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NEWS RELEASE

Johnson & Johnson advances leadership in rheumatic disease innovation with 43 abstracts at ACR 2024

2024-11-07

New data for investigational nipocalimab in Sjögren's Disease (SjD) and new research on the impact of TREMFYA® (guselkumab) in psoriatic arthritis (PsA) will be highlighted across three oral sessions and a plenary session

Results from the Phase 2 DAHLIAS study of nipocalimab in SjD show nipocalimab met the primary endpoint with a reduction in ClinESSDAI score from baseline and other key efficacy endpoints at Week 24 compared with placebo, presented in a plenary session

Results from the PsABIOnd observational study highlight the patient-reported impact in psoriatic arthritis (PsA) disease burden following treatment with TREMFYA®, presented as an oral presentation

SPRING HOUSE, Pa., Nov. 7, 2024 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) announced today that 43 presentations showcasing the Company's rheumatology pipeline and portfolio will be featured at the American College of Rheumatology (ACR) 2024 Annual Meeting. Presentations include three oral sessions and a plenary session, highlighting new data for investigational nipocalimab in SjD and new research on the impact of TREMFYA® in PsA.

"Johnson & Johnson is proud to share new data and analyses that demonstrate the potential of nipocalimab and support the well-established efficacy and safety profile of TREMFYA®," said Terence Rooney, M.D., Vice President, Medical Rheumatology Disease Area Leader, Johnson & Johnson Innovative Medicine. "This is a testament to our decades-long legacy of innovation and continued exploration of new ways to meet the needs of patients with rheumatic diseases, focusing on treatments that improve patient outcomes."

Progressing research in autoantibody-driven diseases

The plenary session will feature data from the Phase 2 DAHLIAS study **presented earlier this year**. The data showed that adult patients who received nipocalimab 15 mg/kg every two weeks demonstrated a greater than 70% relative average improvement on the primary endpoint compared to patients who received placebo.[1] More than twice as many patients on 15 mg/kg nipocalimab compared to placebo experienced at least a 50% increase in saliva production at Week 24 in a post-hoc analysis.[1]

Additional nipocalimab data highlights include:

- SjD pharmacokinetics (PK), pharmacodynamics (PD), and biomarker data: Two posters will show decreases in rheumatoid factor, circulating immune complexes and all IgG subclasses, and will demonstrate through PK/PD modeling that the median for the maximum potential reduction in total IgG is greater than 77%, providing evidence of interaction of nipocalimab with FcRn and its mechanism of action (MOA) (Abstract #1427 and #2294)
- Assessment of nipocalimab as an immunoselective investigational therapy: Two posters will be shared showing that nipocalimab-treated study participants respond to vaccines by increasing anti-vaccine IgG levels. In addition, a majority of rheumatoid arthritis (RA) patients treated with nipocalimab showed anti-vaccine antibody levels consistently above protective thresholds during treatment. (Abstract #1988 and #1976)

Driving leadership in IL-23 research across patient types

Interim results from the PsABIOnd study, an ongoing, prospective, observational cohort study, assessing the effect of TREMFYA® and IL-17 inhibitors on patient-perceived impact of PsA will be presented during the abstract session as an oral presentation. The study highlights reductions in joint pain, skin symptoms, and overall disease activity, demonstrating the positive impact of TREMFYA® in PsA.

Additional data across broad patient types and disease manifestations (domains) will highlight the benefits of treatment with TREMFYA® for moderate to severe plaque psoriasis (PsO) and active PsA.

The full list of accepted Johnson & Johnson abstracts is below.

Data presentation highlights: ACR Convergence – November 14-19

**denotes encore

Nipocalimab	
Presenter/Presentation Time (ET) Poster Number	Abstract Name

Oral Session	
Abstracts: Genetics, Genomics & Proteomics Date: Monday, November 18 Session Time: 1:00 PM - 2:30 PM Presentation Time: 2:00 PM - 2:15 PM	scRNAseq SjD Predictors of Disease Progression: Sjögren's Disease and Non-Sjögren's Sicca Patient Subsets Exhibit Cell Type-specific Transcriptional Dysregulations That May Identify Early Molecular Predictors Disease Transition
Abstracts: RA – Diagnosis, Manifestations, & Outcomes III: Best Day (RA Subpopulations) Date: Sunday, November 17 Session Time: 3:00 PM - 4:30 PM Presentation Time: 3:00 PM - 3:15 PM	BRASS 3 RA Remission/Pt Outcomes: What are the Benefits of Treating Rheumatoid Arthritis Patients to Remission After Achieving Low Disease Activity in Clinical Practice?
Plenary Session	
#2527 Date: Monday, November 18 Presentation Time: 9:00 AM - 9:15 AM	** Nipo DAHLIAS SjD: Efficacy and Safety of Nipocalimab, an Anti-FcRn Monoclonal Antibody, in Primary Sjogren's Disease: Results From a Phase 2, Multicenter, Randomized, Placebo-controlled, Double-blind Study (DAHLIAS)
Poster Session	
#1427 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	DAHLIAS SjD PK/PD: Observed and Simulated Pharmacokinetics and Pharmacodynamics of Nipocalimab, a Fully Human FcRn Blocking Monoclonal Antibody, in Adults With Sjögren's Disease: Results From a Phase 2, Multicenter, Randomized, Placebo-controlled, Double-blind Study
#2294 Date: Monday, November 18 Presentation Time: 10:30 AM - 12:30 PM	DAHLIAS SjD PD/Clinical Biomarkers: Pharmacodynamic Effects of Nipocalimab on Disease Biomarkers in Patients with Moderate-to-Severe Active Sjögren's Disease: Results from a Multicenter, Randomized, Double-blinded, Placebo-controlled Phase 2 Study
#1509 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	GLADEL Infection Score SLE: Validation of a Score for the Prediction of Serious Infection in Patients With Systemic Lupus Erythematosus: Data From a Latin American Lupus Cohort
#0639 Date: Saturday, November 16 Presentation Time: 10:30 AM - 12:30 PM	GLADEL 2.0 Delayed Diagnosis SLE: Delayed Diagnosis in Systemic Lupus Erythematosus
#1360 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	BRASS 4 RA LDA/HCRU: Impact of Maintaining Low Disease Activity on Patient Outcomes and Healthcare Resource Utilization in Rheumatoid Arthritis Patients Receiving Advanced Treatment
#0136 Date: Saturday, November 16 Presentation Time: 10:30 AM - 12:30 PM	LupusNet SLE Pt Characteristics: Demographic and Clinical Characteristics of Patients With SLE Across 5 Registries – The LupusNet Federated Data Network
#1331 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	Refractory RA Pt Global Assessment: Does Refractory Rheumatoid Arthritis Status Matter in Modeling Patient Global Assessment Trajectories Over 20 Years in a Large US Registry?
#1988 Date: Monday, November 18 Presentation Time: 10:30 AM - 12:30 PM	** Nipo Effect on Vaccine Response: A Randomized, Open-Label Study on the Effect of Nipocalimab on Vaccine Responses in Healthy Participants
#1976 Date: Monday, November 18 Presentation Time: 10:30 AM - 12:30 PM	** Nipo Anti-Vaccine Ab in RA: Post-Hoc Analysis of Clinically Relevant Anti-Vaccine Antibodies in Participants With Rheumatoid Arthritis Treated With Nipocalimab
#1511 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	** GLADEL Lupus Nephritis Response: Lupus Nephritis and Response to Treatment in Latin America
#1510 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	** GLADEL Lupus Nephritis QoL: Impact of Active Lupus Nephritis on the Quality of Life of Patients From a Latin American Lupus Cohort
#2416 Date: Monday, November 18 Presentation Time: 10:30 AM - 12:30 PM	** GLADEL Lupus Nephritis Work Productivity: The Impact of Active Lupus Nephritis on Work Productivity in Patients From a Latin American Lupus Cohort
#1051 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	** IIM MarketScan LT OC HCRU in DM/PM: Healthcare Costs and Resource Utilization Associated With Long-term Medium-to-High Dose Oral Corticosteroid Use in Patients With Dermatomyositis or Polymyositis
#2001 Date: Monday, November 18 Presentation Time: 10:30 AM - 12:30 PM	** IIM MarketScan LT OC Complications in DM/PM: Complications and Treatment Use Associated With Long-term Oral Corticosteroid Therapy Among Patients With Dermatomyositis or Polymyositis

Guselkumab	
Presenter/Presentation Time (ET) Poster Number	Abstract Name
Oral Session	
Session: Abstracts: SpA Including PsA – Treatment II	PsABIOnd – 6M PSAID-12/PRO: Guselkumab and IL-17 Inhibitors

	Improve Patient-perceived Impact of Psoriatic Arthritis Similarly: 6-month Interim Results of the PsABIOnd Observational Cohort Study
Poster Session	
#0588 Date: Saturday, November 16 Presentation Time: 10:30 AM - 12:30 PM	GUS Sex Disaggregation @ BL: Sex-Related Differences in Baseline Patient and Disease Characteristics: Post Hoc Analyses of Three Phase 3, Randomized, Double-blind, Placebo-Controlled Studies in Patients With Active Psoriatic Arthritis
#2342 Date: Monday, November 18 Presentation Time: 10:30 AM - 12:30 PM	GUS Sex Disaggregation – Domain Efficacy: Guselkumab Shows Similar Domain-Specific Efficacy in Females and Males With Active Psoriatic Arthritis: Post Hoc Analyses of Three Phase 3, Randomized, Double-blind, Placebo-Controlled Studies
#0583 Date: Saturday, November 16 Presentation Time: 10:30 AM - 12:30 PM	GUS RCT MCII by TNFi and Disease Activity: Impact of Prior Tumor Necrosis Factor Inhibitor Treatment and Baseline Psoriatic Arthritis Disease Activity on Minimal Clinically Important Improvement Thresholds for Efficacy Outcomes: Post hoc Analysis of Three Phase 3 Studies of Guselkumab in Patients With Active Psoriatic Arthritis
#1464 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	PsABIOnd - 6M Clinical Outcomes: Guselkumab and IL-17 Inhibitors Show Comparable Treatment Persistence and Effectiveness in Psoriatic Arthritis: 6-month Interim Results of the PsABIOnd Observational Cohort Study
#1912 Date: Monday, November 18 Presentation Time: 10:30 AM - 12:30 PM	PsA RISE Regional GC vs AdvTx: Greater Glucocorticoid and Less Biologic/Targeted Therapy Use in Midwest PsA Patients Despite Prevalent Comorbidity
#1458 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	TIGERS – Synovial Transcriptome by Sex: Synovial Transcriptomic Sex-Specific Difference in the Response to Biologics in Psoriatic Arthritis Patients
#2316 Date: Monday, November 18 Presentation Time: 10:30 AM - 12:30 PM	TIGERS 2 – PsD Gene Expression by Sex: Gene Expression Profile is Different Between Men and Women in Psoriatic Disease
#1469 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	Spain RWE 2L GUS v TNFi Persistence: Manhattan Study: Observational, Ambispective Study to Describe Persistence and Effectiveness of a Second-line Guselkumab or TNF Inhibitors After First-line TNF Inhibitors for the Treatment of Active Psoriatic Arthritis in Spain
#1904 Date: Monday, November 18 Presentation Time: 10:30 AM - 12:30 PM	IIS Bautista Economic Burden PsA: Evaluation of the Economic Burden of Psoriatic Arthritis: Assessment of Direct and Indirect Costs Using National Administrative Databases at National Level
#0082 Date: Saturday, November 16 Presentation Time: 10:30 AM - 12:30 PM	IL-23 in Axial vs Peripheral Entheseal Sites: Comparative Immunology of Entheseal Anchorage Sites Between Spine, Hip and Knee Demonstrates up to 70-Fold Greater IL-23 Induction From Axial Enthesis Bone: A New Angle on the Failure of IL-23 Blockade in Ankylosing Spondylitis
#1456 Date: Sunday, November 17 Presentation Time: 10:30 AM – 12:30 PM	MONITOR-PsA BL Characteristics: Real-World Treat-to-Target Strategy in Psoriatic Arthritis: Baseline Characteristics From the MONITOR-PsA Cohort
#2353 Date: Monday, November 18 Presentation Time: 10:30 AM - 12:30 PM	** D1+D2 cDAPSA Deep Dive: Effects of Guselkumab on cDAPSA Disease Activity State and Its Association With Long-Term Radiographic Progression in a Cohort of Patients With Moderately-Highly Active Psoriatic Arthritis: Post Hoc Analyses of Phase 3 Randomized Controlled Studies
#1472 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	** GUS cDAPSA Deep Dive by BL Characteristics: Achievement of Low Disease Activity/Remission in Guselkumab-Treated Patients With Moderately-Highly Active Psoriatic Arthritis Regardless of Baseline Characteristics: Pooled Post-Hoc Analysis of Two Phase 3/Randomized Studies
#1478 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	** STAR Screening MRI: Associations Between Clinical Characteristics and Screening MRI Findings: Exploratory Analysis of the Ongoing Phase 4, Multicenter, Randomized, Controlled STAR Study of Biologic-naïve Patients With PsA With MRI-confirmed Axial Involvement
#1474 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	** GUS Severe PsA Disease Activity: Efficacy of Guselkumab in Bionaive Psoriatic Arthritis Patients With Severe Disease Activity: Post-hoc Analysis of a Phase 3, Randomized, Double-blind, Placebo-Controlled Study
#2357 Date: Monday, November 18 Presentation Time: 10:30 AM - 12:30 PM	** GUS NLR CV Risk in PsD: Longitudinal Evaluation of Neutrophil-to-Lymphocyte Ratio in Guselkumab-Treated Patients With Psoriatic Disease and Levels of Systemic Inflammation Associated With Elevated Cardiovascular Risk: Post hoc Analysis of 4 Phase 3, Randomized, Controlled Studies
#0447 Date: Saturday, November 16 Presentation Time: 10:30 AM - 12:30 PM	** GUS Pooled Pregnancy: Pregnancy Outcomes in Women Exposed to Guselkumab: Review of Cases Reported to the Manufacturer's Global Safety Database
#2047 Date: Monday, November 18	** GUS LTBI Safety Pooled PsD: Safety in Patients With Latent Tuberculosis who Received Concomitant Anti-Tuberculosis Medications: Analysis of 11 Studies of Guselkumab in Psoriatic

Presentation Time: 10:30 AM - 12:30 PM	Medications: Analysis of 11 Studies of Guselkumab in Psoriatic Disease
#1462 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	** IQVIA GUS vs SC IL-17Ai Persistence: Comparison of On-Label Treatment Persistence in Real-World Patients With Psoriatic Arthritis Receiving Guselkumab Versus Subcutaneous IL-17A Inhibitors
#1136 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	**GUS CD GALAXI 2&3: Efficacy and Safety of Guselkumab Therapy in Patients With Moderately to Severely Active Crohn's Disease: Results of the GALAXI 2 & 3 Phase 3 Studies
#1132 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	**VEGA UC MoA Wk38: Guselkumab and Golimumab Combination Induction Therapy in Ulcerative Colitis Results in Early Local Tissue Healing That is Sustained Through Guselkumab Maintenance Therapy
#0605 Date: Saturday, November 16 Presentation Time: 10:30 AM - 12:30 PM	**GUS Molecular Differentiation Co-culture: Guselkumab Binding to CD64^{+} IL-23–producing Myeloid Cells Enhances Potency for Neutralizing IL-23 Signaling

Ustekinumab	
Presenter/Presentation Time (ET) Poster Number	Abstract Name
Poster Session	
#0384 Date: Saturday, November 16 Presentation Time: 10:30 AM - 12:30 PM	UST PK in RWE jPsA: Pharmacokinetics of Ustekinumab in Patients With Juvenile Psoriatic Arthritis in a Real World Opportunistic Study
#1496 Date: Sunday, November 17 Presentation Time: 10:30 AM - 12:30 PM	** SLE BL Biomarker + Clinical Features: Dysregulated Serum Cytokines in Association With Clinical Manifestations in Patients With Systemic Lupus Erythematosus

JNJ-2113	
Presenter/Presentation Time (ET) Poster Number	Abstract Name
Poster Session	
#0303 Date: Saturday, November 16 Presentation Time: 10:30 AM - 12:30 PM	** FRONTIER-2 1Y: Phase 2b, Long-term Extension, Dose-ranging Study of Oral JNJ-77242113 for the Treatment of Moderate-to-Severe Plaque Psoriasis: FRONTIER-2

About Sjögren's Disease

Sjögren's disease (SjD) is one of the most prevalent autoantibody-driven diseases for which no therapies are currently approved that treat the underlying and systemic nature of the disease.[2] It is a chronic autoimmune disease that is estimated to impact approximately four million people worldwide and is nine times more common in women than men.[3,4] SjD is characterized by autoantibody production, chronic inflammation, and lymphocytic infiltration of exocrine glands. Most patients are affected by mucosal dryness (eyes, mouth, vagina), joint pain and fatigue.[2] More than 50% of SjD patients have a moderate to severe form of the condition, and disease burden can be as high as that of rheumatoid arthritis or systemic lupus erythematosus and is often associated with impaired quality of life and functional capacity.[5, 3,6]

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic, symmetric, inflammatory disease involving the synovial joints.[7] RA occurs

when the immune system loses its normal state of balanced control and activates sustained inflammation in the soft inner lining of joints, called synovial tissue.[8] This inflammation produces joint pain, swelling, and stiffness, and can lead to permanent damage and deformity in structural joint elements like cartilage and bone.[8] Significantly reduced physical function and health-related quality of life typically accompany these features.[9] Antibody systems, such as rheumatoid factor (RF) and anti-citrullinated protein antibodies (ACPAs) are associated with RA, having been identified based on the antigens these antibodies bind to.[10] RA is the most common inflammatory arthritis and affects an estimated 13 million people worldwide.[11] It is estimated that 1.5 million people in the United States are affected by RA.[8,12]

About Systemic Lupus Erythematosus

Lupus is a chronic, inflammatory autoimmune disorder that can affect many different body systems, including joints, skin, heart, lungs, kidneys and brain.[13] Systemic lupus erythematosus (SLE), the most common form of lupus, can range from mild to severe and is characterized by inflammation of any organ system including kidneys, nervous system, brain or brain vasculature, as well as potential hardening of the arteries or coronary artery disease.[14] The disease most often affects women and disproportionately affects women of African American, Hispanic, Asian American, Native Hawaiian and Pacific Islander (AAHPI) and Native American descent compared to Caucasian women.[15] Lupus is estimated to affect at least 5 million people worldwide.[16]

About Idiopathic Inflammatory Myopathies

Idiopathic inflammatory myopathies (IIM), generally referred to as myositis, are a heterogeneous group of rare, chronic, autoimmune diseases that are characterized by progressive muscle weakness and damage to joints and major organs.[17] It is thought to be caused by an overactive immune system that attacks the body's own muscles, skin and other organs, but the specific cause of the disease is unknown.[17] The most common symptom of IIM is muscle weakness in the large muscles of the shoulders, neck or hips and can result in difficulty performing typical daily-life activities such as swallowing, walking, driving, climbing stairs, rising from a seated position, turning over in bed and raising arms overhead.[17] It is currently estimated that 5-10 people per million are diagnosed with a type of IIM each year.[17]

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, immune-mediated, inflammatory disease characterized by peripheral joint inflammation, enthesitis (pain where the bone, tendon and ligament meet), dactylitis (a type of inflammation in the fingers and toes that can result in a swollen, sausage-like appearance), axial disease and the skin lesions associated with plaque psoriasis (PsO).[18,19,20] The disease causes pain, stiffness and swelling in and around the joints; it commonly appears between the ages of 30 and 50, but can develop at any age.[21] Nearly half of patients with PsA

experience moderate fatigue and about 30% suffer from severe fatigue as measured by the modified fatigue severity scale.[22] In patients with PsA, comorbidities such as obesity, cardiovascular disease, anxiety and depression are often present.[23] Studies show up to 30% of people with plaque PsO also develop PsA.[24] Although the exact cause of PsA is unknown, genes, the immune system and environmental factors are all believed to play a role in disease onset.[25]

About Ulcerative Colitis

Ulcerative colitis (UC) is a chronic disease of the large intestine, also known as the colon, in which the lining of the colon becomes inflamed and develops tiny open sores, or ulcers, that produce pus and mucus. It is the result of the immune system's overactive response.[26] Symptoms vary but may typically include loose and more urgent bowel movements, rectal bleeding or bloody stool, persistent diarrhea, abdominal pain, loss of appetite, weight loss, and fatigue. People with UC also have increased rates of depression.[27]

About Crohn's Disease

Crohn's disease is one of the two main forms of inflammatory bowel disease, which affects an estimated three million Americans and an estimated four million people across Europe.[28,29] Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract with no known cause, but the disease is associated with abnormalities of the immune system that could be triggered by a genetic predisposition, diet, or other environmental factors.[30] Symptoms of Crohn's disease can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever.

About Nipocalimab

Nipocalimab is an investigational monoclonal antibody, designed to bind with high affinity to block FcRn and reduce levels of circulating immunoglobulin G (IgG) antibodies potentially without impact on other immune functions. This includes autoantibodies and alloantibodies that underlie multiple conditions across three key segments in the autoantibody space including Rare Autoantibody diseases, Maternal Fetal diseases mediated by maternal alloantibodies and Prevalent Rheumatology.[1,31,32,33,34,35,36,37,38] Blockade of IgG binding to FcRn in the placenta is also believed to limit transplacental transfer of maternal alloantibodies to the fetus.[39,40]

The U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have granted several key designations to nipocalimab including:

- U.S. FDA Fast Track designation in hemolytic disease of the fetus and newborn (HDFN) and warm autoimmune hemolytic anemia (wAIHA) in July 2019, gMG in December 2021 and fetal neonatal alloimmune

thrombocytopenia (FNAIT) in March 2024

- U.S. FDA Orphan drug status for wAIHA in December 2019, HDFN in June 2020, gMG in February 2021, chronic inflammatory demyelinating polyneuropathy (CIDP) in October 2021 and FNAIT in December 2023
- U.S. FDA Breakthrough Therapy designation for HDFN in February 2024 by the FDA
- EU EMA Orphan medicinal product designation for HDFN in October 2019

About TREMFYA® (guselkumab)

Developed by Johnson & Johnson, TREMFYA® is the first approved fully-human, dual-acting monoclonal antibody designed to neutralize inflammation at the cellular source by blocking IL-23 and binding to CD64 (a receptor on cell that produce IL-23). Findings for dual-acting are limited to in vitro studies that demonstrate guselkumab binds to CD64, which is expressed on the surface of IL-23 producing cells in an inflammatory monocyte model. The clinical significance of this finding is not known.

TREMFYA® is a prescription medicine approved in the U.S. to treat:

- adults with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light).
- adults with active psoriatic arthritis.
- adults with moderately to severely active ulcerative colitis.[41]

TREMFYA® is approved in Europe, Canada, Japan, and a number of other countries for the treatment of adults with moderate-to-severe plaque psoriasis and for the treatment of adults with active psoriatic arthritis.

Johnson & Johnson maintains exclusive worldwide marketing rights to TREMFYA®. For more information, visit: **www.tremfya.com**.

Important Safety Information for TREMFYA®

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

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. Pregnancy Registry: If you become pregnant during treatment with TREMFYA®, talk to your healthcare provider about registering in the pregnancy exposure registry for TREMFYA®. You can enroll by visiting **www.mothertobaby.org/ongoing-study/tremfya-guselkumab**, by calling **1-877-311-8972**, or emailing **MotherToBaby@health.ucsd.edu**. The purpose of this registry is to collect information about the

safety of TREMFYA® during pregnancy.
- 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: respiratory tract infections, headache, injection site reactions, joint pain (arthralgia), diarrhea, stomach flu (gastroenteritis), fungal skin infections, herpes simplex infections, and bronchitis.

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**.

Dosage Forms and Strengths: TREMFYA® is available in a 100 mg/mL prefilled syringe and One-Press patient-controlled injector for subcutaneous injection, a 200 mg/2 mL prefilled syringe and prefilled pen (TREMFYA® PEN) for subcutaneous injection, and a 200 mg/20 mL (10 mg/mL) single dose vial for intravenous infusion.

ABOUT STELARA® (ustekinumab)

STELARA® (ustekinumab), a human interleukin (IL)-12 and IL-23 antagonist, is a prescription medicine approved in the United States to treat:

- adults and children 6 years and older with moderate to severe psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
- adults and children 6 years and older with active psoriatic arthritis.

- adults 18 years and older with moderately to severely active Crohn's disease.
- adults 18 years and older with moderately to severely active ulcerative colitis.[42]

Johnson & Johnson maintains exclusive worldwide marketing rights to STELARA®.

Important Safety Information for STELARA® (Ustekinumab)

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 or have any open cuts.
- 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). These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications. 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.

Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is a rare condition that affects the brain and can cause death. The cause of PRES is not known. If PRES 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 PRES.
- 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® if you 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 6 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, bronchitis, diarrhea, stomach pain, and joint pain. 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 click to 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 Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity.

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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 and the potential benefits and treatment impact of nipocalimab. 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, Janssen Biotech, Inc. 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, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other 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 Janssen Research & Development, LLC, 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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