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For immediate release

Johnson & Johnson showcases innovation and leadership in rheumatology at EULAR 2024 Congress

30 abstracts highlight the company's robust portfolio and commitment to improving outcomes for patients with immune-mediated diseases

Features positive results from a Phase 2 study of nipocalimab in Sjögren's disease as a late-breaking oral presentation

SPRING HOUSE, Pa. (June 4, 2024) – Johnson & Johnson announced today new clinical and investigational data will be featured across 30 abstracts at the European Alliance of Associations for Rheumatology (EULAR) 2024 Congress (Vienna, Austria, June 12-15). Among the accepted data, 21 abstracts and presentations will feature TREMFYA® (guselkumab) and nine will feature nipocalimab, including a late-breaking abstract on new positive Phase 2 data in Sjögren's disease.

"It is estimated that one in 10 individuals are living with an immune-mediated rheumatic disease. There is a clear need for additional treatment options that deliver sustained remission for patients," said Terence Rooney, Vice President, Rheumatology Disease Area Leader, Johnson & Johnson Innovative Medicine.[1] "The breadth of data to be presented at EULAR underscores our unwavering commitment to advance science and deliver transformational therapies for patients with rheumatic disease."

With a nearly 30-year legacy pioneering the science of immunology, Johnson & Johnson continues to build upon its commitment to advance the field of rheumatology and is proud to present the latest data from the portfolio and pipeline at EULAR, which include:

Guselkumab		
Psoriatic arthritis, plaque psoriasis		
Poster/ Presentation #	**Abstract Name**	**Presentation Time**
AB0426	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	Book only
AB0431	Musculoskeletal Ultrasound Abnormalities in Patients with Psoriasis at High Risk of Progression to Psoriatic Arthritis	Book only
Psoriatic arthritis		
AB0401	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	Book only
POS0254	A Novel Composite Endpoint Including Low Peripheral Joint Disease Activity State and Clear/Almost Clear Skin in Patients with Active Psoriatic Arthritis: Post Hoc Analyses of 2 Phase 3, Randomized, Double-Blind, Placebo-Controlled Studies	Poster tour Friday, June 14 9:30-10:30 CEST
AB0472	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	Book only
POS0249	Associations Between Clinical Characteristics and Screening MRI Findings: Exploratory Analysis of the Ongoing Phase 4, Multicenter, Randomized, Controlled	Poster tour Friday, June 14 9:30-10:30 CEST

	STAR Study of Biologic-naïve Patients with PsA with MRI-confirmed Axial Involvement	
AB0438	Baseline Characteristics of Real-World Psoriatic Arthritis Patients Treated with Guselkumab or IL-17 Inhibitors: Results from the Ongoing Multinational PsABIOnd Study	Book only
POS0943	Guselkumab Provides Durable Improvements in Pain Among Patients with Psoriatic Arthritis and an Inadequate Response to TNFi: COSMOS Phase 3b Trial	Poster view Friday, June 14 9:30-10:30 CEST
POS0322	Guselkumab Binding to CD64+ IL-23–Producing Myeloid Cells Enhances Potency for Neutralizing IL-23 Signaling	Poster tour Friday, June 14 12:00-13:30 CEST
POS0966	Psoriatic Arthritis Patient Profiles are Different Between Randomised Controlled Trials of Biological Disease-Modifying Antirheumatic Drugs and a Real-World Study Over the Same Timeframe (PsABio) – a Literature Review with Meta-Analysis	Poster view Friday, June 14 9:30 - 10:30 CEST
AB0410	Comparison of On-Label Treatment Persistence in Real-World Patients with Psoriatic Arthritis Receiving Guselkumab versus Subcutaneous TNF Inhibitors	Book only
POS0984	Comparison of On-Label Treatment Persistence in Real-World Patients with Psoriatic Arthritis Receiving Guselkumab versus Subcutaneous IL-17A Inhibitors	Poster view Friday, June 14 9:30-10:30 CEST
AB1668-PARE	Improvements in Patient-Reported Outcomes Through 6 Months of Guselkumab Treatment in Patients with Active Psoriatic Arthritis: Real-World Data from the CorEvitas Psoriatic Arthritis/Spondyloarthritis Registry	Book only
POS0983	Pooled Analysis of Three Phase 3, Randomized, Double-Blind, Placebo-Controlled Studies to Longitudinally Evaluate the Novel Psoriatic Arthritis 5-Thermometer Scale (PsA-5Ts) Domains During Guselkumab Treatment	Poster view Friday, June 14 9:30-10:30 CEST
AB0491	Efficacy of Guselkumab in Early-Onset and Late-Onset Psoriatic Arthritis: Post hoc Pooled Analyses of Two Phase 3 Randomized Controlled Trials in Patients with Active Psoriatic Arthritis	Book only
AB0480	Early Fatigue Improvement with Guselkumab Associates with Longer Term Disease Control in Patients with Active Psoriatic Arthritis Reporting Substantial Fatigue: Post Hoc Analyses of a Sub-Population of a Phase 3, Randomized, Controlled Trial of Guselkumab in Biologic-Naïve Patients	Book only
AB0412	Guselkumab Provides Clinically Meaningful Improvements in Patient-Reported Outcomes in Patients with Active Psoriatic Arthritis who are Inadequate Responders to Tumour Necrosis Factor Inhibitors: Results Through One Year of a Phase 3b, Randomized, Controlled study (COSMOS)	Book only
Plaque psoriasis		
POS0942	VISIBLE: Clearance and Symptom Improvement with Guselkumab at Week 16 in Skin of Color Participants with Moderate-to-Severe Plaque Psoriasis	Poster view Friday, June 14 9:30-10:30 CEST
Ulcerative colitis		
AB1410	Early Symptomatic Improvement with Guselkumab Induction Treatment in Moderately to Severely Active Ulcerative Colitis: Results from the Phase 3 QUASAR Induction Study	Book only
AB1415	Guselkumab Induction Restores Intestinal Immune Homeostasis and Promotes Epithelial Repair in Moderately to Severely Active Ulcerative Colitis	Book only
AB1381	Guselkumab and Golimumab Combination Induction Therapy in Ulcerative Colitis Results in Early Local Tissue Healing that is Sustained Through Guselkumab Maintenance Therapy	Book only

Nipocalimab		
Sjögren's disease		
LBA90	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)	Oral abstract session Saturday, June 15 9:00-10:00 CEST
POS1243	Association of Sjögren's Disease Activity (ClinESSDAI) and Symptom Burden (ESSPRI) with Patient-Reported Outcome Measures	Poster view Friday, June 14 14:45-15:45 CEST
POS1236	Sjögren's Disease Activity and Clinical Characteristics of Patients with Seropositive and Seronegative Anti-SSA/Ro and Anti-SSB/La Antibody Test Results	Poster view Friday, June 14 14:45-15:45 CEST
Lupus		
POS0114	Lupus Nephritis and Response to Treatment in Latin America	Poster tour Thursday, June 13 9:30-10:30 CEST
POS0741	Impact of Active Lupus Nephritis on the Quality of Life of Patients from a Latin American Lupus Cohort	Poster view Thursday, June 13 12:00-13:30 CEST
POS1016	The Impact of Active Lupus Nephritis on Work Productivity in Patients from a Latin American Lupus Cohort	Poster view Friday, June 14 9:30–10:30 CEST
AB1553-HPR	Baseline Characteristics of Patients with SLE Across 5 Registries – the LupusNet Federated Data Network	Book only
Idiopathic inflammatory myopathies		
AB0250	A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Clinical Trial of Nipocalimab in Participants with Active Idiopathic Inflammatory Myopathies (SPIREA): Study Design	Book only
POS1280	Complications and Treatment Use Associated with Long-term Oral Corticosteroid Therapy Among Patients with Dermatomyositis or Polymyositis	Poster view Friday, June 14 14:45–15:45 CEST

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).[2,3,4] 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.[5] Nearly half of patients with PsA experience moderate fatigue and about 30 percent suffer from severe fatigue as measured by the modified fatigue severity scale.[6] In patients with PsA, comorbidities such as obesity, cardiovascular disease, anxiety and depression are often present.[7] Studies show up to 30 percent of people with plaque PsO also develop PsA.[5] 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.[8]

About Plaque Psoriasis

Plaque psoriasis (PsO) is an immune-mediated disease resulting in overproduction of skin cells, which causes inflamed, scaly plaques that may be itchy or painful.[9] It is estimated that eight million Americans and more than 125 million people worldwide live with the disease.[10] Nearly one-quarter of all people with plaque PsO have cases that are considered moderate to severe.[10] Living with plaque PsO can be a challenge and impact life beyond a person's physical health, including emotional health, relationships, and handling the stressors of life.[11]

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.[12] 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. UC patients also have increased rates of depression.[12]

About Sjögren's Disease (SjD)

Sjögren's disease (SjD) is an autoantibody-driven disease for which no therapies are currently approved that treat the underlying and systemic nature of the disease.[13] It is a chronic autoimmune disease that is estimated to impact as many as four million people worldwide, and it is nine times more common in women than men.[14] SjD is characterized by autoantibody production, chronic inflammation, and lymphocytic infiltration of exocrine glandular systems. Most patients are affected by mucosal dryness (eyes, mouth, vagina), joint pain, and fatigue. Extraglandular manifestations are common and may impact multiple organ systems, including joints, lungs, kidneys, and the nervous system. Patients with SjD have a high risk of developing numerous associated conditions, including up to 20 times higher risk of developing B-cell lymphomas when compared to the general population. Disease burden can be as high as that of rheumatoid arthritis or systemic lupus erythematosus. It is usually associated with impaired quality of life and functional capacity.[15,16]

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 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.[18] 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.[19] 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.[20] Lupus is estimated to affect at least 5 million people worldwide.[21]

About TREMFYA® (guselkumab)

Developed by Johnson & Johnson, TREMFYA® is the first approved fully-human dual-acting monoclonal antibody that blocks IL-23 by binding to the p19 subunit of IL-23 and binding to CD64, a receptor on cells that produce IL-23.[22] IL-23 is an important driver of the pathogenesis of inflammatory diseases.[22] 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.[23,24,25,26]

TREMFYA® is approved in the U.S.,[22,27] and a number of other countries for the treatment of adults with moderate to severe plaque PsO who are candidates for injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light) and for the treatment of adult patients with active PsA.[22] It is also approved in the EU for the treatment of moderate to severe plaque PsO in adults who are candidates for systemic therapy and for the treatment of active PsA in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug therapy.[28]

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

About Nipocalimab

Nipocalimab is an investigational, high-affinity, fully human, aglycosylated, effectorless, monoclonal antibody that aims to selectively block FcRn to reduce levels of circulating immunoglobulin G (IgG) antibodies, including autoantibodies and alloantibodies that underlie multiple conditions.[29] Nipocalimab is the only FcRn blocker being studied across three key segments in the autoantibody space: Rare Autoantibody diseases (e.g., generalized myasthenia gravis in adults and children, chronic inflammatory demyelinating polyneuropathy, warm autoimmune hemolytic anemia, and idiopathic inflammatory myopathies); Maternal Fetal diseases mediated by maternal alloantibodies (e.g., hemolytic disease of the fetus and newborn and fetal and neonatal alloimmune thrombocytopenia); and Prevalent Rheumatology (e.g., rheumatoid arthritis, Sjögren's disease, and systemic lupus erythematosus).[30,31,32,33,34,35,36,37,38] Blockade of FcRn has the potential to reduce overall IgG including pathogenic alloantibody levels while preserving immune function

without causing broad immunosuppression. Blockade of IgG binding to FcRn in the placenta is also believed to prevent transplacental transfer of maternal alloantibodies to the fetus.[39,40]

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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Janssen Research & Development, LLC and Janssen Biotech, Inc. are both Johnson & Johnson companies.

IMPORTANT SAFETY INFORMATION

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 use 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, 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.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding TREMFYA®, as well as 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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