Johnson&Johnson

NEWS RELEASE

Johnson & Johnson announces TREMFYA® (guselkumab) is the first and only IL-23 inhibitor to show significant improvement in spinal pain and stiffness in landmark axial psoriatic arthritis (PsA) study

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- Topline results show TREMFYA met the primary and major secondary endpoints of axial involvement in PsA - including spinal pain and stiffness - and demonstrated significant improvement in MRI-confirmed inflammation
- First-ever study to use objective MRI assessments to confirm presence of axial involvement and demonstrate axial inflammation reduction in PsA

SPRING HOUSE, Pa., Sept. 25, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced that TREMFYA® (guselkumab) met the primary and major secondary endpoints demonstrating both improvement in axial symptoms and reduction in inflammation by MRI assessment in the Phase 4 STAR study evaluating biologic-naïve adults with active psoriatic arthritis and axial involvement (axial PsA). STAR is the first and only dedicated randomized, double-blind, placebo-controlled study of its kind designed to prospectively evaluate an IL-23 inhibitor specifically in patients with axial involvement confirmed by magnetic resonance imaging (MRI).[1] These topline findings represent an important milestone in advancing disease-specific evidence for patients living with axial PsA. Detailed efficacy and safety results, including MRI findings, will be presented at an upcoming scientific congress.

In the STAR study, TREMFYA met the primary endpoint evaluating improvement in a composite patient-reported disease activity score that includes spinal pain, stiffness, fatigue, joint symptoms and areas of tenderness (the Bath Ankylosing Spondylitis Disease Activity Index [BASDAI])[a] at Week 24 versus placebo. TREMFYA also met major secondary endpoints demonstrating a significant reduction in both axial symptoms, as measured by ASDAS-CRP[b],

and objective (MRI) inflammation of the sacroiliac joints. The overall safety profile observed in the STAR study was consistent with the established safety profile of TREMFYA in PsA, and no new safety signals were identified.[1]

"Axial PsA involves inflammation of the spine and sacroiliac joints, often leading to debilitating pain, stiffness, and fatigue. Patients face reduced mobility and a diminished quality of life, underscoring the urgent need for a treatment that helps stop further joint damage and targets the underlying disease," said David M. Lee, M.D., Ph.D., Global Immunology Therapeutic Area Head, Johnson & Johnson. "As the first Phase 4 study of an IL-23 inhibitor in this patient population, STAR further strengthens the growing body of evidence supporting TREMFYA as a first-line treatment option proven to help stop further joint damage."

Advancing the evidence in psoriatic arthritis with axial involvement

Axial involvement is a clinical domain of PsA in which inflammation affects the spine and sacroiliac joints.[2] It can cause back pain, morning stiffness, fatigue, impaired mobility and reduced physical function, and is associated with poorer quality of life than PsA without axial involvement.[3] Axial involvement may affect approximately 5 to 28 percent of patients with early PsA and 25 to 70 percent of those with longer-standing disease.[4]

Despite advances in treating PsA, axial involvement remains an area of significant unmet need. There are currently no universally accepted classification criteria specific to axial PsA,[5] and very few prospective clinical trials have been dedicated specifically to this patient population.

Building on the growing body of evidence supporting TREMFYA in psoriatic arthritis

"Clinical data continue to expand the evidence base for TREMFYA effectiveness across multiple domains of psoriatic arthritis," said Philip J. Mease, M.D., MACR, FRCP, Director of Rheumatology Research at the Providence Swedish Medical Center and Clinical Professor at the University of Washington School of Medicine in Seattle, WA.[c] "What makes the STAR study particularly noteworthy is that, for the first time in a prospective, randomized, double-blinded, placebo-controlled PsA study, it evaluates MRI assessments for inclusion and provides a rigorous and objective measure of improvements in inflammation alongside clinical outcomes in axial PsA. Together, these findings contribute to a more comprehensive understanding of disease activity and treatment effects."

Johnson & Johnson recently **received U.S. Food and Drug Administration (FDA) approval** of a label expansion for the inhibition of progression of structural joint damage in adults with active PsA, cementing TREMFYA as the only IL-23 inhibitor proven to help stop further joint damage.

TREMFYA is the first and only fully-human, dual-acting monoclonal antibody approved to treat PsA that blocks IL-23 while also binding to CD64, a receptor on cells that produce IL-23. IL-23 is a cytokine secreted by activated

monocyte/macrophages and dendritic cells that is known to be a driver of immune-mediated diseases including active psoriatic arthritis. Findings are based on in vitro studies.[6,7,8,9,10]

Editor's notes:

a. BASDAI is a validated patient-reported outcome (PRO) originally developed to measure disease activity on a 0 to 10 scale in ankylosing spondylitis (AS), now referred to as radiographic axial spondyloarthritis (r-axSpA).[11]
b. ASDAS-CRP, or Ankylosing Spondylitis Disease Activity Score with C-Reactive Protein, is a validated, composite index that combines patient-reported symptoms with a laboratory biomarker to objectively measure inflammation and disease severity.[12,13]
c. Dr. Philip Mease is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

About the STAR study (**NCT04929210**)

STAR is a Phase 4, multicenter, randomized, double-blind, placebo-controlled study evaluating TREMFYA in biologic-naïve adults with active psoriatic arthritis (PsA) and axial involvement. Eligible participants had active PsA with objective evidence of axial inflammation confirmed by centrally read MRI and elevated C-reactive protein despite previous treatment with non-biologic disease-modifying antirheumatic drugs (DMARDs), apremilast and/or nonsteroidal anti-inflammatory drugs (NSAIDs).[14]

The study enrolled 411 participants worldwide and includes a 24-week placebo-controlled treatment period followed by a 24-week active treatment period. The primary endpoint evaluated change from baseline in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) at Week 24. Secondary endpoints include additional assessments of axial symptoms, MRI inflammation, physical function, peripheral musculoskeletal manifestations, skin disease and safety.[14]

About psoriatic arthritis with axial involvement

Psoriatic arthritis with axial involvement (axial PsA) is a chronic inflammatory condition where psoriatic arthritis affects the spine and sacroiliac joints (connecting the lower spine to the pelvis). It can cause inflammatory back pain, neck stiffness, and reduced mobility, in addition to the joint, skin or nail manifestations commonly associated with PsA.[15,16]

Despite significant advances in the treatment of psoriatic arthritis, axial involvement remains an area of substantial ongoing need and research.[7] While it shares some clinical features with axial spondyloarthritis (axSpA), axial

involvement is increasingly recognized as a distinct domain of psoriatic arthritis.[4] However, there is currently no universally accepted definition or validated classification criteria specific to PsA with axial involvement, and prospective studies conducted exclusively in patients with axial involvement remain very limited.[5]

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 cells 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 and children six years and older who also weigh at least 40 kg 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 and children six years and older who also weigh at least 40 kg with active psoriatic arthritis.
- adults with moderately to severely active ulcerative colitis.
- adults with moderately to severely active Crohn's disease.

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

The manufacturer for TREMFYA is Janssen Biotech, Inc.

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

IMPORTANT SAFETY INFORMATION

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

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

- Serious Allergic Reactions. Stop using TREMFYA and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:

o fainting, dizziness, feeling lightheaded (low blood pressure)
o swelling of your face, eyelids, lips, mouth, tongue or throat
o trouble breathing or throat tightness
o chest tightness
o skin rash, hives
o 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:

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

- Liver problems. With the treatment of Crohn's disease or ulcerative colitis, your healthcare provider will do blood tests to check your liver before and during treatment with TREMFYA. With the treatment of plaque psoriasis or psoriatic arthritis, your healthcare provider may do blood tests to check your liver before and as necessary during treatment with TREMFYA. Your healthcare provider may stop treatment with TREMFYA if you develop liver problems. Tell your healthcare provider right away if you notice any of the following symptoms:

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o unexplained rash
o vomiting
o tiredness (fatigue)
o yellowing of the skin or the whites of your eyes
o nausea
o stomach pain (abdominal)
o loss of appetite
o dark urine

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. Children should be brought up to date with all vaccines before starting 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, stomach pain, bronchitis feeling very tired (fatigue), fever (pyrexia), and skin rash.

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 as 100 mg/mL and 200 mg/2mL for subcutaneous injection and as a 200 mg/20 mL (10 mg/mL) single dose vial for intravenous infusion.

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 related 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 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 most recent Annual Report on Form 10-K, 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**, **www.investor.jnj.com** or on request from Johnson & Johnson. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or

developments.

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