled syringe contains latex.
- have recently received or are scheduled to receive an immunization (vaccine). People who take STELARA® should not receive live vaccines. Tell your doctor if anyone in your house needs a live vaccine. The viruses used in some types of live vaccines can spread to people with a weakened immune system, and can cause serious problems. **You should not receive the BCG vaccine during the one year before receiving STELARA® or one year after you stop receiving STELARA®.**
- have any new or changing lesions within psoriasis areas or on normal skin.
- are receiving or have received allergy shots, especially for serious allergic reactions.
- receive or have received phototherapy for your psoriasis.
- are pregnant or plan to become pregnant. It is not known if STELARA® can harm your unborn baby. You and your doctor should decide if you will receive STELARA®.
- are breastfeeding or plan to breastfeed. It is thought that STELARA® passes into your breast milk. Talk to your doctor about the best way to feed your baby if you receive STELARA®.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

When prescribed STELARA®:

- Use STELARA® exactly as your doctor tells you to.
- STELARA® is intended for use under the guidance and supervision of your doctor. In children 12 years and older, it is recommended that STELARA® be

administered by a healthcare provider. If your doctor decides that you or a caregiver may give your injections of STELARA® at home, you should receive training on the right way to prepare and inject STELARA®. Your doctor will determine the right dose of STELARA® for you, the amount for each injection, and how often you should receive it. Do not try to inject STELARA® yourself until you or your caregiver have been shown how to inject STELARA® by your doctor or nurse.

Common side effects of STELARA® include: nasal congestion, sore throat, and runny nose, upper respiratory infections, fever, headache, tiredness, itching, nausea and vomiting, redness at the injection site, vaginal yeast infections, urinary tract infections, sinus infection, stomach pain, and diarrhea. These are not all of the possible side effects with STELARA®. Tell your doctor about any side effect that you experience. Ask your doctor or pharmacist for more information.

Please read the full Prescribing Information and Medication Guide for STELARA® 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 REMICADE® (infliximab)

REMICADE was the first anti- TNF-alpha treatment approved in the United States in August 1998 and the first TNF inhibitor to be approved in three different therapeutic areas: gastroenterology, rheumatology and dermatology. REMICADE has demonstrated broad clinical utility with indications in Crohn's disease, rheumatoid arthritis (RA), ankylosing spondylitis, psoriatic arthritis, ulcerative colitis (UC), pediatric Crohn's disease and psoriasis. The safety and efficacy of REMICADE have been well established in clinical trials over the past 17 years and through commercial experience with more than 2.7 million patients treated worldwide.

In the U.S., REMICADE is approved for the following indications:

Crohn's Disease:

- Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- Reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease.

Pediatric Crohn's Disease:

- Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

Ulcerative Colitis:

- Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis:

- Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy.

Rheumatoid Arthritis in combination with methotrexate:

- Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease.

Ankylosing Spondylitis:

- Reducing signs and symptoms in patients with active disease.

Psoriatic Arthritis:

- Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function.

Plaque Psoriasis:

- Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

Janssen Biotech, Inc. discovered and developed REMICADE and markets the product in the United States. The Janssen Pharmaceutical Companies market REMICADE in Canada, Central and South America, the Middle East, Africa and Asia Pacific.

In Japan, Indonesia, and Taiwan, Janssen Biotech, Inc. licenses distribution rights to REMICADE to Mitsubishi Tanabe Pharma Corporation. In Europe, Russia and Turkey, Janssen Biotech, Inc. licenses distribution rights to REMICADE to Schering-Plough (Ireland) Company, a subsidiary of Merck & Co, Inc.

REMICADE® (INFLIXIMAB) IMPORTANT SAFETY INFORMATION

Only your doctor can recommend a course of treatment after checking your health condition. REMICADE® (infliximab) can cause serious side effects such as lowering your ability to fight infections. **Some patients, especially those 65 years and older, have had serious infections which include tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body or caused infections in certain areas (such as skin). Some of these infections have been fatal. Your doctor should monitor you closely for signs and symptoms of TB during treatment with REMICADE®.**

Unusual cancers have been reported in children and teenage patients taking tumor necrosis factor (TNF) blocker medicines. Hepatosplenic T-cell lymphoma, a rare form of fatal lymphoma, has occurred mostly in male teenagers or young men with Crohn's disease or ulcerative colitis who were taking REMICADE® and azathioprine or 6-mercaptopurine. For children and adults taking TNF blockers, including REMICADE®, the chances of getting lymphoma or other cancers may increase. You should discuss any concerns about your health and medical care with your doctor.

It is not known if REMICADE® is safe and effective in children under 6 years of age.

What should I tell my doctor before I take REMICADE®?

You should let your doctor know if you have or ever had any of the following:

- Tuberculosis (TB) or have been near someone who has TB. Your doctor will check you for TB with a skin test. If you have latent (inactive) TB, you will begin TB treatment before you start REMICADE®.
- Lived in a region where certain fungal infections like histoplasmosis or coccidioidomycosis are common.
- Infections that keep coming back, have diabetes or an immune system problem.
- Any type of cancer or a risk factor for developing cancer, for example, chronic obstructive pulmonary disease (COPD) or had phototherapy for psoriasis.
- Heart failure or any heart condition. Many people with heart failure should not take REMICADE®.
- Hepatitis B virus (HBV) infection or think you may be a carrier of HBV. Your doctor will test you for HBV.
- Nervous system disorders (like multiple sclerosis or Guillain-Barré syndrome).

Also tell your doctor if you:

- Use the medicines Kineret® (anakinra), Orencia® (abatacept) or Actemra® (tocilizumab) or other medicines called biologics used to treat the same problems as REMICADE®.
- Are pregnant, plan to become pregnant, are breast-feeding, or have a baby and were using REMICADE® during your pregnancy. Tell your baby's doctor about your REMICADE® use. If your baby receives a live vaccine within 6 months after birth, your baby may develop infections with serious complications that can lead to death.
- Recently received or are scheduled to receive a vaccine. Adults and children taking REMICADE® should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer) while taking REMICADE®.

What should I watch for and talk to my doctor about before or while taking REMICADE®?

The following serious (sometimes fatal) side effects have been reported in people taking REMICADE®.

You should tell your doctor right away if you have any of the signs listed below:

- **Serious infections (like TB, blood infections, pneumonia)**—fever, tiredness, cough, flu-like symptoms, or warm, red or painful skin or any open sores. REMICADE® can make you more likely to get an infection or make any infection that you have worse.
- **Reactivation of HBV**—feeling unwell, poor appetite, tiredness, fever, skin rash and/or joint pain.
- **Lymphoma, or any other cancers in adults and children.**
- **Skin cancer**—any changes in or growths on your skin.
- **Cervical cancer**—your doctor may recommend that you be regularly screened. Some women with rheumatoid arthritis, particularly those over 60, have developed cervical cancer.

- **Heart failure**—new or worsening symptoms, such as shortness of breath, swelling of ankles or feet, or sudden weight gain.
- **Other heart problems within 24 hours of infusion, including heart attack, low blood flow to the heart, or abnormal heart rhythm**—chest discomfort or pain, arm pain, stomach pain, shortness of breath, anxiety, lightheadedness, dizziness, fainting, sweating, nausea, vomiting, fluttering or pounding in your chest, and/or a fast or a slow heartbeat.
- **Liver injury**—jaundice (yellow skin and eyes), dark brown urine, pain on the right side of your stomach area, fever, or severe tiredness.
- **Blood problems**—fever that doesn't go away, bruising, bleeding or severe paleness.
- **Nervous system disorders**—changes in your vision, numbness or tingling in any part of your body, seizures, or weakness in your arms or legs.
- **Stroke within 24 hours of infusion**—numbness or weakness of the face, arm or leg, especially on one side of the body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking; dizziness; loss of balance or coordination; or a sudden, severe headache.
- **Allergic reactions during or after infusion**—hives, difficulty breathing, chest pain, high or low blood pressure, and fever or chills.
- **Delayed allergic reactions (3 to 12 days after infusion)**—fever, rash, headache, sore throat, muscle or joint pain, swelling of the face and hands, or difficulty swallowing.
- **Lupus-like syndrome**—chest discomfort or pain that does not go away, shortness of breath, joint pain, rash on the cheeks or arms that gets worse in the sun.
- **Psoriasis**—new or worsening psoriasis such as red scaly patches or raised bumps on the skin that are filled with pus.

The more common side effects of REMICADE® include respiratory infections (such as sinus infections and sore throat), headache, coughing and stomach pain.

Please read the full Prescribing Information and Medication Guide for REMICADE® 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 Janssen 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 and www.twitter.com/JanssenUS. Janssen Research & Development, LLC, Janssen Biotech, Inc. and Janssen Scientific Affairs, 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 the ongoing and planned development efforts involving SIMPONI ARIA®, REMICADE®, TREMFYA® and STELARA®. 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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