

NEWS RELEASE

TREMFYA® (guselkumab) is the first and only IL-23 inhibitor to significantly reduce both the signs and symptoms and the progression of structural damage in adults living with active psoriatic arthritis

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TREMFYA® demonstrated clinically meaningful and statistically significant efficacy in patients with active psoriatic arthritis at risk for structural damage in Phase 3b study

Topline results demonstrate efficacy across multiple domains at Week 24, reinforcing TREMFYA® as a first-line treatment option for patients with active psoriatic arthritis

SPRING HOUSE, Pa., April 4, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced that the TREMFYA® (guselkumab) Phase 3b APEX study achieved both its primary endpoint (ACR20^a) of reducing signs and symptoms and its major secondary endpoint of reducing progression of structural damage as measured by radiographic progression at 24 weeks, in adults living with active psoriatic arthritis (PsA), compared to placebo.¹

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}

In the Phase 3b APEX study, TREMFYA®-treated patients also exhibited significantly less progression of structural damage versus patients receiving placebo at Week 24 as assessed by the PsA modified van der Heijde-Sharp (vdH-S) score, which includes joint space narrowing and erosion subscores. Data were consistent with the well-established safety profile of TREMFYA® with no new safety signals identified.¹

"Psoriatic arthritis can be a progressive and debilitating disease, and without early identification and treatment, patients may experience irreversible joint damage that significantly impacts their daily activities," said Terence Rooney, Vice President, Rheumatology Disease Area Leader, Johnson & Johnson Innovative Medicine. "These new topline data highlight the importance of addressing both inflammation and structural damage at the source as early as possible. As the only IL-23 treatment to show significant inhibition of structural damage, TREMFYA equips healthcare providers with critical data so their patients do not have to compromise their future joint health."

APEX is a Phase 3b study with long-term extension data through three years that will further assesses the sustained efficacy of TREMFYA® on inhibition of structural damage in patients with active PsA. Results from the APEX study are being prepared for presentation at upcoming medical congresses.

Editor's notes:

a. ACR20 response is defined as both at least 20 percent improvement from baseline in the number of tender and number of swollen joints, and a 20 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

ABOUT 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.⁸

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).^{9,10,11} 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.¹² 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.¹³ In patients with PsA, comorbidities such as obesity, cardiovascular disease, anxiety and depression

are often present.¹⁴ 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.¹⁰

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:

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

- 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:

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

- 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.mothersbaby.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.

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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 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 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 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. 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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¹ Data on file

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