Johnson&Johnson

NEWS RELEASE

New data show TREMFYA® (guselkumab) is the only IL-23 inhibitor proven to significantly inhibit progression of joint structural damage in active psoriatic arthritis

2025-06-11

TREMFYA ® demonstrated two and a half times greater ability to inhibit joint structural damage versus placebo in the Phase 3b APEX study

More than 40% of TREMFYA®-treated patients across both dose groups achieved ACR50 at Week 24

Improvement in both joint and skin symptoms reinforce TREMFYA® as a first-line treatment option with a proven safety profile for adults with active psoriatic arthritis

BARCELONA, June 11, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced findings from the Phase 3b APEX study showing that TREMFYA® (guselkumab) significantly reduced both signs and symptoms of active psoriatic arthritis (PsA) and inhibited progression of joint structural damage at 24 weeks compared to placebo.[1] These data from a late-breaking abstract are among the 30 oral and poster presentations Johnson & Johnson is highlighting at the European Alliance of Associations for Rheumatology (EULAR) 2025 Congress.

In the Phase 3b APEX study, TREMFYA® significantly inhibited progression of joint structural damage, including joint erosions and space narrowing, in patients with active PsA at Week 24 as assessed by the PsA modified van der Heijde-Sharp (vdH-S) score. The mean change from baseline to Week 24 in the modified van der Heijde-Sharp (vdH-S) score was 0.55 and 0.54 for patients receiving TREMFYA® every four weeks (Q4W) and every eight weeks (Q8W) respectively, compared with 1.35 in the placebo group (p=0.002 for Q4W and p<0.001 for Q8W dosing versus placebo, respectively). In the two TREMFYA® dose groups, 67% (Q4W) and 63% (Q8W) of patients experienced no

radiographic progression, versus 53% in the placebo group.[a,1]

"In psoriatic arthritis, joint damage can begin early and progress quickly if left untreated, significantly impacting a patient's ability to move, work and maintain independence," said Philip J. Mease, MD, Director of Rheumatology Research at the Swedish Medical Center and study investigator.[b] "The results of the APEX study are promising as the data show guselkumab to be the only IL-23 inhibitor in its class that has inhibited the progression of structural damage in patients, providing new clinical insights for the psoriatic community and underscoring the need for safe, effective options that address the full burden of disease."

TREMFYA® also improved both joint and skin symptoms in patients with active PsA.

- Significantly greater proportions of TREMFYA®-treated patients (67% for Q4W and 68% for Q8W) achieved American College of Rheumatology response criteria (ACR20[c]) at Week 24 versus 47% receiving placebo ($p<0.001$)
- More than twice as many patients treated with TREMFYA® achieved ACR50[c] (41% for Q4W and 42% for Q8W) versus 20% receiving placebo at Week 24.[1]
- In assessing skin clearance, greater proportions of TREMFYA®-treated patients (73% for Q4W and 68% for Q8W) achieved an Investigator's Global Assessment (IGA) score of 0/1[d] (clear or almost clear skin) at Week 24 versus 31% receiving placebo.[1]

The data from the APEX study were consistent with the well-established safety profile of TREMFYA®, with no new safety signals identified.[1]

"With these results from the APEX study, TREMFYA has set a new bar for joint preservation as the only IL-23 inhibitor proven to significantly inhibit structural damage in active psoriatic arthritis, an inflammatory arthritis that can develop in up to 30% of people living with psoriasis," said Terence Rooney, Vice President, Rheumatology Disease Area Leader, Johnson & Johnson Innovative Medicine. "The efficacy and safety profile of TREMFYA offers psoriatic healthcare providers and patients an innovative option for disease control."

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.[2,3,4,5,6]

Editor's notes:

a. TREMFYA is not approved for Q4W dosing in the U.S.

b. Dr. Philip J. Mease is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

c. ACR20/50 response is defined as both at least 20/50 percent improvement from baseline in the number of tender and number of swollen joints, and a 20/50 percent improvement from baseline in three of the following five criteria: patient GA, physician GA, functional ability measure (HAQ-DI), patient-reported pain using a visual analog scale, and erythrocyte sedimentation rate or C-reactive protein.[7]

d. The IGA is a five-point scale with a severity score ranging from 0 to 4, where 0 indicates clear, 1 is minimal, 2 is mild, 3 is moderate and 4 indicates severe disease.[8]

ABOUT THE APEX STUDY (**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 period is scheduled prior to the final safety follow-up.[9]

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).[10,11,12] 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.[13] 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.[14] In patients with PsA, comorbidities such as obesity, cardiovascular disease, anxiety and depression are often present.[15] Studies show up to 30% of people with plaque PsO also develop PsA.[11]

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 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.
- adults with moderately to severely active Crohn's disease.[16]

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

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:

- 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®. 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®, 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, stomach pain, 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 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 **https://innovativemedicine.jnj.com/**

Follow us at **@JNJInnovMed.**

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

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 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 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.

REFERENCES

[1] 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.

[2] 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.

[3] 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.

[4] TREMFYA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.

[5] Skyrizi® [Prescribing Information]. North Chicago, IL: AbbVie, Inc.

[6] Omvoh™ [Prescribing Information]. Indianapolis, IN: Eli Lilly and Company.

[7] Felson, D. T., & LaValley, M. P. The ACR20 and defining a threshold for response in rheumatic diseases: too much

of a good thing. Arthritis Research & Therapy, 2014:16(1), 101. **https://doi.org/10.1186/ar4428**

[8] Simpson E, Bissonnette R, Eichenfield LF, et al. The validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD™): The development and reliability testing of a novel clinical outcome measurement instrument for the severity of atopic dermatitis [published online April 25, 2020]. J Am Acad Dermatol. doi: 10.1016/j.jaad.2020.04.104. Accessed April 2025.

[9] **ClinicalTrials.gov**. A Study of Guselkumab in Participants With Active Psoriatic Arthritis (APEX). Identifier: NCT04882098. Available at: **https://clinicaltrials.gov/study/NCT04882098**. Accessed March 2025.

[10] Donvito T., CreakyJoints: What Is Dactylitis? The 'Sausage Finger' Swelling You Should Know About. Available at: **https://creakyjoints.org/symptoms/what-is-dactylitis/**. Accessed March 2025.

[11] 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 March 2025.

[12] 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 March 2025.

[13] National Psoriasis Foundation. About Psoriatic Arthritis. Available at: **https://www.psoriasis.org/about-psoriatic-arthritis/**. Accessed March 2025.

[14] 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 March 2025.

[15] 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 March 2025.

[16] TREMFYA® Prescribing Information. Available at: **https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf** Accessed March 2025.

Media contact:
Craig Stoltz
cstoltz@its.jnj.com

Investor contact:
Lauren Johnson
investor-relations@its.jnj.com

View original content to download multimedia:**https://www.prnewswire.com/news-releases/new-data-show-tremfya-guselkumab-is-the-only-il-23-inhibitor-proven-to-significantly-inhibit-progression-of-joint-structural-damage-in-active-psoriatic-arthritis-302475588.html**

SOURCE Johnson & Johnson