



News Release

Media contacts:

Kellie McLaughlin
Mobile: 609-468-8356
kmclaugh@its.jnj.com

Camilia Aberra
Mobile: 267-303-3857
caberra@its.jnj.com

Investor Contacts:

Christopher DelOrefice
Johnson & Johnson
Office: 732-524-2955

Lesley Fishman
Johnson & Johnson
Office: 732-524-3922

JANSSEN TO HIGHLIGHT DATA FROM BROAD RHEUMATOLOGY PORTFOLIO AT THE 2018 ANNUAL MEETING OF THE AMERICAN COLLEGE OF RHEUMATOLOGY

One-Year Results from Phase 2 Study Evaluating STELARA® (ustekinumab) in Patients with Active Systemic Lupus Erythematosus Featured in a Plenary Presentation

Twenty Presentations from Approved and Pipeline Products Provide Real-World, Treatment and Disease Insights Across Multiple Immune-Mediated Diseases

Chicago, IL., October 11, 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that it will be presenting results from 20 abstracts across the company's rheumatology portfolio and pipeline products during the 2018 American College of Rheumatology (ACR)/Association for Rheumatology Health Professionals (ARHP) Annual Meeting taking place in Chicago, IL, from October 19 – 24. New results from a Phase 2 trial evaluating STELARA® (ustekinumab) in patients with active systemic lupus erythematosus (SLE) treated through one year will be presented in a plenary presentation on Tuesday, October 23, with additional data from that study also featured as an oral presentation. Data from a Phase 3 study of SIMPONI ARIA® (golimumab) administered intravenously in patients with active psoriatic arthritis will also be featured in an oral presentation at the meeting.

These results highlight the depth and breadth of the Janssen rheumatology portfolio, advancing the understanding of the safety and efficacy of SIMPONI ARIA and STELARA, as well as TREMFYA® (guselkumab) across multiple immune-mediated diseases, including moderately-to-severely active rheumatoid arthritis (RA), SLE, moderate-to-severe plaque psoriasis (PsO), active psoriatic arthritis (PsA) and active ankylosing spondylitis (AS).

Beyond data from clinical programs, Janssen will also present findings from the real-world evidence AWARE trial (Comparative and Pragmatic Study of Golimumab IV Versus Infliximab in Rheumatoid Arthritis), which provides greater understanding of the use of SIMPONI ARIA in the standard clinical settings in RA. AWARE is an ongoing prospective Phase 4 comparator study designed to provide a real-world assessment of SIMPONI ARIA and REMICADE® (infliximab) in

patients with RA and part of Janssen's growing focus on leveraging real world evidence to better understand treatment effectiveness in the clinical practice setting and the patient treatment experience.

"The broad range of data being presented at this year's annual meeting spans the spectrum from clinical investigational studies to real world evidence about our marketed products like SIMPONI ARIA in clinical practice settings," said Andrew Greenspan, M.D., Vice President, Medical Affairs Immunology, Janssen Scientific Affairs, LLC. "These studies build on our longstanding heritage of innovation in rheumatology and help further our understanding of potential new treatment pathways in diseases like lupus, where there is significant unmet patient need."

JANSSEN ABSTRACTS TO BE PRESENTED DURING ACR INCLUDE:

Abstracts can be accessed on the ACR 2018 Annual Meeting website at: <http://acrabstracts.org/>.

Abstract No.	Title	Date/Time
STELARA (ustekinumab)		
Abstract 636	Remission/low disease activity is a reasonable treatment target in PsA: Results from a routine care European cohort of PsA patients treated with ustekinumab or TNF inhibitors	Poster presentation Sunday, October 21, 2018 9:00 AM - 11:00 AM
Abstract 2557	Efficacy of ustekinumab on spondylitis-associated endpoints in TNF-naïve active psoriatic arthritis patients with physician-reported spondylitis	Poster presentation Tuesday, October 23, 2018 9:00 AM - 11:00 AM
Abstract 2658	Real world medication use in incident systemic lupus erythematosus and lupus nephritis patients	Poster presentation Tuesday, October 23, 2018 9:00 AM - 11:00 AM
Abstract 2643	SLEDAI-2K responder index-50 is effective in demonstrating partial response in a phase 2, randomised placebo-controlled study of ustekinumab in patients with active systemic lupus erythematosus	Poster presentation Tuesday, October 23, 2018 9:00 AM - 11:00 AM
Abstract 2785	Efficacy and safety of ustekinumab, an interleukin-12/23 inhibitor, in patients with active systemic lupus erythematosus: 1-year results of a phase 2, randomised placebo-controlled, crossover study	Plenary presentation Tuesday, October 23, 2018 11:00 AM - 12:30 PM
Abstract 2951	Ustekinumab treatment response in SLE is associated with changes in type II but not type I interferons	Oral presentation Wednesday, October 24, 2018 11:00 AM - 12:30 PM
SIMPONI ARIA (golimumab) infusion		
Abstract 1517	Integrated safety analysis across Phase 3 clinical studies including the controlled and uncontrolled periods for intravenous golimumab in rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis	Poster Presentation Monday, October 22, 2018 9:00 AM - 11:00 AM
Abstract 2552	Fatigue in psoriatic arthritis patients treated with intravenous golimumab: early improvement is associated with Week 24	Poster Presentation Tuesday, October 23, 2018 9:00 AM - 11:00 AM

	outcomes in ACR 20, 50, and health-related quality of life	
Abstract 2567	Clinically meaningful improvement in skin and nail psoriasis in bio-naïve active psoriatic arthritis patients treated with intravenous golimumab: results through week 24 from a Phase 3 study	Poster Presentation Tuesday, October 23, 2018 9:00 AM - 11:00 AM
Abstract 2889	Inhibition of radiographic progression and correlation with changes in composite indices of disease activity in patients with active psoriatic arthritis treated with intravenous golimumab, as measured in a Phase III trial	Oral Presentation Tuesday, October 23, 2018 4:30 PM - 6:00 PM

AWARE Study Analyses

Abstract 571	United States rheumatology practice-based real-world evidence of methotrexate utilization and response to therapy in rheumatoid arthritis patients treated with intravenous golimumab	Poster Presentation Sunday, October 21, 2018 9:00 AM - 11:00 AM
Abstract 2475	PROMIS pain interference 6b and fatigue 7a short forms and PROFILE-29 in rheumatoid arthritis patients treated with TNF inhibitors	Poster Presentation Tuesday, October 23, 2018 9:00 AM - 11:00 AM
Abstract 2490	Real world evidence describing infliximab utilization patterns in rheumatoid arthritis patients in community rheumatology practices in the United States: implications for cost efficiencies?	Poster Presentation Tuesday, October 23, 2018 9:00 AM - 11:00 AM

TREMFYA (guselkumab)

Abstract 633	The effect of guselkumab on dactylitis: results from a phase 2 study in patients with active psoriatic arthritis	Poster presentation Sunday, October 21, 2018 9:00 AM - 11:00 AM
Abstract 1657	The effect of guselkumab on enthesitis: results from a phase 2 study in patients with active psoriatic arthritis	Poster presentation Monday, October 22, 2018 9:00 AM - 11:00 AM
Abstract 989	Reduction of serum IL17F and IL22 by IL23p19 blockade with guselkumab is associated with improvement in joint symptoms in psoriatic arthritis	Poster presentation Monday, October 22, 2018 9:00 AM - 11:00 AM
Abstract 2560	Efficacy of guselkumab in psoriasis patients with self-reported psoriatic arthritis with involvement of the scalp, nails, hands, and feet: a pooled analysis from 2 pivotal Phase 3 psoriasis studies	Poster presentation Tuesday, October 23, 2018 9:00 AM - 11:00 AM
Abstract 2566	Impact of guselkumab versus placebo and adalimumab on patient reported outcomes in patients with and without psoriatic arthritis in a phase 3 pivotal psoriasis study	Poster presentation Tuesday, October 23, 2018 9:00 AM - 11:00 AM
Abstract 2600	Clinically meaningful improvement in health-related quality of life and the association with disease activity in psoriatic arthritis after treatment with guselkumab: results from a randomised placebo-controlled phase II clinical trial	Poster presentation Tuesday, October 23, 2018 9:00 AM - 11:00 AM

IBD and PsO

Abstract 367	Incidence of inflammatory bowel disease (IBD) among patients (Pts) with other chronic inflammatory diseases (CID) treated with interleukin-17a (IL-17a) or phosphodiesterase 4 (PDE4) inhibitors	Poster presentation Sunday, October 21, 2018 9:00 AM - 11:00 AM
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About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic, systemic inflammatory condition that is often characterized by symptoms that include pain, stiffness and inflammation of the joints, and in some cases, joint destruction and disability.¹ An estimated 1.5 million Americans have the condition, which affects nearly three times as many women as men.² While the cause of RA is unknown, many cases are believed to result from genetic and environmental factors. There is no medical cure for RA, but there are numerous medications available to help alleviate symptoms and prevent joint destruction.

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.^{3,4} 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.⁵ 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.³ 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.³

There are numerous medications available to help alleviate symptoms and prevent joint destruction.

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. It is the primary disease in a group of arthritis-related diseases known as spondyloarthritis.⁶ It is estimated that 700,000 people in the U.S. are living with AS.⁷ Peripheral joint involvement 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.⁸ In contrast to mechanical low back pain, inflammatory 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.⁸

About Systemic Lupus Erythematosus

Lupus is a chronic, inflammatory autoimmune disease that can affect many different body systems, including joints, skin, heart, lungs, kidneys and brain.⁹ 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).¹⁰ The disease most often affects women and disproportionately affects women of African American, Hispanic, Asian and Native American descent compared to Caucasian women.¹¹ 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.¹²

About SIMPONI ARIA (golimumab)

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.

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 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, 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 is a human interleukin-12 and -23 antagonist indicated in the U.S. for the treatment of adult patients with: moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy, active psoriatic arthritis (PsA), alone or in combination with methotrexate, moderately to severely active Crohn's disease (CD) who have failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or failed or were intolerant to treatment with one or more TNF. STELARA is in Phase 3 development for the treatment of systemic lupus erythematosus, however, safety and efficacy in the treatment of patients with SLE has not been established and STELARA is not approved for this indication.

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.
- 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: upper respiratory infections, headache, and tiredness **in psoriasis** patients; joint pain and nausea **in psoriatic arthritis** patients; and upper respiratory infections, redness at the injection site, vaginal yeast infections, itching, urinary tract infections, and vomiting **in Crohn's disease** patients. 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 TREMFYA (guselkumab)

TREMFYA is a human monoclonal antibody developed by Janssen that selectively blocks the protein interleukin (IL)-23 and is approved in the U.S., Canada and Europe 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 or UV light). Ongoing trials include: Phase 3 program evaluating TREMFYA in the treatment of active psoriatic arthritis, Phase 3 study evaluating the efficacy of TREMFYA compared with Cosentyx (secukinumab) in the treatment of moderate to severe plaque psoriasis, and a Phase 3 program in Crohn's disease.

Applications seeking approval of TREMFYA are currently under review worldwide.

TREMFYA is a trademark of Janssen Biotech, Inc.

IMPORTANT SAFETY INFORMATION

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

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

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 REMICADE (infliximab)

REMICADE was the first anti-tumor necrosis factor (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.

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 caused by viruses, fungi or bacteria that have spread throughout the body, including tuberculosis (TB) and histoplasmosis. 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 TNF-blocker medicines. Hepatosplenic T-cell lymphoma, a rare form of fatal lymphoma, has occurred mostly in teenage or young adult males 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.

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:

- Infections (like TB, blood infections, pneumonia)—fever, tiredness, cough, flu, 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 your 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, right-sided abdominal pain, fever, or severe tiredness.
- Blood disorders—fever that doesn't go away, bruising, bleeding or severe paleness.
- Nervous system disorders—numbness, weakness, tingling, changes in your vision or seizures.
- 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 the 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 most common side effects of REMICADE® include respiratory infections (that may include sinus infections and sore throat), headache, rash, coughing and stomach pain.

Please read the full Prescribing Information and Medication Guide for REMICADE® and discuss it 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 at www.twitter.com/JanssenGlobal and www.twitter.com/JanssenUS. Janssen Research & Development, LLC and Janssen Biotech, Inc. 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 ongoing and planned development efforts involving SIMPONI ARIA®, STELARA® and TREMFYA®. 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 of Johnson & Johnson 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 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Report on Form 10-Q and in 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 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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