

## FDA approves label expansion, cementing TREMFYA® as the only IL-23 inhibitor proven to help stop further joint damage

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TREMFYA® showed significant inhibition of structural joint damage in adults with active psoriatic arthritis

HORSHAM, Pa., May 28, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) announced today that the U.S. Food and Drug Administration (FDA) has approved a supplemental Biologics License Application (sBLA) to include evidence in the TREMFYA® (guselkumab) label for the inhibition of progression of structural joint damage in adults with active psoriatic arthritis (PsA). The inclusion of this key outcome reflects that TREMFYA is the only IL-23 inhibitor proven to help stop further structural damage, offering patients with active PsA a first-line treatment option that provides effective symptom control and no new safety signals, while significantly inhibiting irreversible joint damage.

"Joint damage associated with active psoriatic arthritis can happen as soon as six months after onset of disease, so it's important to have treatment solutions that can help provide daily symptom relief while also protecting joints from long-term structural damage," said Philip J. Mease,<sup>a</sup> M.D., Director of Rheumatology Research at the Swedish Medical Center/Providence St. Joseph Health and Clinical Professor at the University of Washington School of Medicine in Seattle, WA. "With the inclusion of these findings in the label, we now have stronger clinical evidence that sets TREMFYA apart as a treatment option for patients with active psoriatic arthritis at risk for joint damage."

The label update is supported by 24-week results from the Phase 3b APEX study. The study met its primary endpoint of reducing joint symptoms (ACR20) and its major secondary endpoint of inhibiting progression of structural damage, as measured by change in the PsA-modified van der Heijde-Sharp (vdH-S) score<sup>b</sup>, compared to placebo in bio-naïve patients.<sup>1,2,3</sup>

Additionally, for patients in the study's placebo group who switched to TREMFYA at Week 24, the rate of radiographic progression was reduced by 57% from Week 24 through Week 48, demonstrating benefit even after initial disease progression. Data from the APEX study were consistent with the well-established safety profile of TREMFYA, with no new safety signals identified.<sup>4</sup>

"Up to half of all patients living with active psoriatic arthritis can develop early irreversible joint damage, leaving them unable to perform simple daily tasks or go to work," said Brandee Pappalardo, Ph.D., M.P.H., Vice President, Medical Affairs, Dermatology & Rheumatology, Johnson & Johnson Innovative Medicine. "This label update reinforces our commitment to advancing innovation for these patients by offering the only IL-23 inhibitor with structural inhibition in its label, making TREMFYA a differentiated treatment option for symptom relief and joint preservation that helps address the progressive nature of active psoriatic arthritis."

TREMFYA is the 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 monocytes, macrophages, and dendritic cells that is known to be a driver of immune-mediated diseases including active PsA, moderate to severe plaque psoriasis (PsO), moderate to severely active ulcerative colitis (UC) and moderately to severely active Crohn's disease (CD). Findings are based on in vitro.<sup>5,6,7,8,9</sup>

#### Editor's notes:

- a. Dr. Philip Mease is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.
- b. VdH-S scores are from the Week 48 x-ray read.

#### **ABOUT APEX (NCT04882098)**

APEX is a multicenter, randomized, double-blind, placebo-controlled study in patients with active PsA who are biologic naïve and have had an inadequate response to standard therapies (e.g., csDMARDs, apremilast, and/or NSAIDs). The treatment duration includes a 24-week, double-blind, placebo-controlled period, followed by a 24-week active treatment period, followed by a 12-week safety follow-up period. For patients who agree to enter the long-term extension, an additional 2 years of active treatment is scheduled prior to the final safety follow-up.<sup>10</sup>

#### **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).<sup>11,12,13</sup> 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.<sup>14</sup> Nearly half of patients with PsA experience moderate fatigue and about one-third suffer from severe fatigue as measured by the modified fatigue

severity scale.<sup>15</sup> In patients with PsA, comorbidities such as obesity, cardiovascular disease, anxiety and depression are often present.<sup>16</sup> Studies show up to 30% of people with plaque PsO also develop PsA.<sup>10</sup>

## 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 6 years of age and older who also weigh at least 88 pounds (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 6 years and older who also weigh at least 88 pounds (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 and for the treatment of adults with active psoriatic arthritis.

The legal manufacturer for TREMFYA is Janssen Biotech, Inc.

Johnson & Johnson maintains exclusive worldwide marketing rights to TREMFYA. For more information, visit: [www.tremfya.com](http://www.tremfya.com).

## TREMFYA<sup>®</sup> IMPORTANT SAFETY INFORMATION

What is the most important information I should know about TREMFYA<sup>®</sup>?

TREMFYA<sup>®</sup> is a prescription medicine that may cause serious side effects, including:

- Serious Allergic Reactions. Stop using TREMFYA<sup>®</sup> 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

- 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:

- 
- unexplained rash
  - vomiting
  - tiredness (fatigue)
  - yellowing of the skin or the whites of your eyes

- nausea
- stomach pain (abdominal)
- loss of appetite
- 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<sup>®</sup>, 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<sup>®</sup>?"
- 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<sup>®</sup>. Children should be brought up to date with all vaccines before starting TREMFYA<sup>®</sup>
- are pregnant or plan to become pregnant. It is not known if TREMFYA<sup>®</sup> can harm your unborn baby.
- Pregnancy Registry: If you become pregnant during treatment with TREMFYA<sup>®</sup>, talk to your healthcare provider about registering in the pregnancy exposure registry for TREMFYA<sup>®</sup>. You can enroll by visiting [www.mothersbaby.org/ongoing-study/tremfya-guselkumab](http://www.mothersbaby.org/ongoing-study/tremfya-guselkumab), by calling **1-877-311-8972**, or emailing [MotherToBaby@health.ucsd.edu](mailto:MotherToBaby@health.ucsd.edu). The purpose of this registry is to collect information about the safety of TREMFYA<sup>®</sup> during pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if TREMFYA<sup>®</sup> 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<sup>®</sup>?

TREMFYA<sup>®</sup> may cause serious side effects. See "What is the most important information I should know about TREMFYA<sup>®</sup>?"

The most common side effects of TREMFYA<sup>®</sup> 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<sup>®</sup>. Call your doctor for medical advice about side effects.

Use TREMFYA<sup>®</sup> exactly as your healthcare provider tells you to use it.

Please read the full **Prescribing Information**, including **Medication Guide**, for TREMFYA<sup>®</sup> 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](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

**Dosage Forms and Strengths:** TREMFYA<sup>®</sup> 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 to TREMFYA<sup>®</sup>. 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: competition, including technological advances, new products and patents attained by competitors; uncertainty of commercial success for new products; the ability of the company to successfully execute strategic plans; impact of business combinations and divestitures; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; and 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](http://www.sec.gov), [www.jnj.com](http://www.jnj.com), [www.investor.jnj.com](http://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.

<sup>1</sup> Mease PJ, Ritchlin CT, Coates LC, 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. Abstract presented at: European Alliance of Associations for Rheumatology (EULAR) 2025 Congress; June 11-14, 2025; Barcelona, Spain. Late-Breaking Abstracts Session II.

<sup>2</sup> Mease PJ, Ritchlin CT, Coates LC, 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. Oral presentation at: European Alliance of Associations for Rheumatology (EULAR) 2025 Congress; June 11-14, 2025; Barcelona, Spain.

<sup>3</sup> Mease PJ, Ritchlin CT, Coates LC, et al. Inhibition of structural damage progression with the selective interleukin-23 inhibitor guselkumab in participants with active PsA: results through week 24 of the phase 3b, randomised, double-blind, placebo-controlled APEX study. *Ann Rheum Dis.* 2025;84(12):1983-1994.

<sup>4</sup> Ritchlin CT, et al. Durable Inhibition of Structural Damage Progression and Improvements in Joint Disease Activity With the Selective Interleukin-23 Inhibitor Guselkumab in Active and Erosive Psoriatic Arthritis: Week 48 Results From a Phase 3, Randomized, Double-Blind, Placebo-Controlled Study. Presented at ISDS 2025. November 12-15. Poster 331.

<sup>5</sup> Atreya R, Abreu MT, Krueger JG, et al. Guselkumab, an IL-23p19 subunit-specific monoclonal antibody, binds CD64+ myeloid cells and potentially neutralizes IL-23 produced from the same cells. Poster presented at: 18th Congress of the European Crohn's and Colitis Organization (ECCO); March 1-4, 2023; Copenhagen, Denmark. Poster P504.

<sup>6</sup> 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.

<sup>7</sup> TREMFYA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.

<sup>8</sup> Skyrizi® [Prescribing Information]. North Chicago, IL: AbbVie, Inc.

<sup>9</sup> Omvoh™ [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company.

<sup>10</sup> ClinicalTrials.gov. A Study of Guselkumab in Participants With Active Psoriatic Arthritis (APEX). Identifier: NCT04882098. Available at: <https://clinicaltrials.gov/study/NCT04882098>. Accessed May 2026.

<sup>11</sup> Donvito T., CreakyJoints: What Is Dactylitis? The 'Sausage Finger' Swelling You Should Know About. Available at: <https://creakyjoints.org/symptoms/what-is-dactylitis/>. Accessed May 2026.

<sup>12</sup> Belasco J., Wei N. Psoriatic Arthritis: What is Happening at the Joint? *Rheumatol Ther.* 2019 Sep;6(3):305-315. Available at: <https://pubmed.ncbi.nlm.nih.gov/31102105/>. Accessed May 2026.

<sup>13</sup> Gower, T. Enthesitis and PsA. Arthritis Foundation. Available at: <https://www.arthritis.org/health-wellness/about-arthritis/related-conditions/physical-effects/enthesitis-and-psa>. Accessed May 2026.

<sup>14</sup> National Psoriasis Foundation. About Psoriatic Arthritis. Available at: <https://www.psoriasis.org/about-psoriatic-arthritis/>. Accessed May 2026.

<sup>15</sup> Husted J.A., et al. Occurrence and correlates of fatigue in psoriatic arthritis. *Ann Rheum Dis.* 2008;68(10), 1553-1558. Available at: <https://doi.org/10.1136/ard.2008.098202>. Accessed May 2026.

<sup>16</sup> Haddad A., Zisman D. Comorbidities in Patients with Psoriatic Arthritis. Rambam Maimonides Med J 2017 Jan 30;8(1):e0004. Available at: <https://doi.org/10.5041/RMMJ.10279>. Accessed May 2026.

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