Johnson&Johnson

NEWS RELEASE

Johnson & Johnson data in psoriatic arthritis (PsA) shows TREMFYA (guselkumab) is the only advanced therapy to demonstrate MRI-confirmed improvements in spinal pain and stiffness

2026-11-20

- TREMFYA showed statistically significant improvement in disease activity on the BASDAI score versus placebo, reflecting meaningful reductions in pain, stiffness, swelling and fatigue in a Phase 4 study
- TREMFYA demonstrated more than 2 times greater reduction in MRI-assessed inflammation versus placebo at Week 24 in the sacroiliac joints, which connect the lower spine to the pelvis and are responsible for pain and stiffness
- TREMFYA was evaluated in first-ever PsA study using objective MRI assessments to confirm and measure axial inflammation alongside patient-reported symptoms

NEW BRUNSWICK, N.J., Nov. 20, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE:JNJ) today announced late-breaking results from the Phase 4 STAR study of TREMFYA (guselkumab) in biologic-naïve adults with active psoriatic arthritis and axial involvement (axial PsA). TREMFYA met primary and major secondary endpoints that demonstrated significant improvement in axial symptoms compared to placebo and significant reduction of MRI-assessed inflammation in the sacroiliac joints.[1,a] The Phase 4 STAR study is the first and only dedicated randomized, double-blind, placebo-controlled study designed to prospectively evaluate an IL-23 inhibitor specifically in patients with axial involvement in PsA confirmed by magnetic resonance imaging (MRI). The late-breaking results are being presented at the Emirates Society for Rheumatology (ESR) Annual Meeting.

For people living with psoriatic arthritis, axial involvement can add another layer of burden to an already complex disease. Chronic inflammation of the spine and sacroiliac joints can cause back pain and stiffness, limiting patients' mobility and physical function.[2] 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.[13] Despite advances in treatment, axial PsA remains challenging to classify, and very few prospective clinical trials have been dedicated specifically to this patient population, underscoring the urgent need for more robust evidence in this subset of PsA patients.

"Axial involvement in psoriatic arthritis can be difficult to identify and evaluate, leaving clinicians with limited evidence to guide patient selection for clinical trials and possibly treatment decisions," said Prof. Mikkel Ostergaard, M.D., Ph.D., DMSc, Clinical Professor of Rheumatology at the University of Copenhagen and Consultant in Rheumatology and Chairperson of the Copenhagen Center for Arthritis Research (COPECARE) at the Center for Rheumatology and Spine Diseases, Rigshospitalet, Glostrup.[f] "In the STAR study, TREMFYA showed significant improvements in patient-reported symptoms and MRI-assessed axial inflammation in the sacroiliac joints, backed by a well-characterized safety profile. Together, these findings provide important evidence to help inform treatment decisions for this debilitating and understudied manifestation of psoriatic arthritis."

TREMFYA demonstrated clinically meaningful improvements, reflecting reductions across patient-reported domains including spinal pain, stiffness, fatigue, joint symptoms and areas of tenderness. At Week 24, mean Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)[b] scores, which are on a 10-point scale, improved by −3.3 with TREMFYA 100 mg every four weeks (Q4W) and −2.9 with TREMFYA every eight weeks (Q8W) versus −2.1 with placebo.[1,c]

TREMFYA Q4W[c] and Q8W also demonstrated significant improvements in symptoms, as measured by the Ankylosing Spondylitis Disease Activity Score using C-reactive protein (ASDAS-CRP)[d] compared with placebo at Week 24 (−1.5 and −1.3, respectively, versus −0.8).[1] These exceeded the internationally recognized standard of ≥1.1 units for clinically important improvement, reflecting a reduction in C-reactive protein, a marker of inflammation in the body.[3]

TREMFYA also provided high levels of skin clearance in patients treated with TREMFYA Q4W and Q8W, consistent with skin clearance demonstrated in other PsA studies such as DISCOVER I and II and APEX.[456] Additionally, the overall safety profile observed in the STAR study was consistent with the established safety profile of TREMFYA in psoriatic disease, and no new safety signals were identified.[1]

The notable measure in this study was MRI-assessed sacroiliac joint inflammation, measured using the Spondyloarthritis Research Consortium of Canada (SPARCC)[e] score. TREMFYA reduced scores by −7.1 and −5.2, with Q4W and Q8W, respectively, versus −2.4 with placebo, representing more than 2 times greater improvement than placebo.[1]

"Psoriatic arthritis is a complex disease that can affect patients in many ways, from skin and peripheral joint symptoms to irreversible joint damage to axial involvement," said David M. Lee, M.D., Ph.D., Global Immunology Therapeutic Area Head, Johnson & Johnson. "The STAR study brings new insight to axial PsA research showing that

TREMFYA can improve axial symptoms and MRI-detected inflammation, while uniquely establishing evidence for an IL-23 inhibitor. Johnson & Johnson continues to pioneer new studies to challenge norms for patients, and these results further reinforce the role of TREMFYA in addressing the diverse manifestations of psoriatic arthritis."

Editor's notes:

a. The change from baseline in Health Assessment Questionnaire - Disability Index (HAQ-DI) was numerically greater for Q8W dosing but did not achieve statistical significance.
b. 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).[7]
c. TREMFYA is not approved for Q4W dosing in the U.S.
d. 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.[89]
e. The Spondyloarthritis Research Consortium of Canada (SPARCC) magnetic resonance imaging (MRI) score is a validated, objective, semiquantitative scoring system used to measure active inflammatory changes in the spine and sacroiliac joint.[10]
f. Prof. Ostergaard 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 and axial disease. 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).[11]

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 disease activity, MRI inflammation, physical function, peripheral musculoskeletal manifestations, skin disease and safety.[11]

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.[12][13]

Despite significant advances in the treatment of psoriatic arthritis, axial involvement remains an area of substantial ongoing need and research.[14] While it shares some clinical features with axial spondyloarthritis (axSpA), axial involvement is increasingly recognized as a distinct domain of psoriatic arthritis.[15] 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.[16]

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:

---

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:

---

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.

Learn more at **https://www.jnj.com/** or at **www.innovativemedicine.jnj.com.** Follow us at **@JNJInnovMed**.

© Johnson & Johnson and its affiliates 2026. All rights reserved.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 related to 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.

[1] Gladman DD, et al. Efficacy and Safety of Guselkumab, a Selective IL-23p19-Subunit Inhibitor, in Participants With Active PsA and MRI-Confirmed Axial Inflammation: Results Through Week 24 of a Phase 4, Randomized, Placebo-Controlled Study. Emirates Society for Rheumatology Annual Meeting; November 20-22, 2026; Dubai, United Arab Emirates.

[2] Mease PJ, Palmer JB, Liu M, et al. Influence of Axial Involvement on Clinical Characteristics of Psoriatic Arthritis: Analysis from the Corrona Psoriatic Arthritis/Spondyloarthritis Registry. The Journal of Rheumatology. 2018;45(10):1389-1396.

[3] Machado P, Landewé R, Lie E, et al. Ankylosing Spondylitis Disease Activity Score (ASDAS): defining cut-off values for disease activity states and improvement scores. Ann Rheum Dis. 2011;70(1):47-53. doi:10.1136/ard.2010.138594

[4] Mease PJ, et al. Inhibition of structural damage progression with guselkumab, a selective IL-23i, in participants with active PsA: Results through Week 24 of the phase 3b, randomized, double-blind, placebo-controlled APEX study. Presented at EULAR 2025, June 11-14. LB0010.

[5] Deodhar A, Helliwell P, Boehncke W et al. Guselkumab in patients with active psoriatic arthritis who were biologic-naive or had previously received TNFα inhibitor treatment (DISCOVER-1): a double-blind, randomised, placebo-controlled phase 3 trial. The Lancet, 2020; 395, 1115-1125.

[6] Mease P, Rahman P, Gottlieb A et al. Guselkumab in biologic-naive patients with active psoriatic arthritis (DISCOVER-2): a double-blind, randomised, placebo-controlled phase 3 trial. The Lancet, 2020; 395, 1126-1136.

[7] Garrett S, Jenkinson T, Kennedy LG, Whitelock H, Gaisford P, Calin A. A new approach to defining disease status in ankylosing spondylitis: the Bath Ankylosing Spondylitis Disease Activity Index. J Rheumatol. 1994;21(12):2286-2291.

[8] van der Heijde D, Lie E, Kvien TK, et al. ASDAS, a highly discriminatory ASAS-endorsed disease activity score in patients with ankylosing spondylitis. Annals of the Rheumatic Diseases. 2009;68(12):1811-1818. doi:10.1136/ard.2008.094870.

[9] Eder L et al. Is ASDAS better than BASDAI as a measure of disease activity in axial psoriatic arthritis?. Ann Rheum Dis. 2010;69(12):2160-2164. doi:10.1136/ard.2010.129726.

[10] Maksymowych, W. P., Lambert, R. G., et al. Defining the minimally important change for the SpondyloArthritis Research Consortium of Canada spine and sacroiliac joint magnetic resonance imaging indices for ankylosing spondylitis. J Rheumatol. 2012;39(8):1666-1674. doi:10.3899/jrheum.120131.

[11] ClinicalTrials.gov. A Study of Guselkumab Administered Subcutaneously in Bio-naive Participants With Active Psoriatic Arthritis Axial Disease (STAR). Identifier: NCT04929210. Available at: **https://clinicaltrials.gov/study/NCT04929210**. Accessed September 2026.

[12] Lopez-Medina C, Ziade N. Axial Disease in Psoriatic Arthritis: how can we Define it, and does it have an Impact on

Treatment? Mediterranean Journal of Rheumatology. 2022;33(Suppl 1):142-149. doi:10.31138/mjr.33.1.142. PMID: 36127925; PMCID: PMC9450188.

[13] Gottlieb AB, Merola JF. Axial psoriatic arthritis: An update for dermatologists. Journal of the American Academy of Dermatology. 2021;84(1):92-101. doi:10.1016/j.jaad.2020.05.089. PMID: 32747079.

[14] Kreuger JG, Eyerich K, Kuchroo VK. Il-23 past, present, and future: a roadmap to advancing IL-23 science and therapy. Front Immunol. 2024; 15:1331217. doi:10.3389/fimmu.2024.1331217.

[15] Feld J, Chandran V, Haroon N, Inman R, Gladman DD. Axial disease in psoriatic arthritis and ankylosing spondylitis: a critical comparison. Nature Reviews Rheumatology. 2018;14(6):363–371. doi:10.1038/s41584-018-0006-8.

[16] Helliwell PS. Axial involvement in psoriatic arthritis: is it unique? Rheumatology. 2024;63(Supplement_2):ii15-ii19. doi:10.1093/rheumatology/keae558.

Media contact:
Camilia Aberra
caberra@its.jnj.com

Investor contact:
Jess Margevich
investor-relations@its.jnj.com

View original content to download multimedia:**https://www.prnewswire.com/news-releases/johnson--johnson-data-in-psoriatic-arthritis-psa-shows-tremfya-guselkumab-is-the-only-advanced-therapy-to-demonstrate-mri-confirmed-improvements-in-spinal-pain-and-stiffness-302946249.html**

SOURCE Johnson & Johnson