

NEWS RELEASE

# TREMFYA® (guselkumab) is first and only IL-23 inhibitor to demonstrate sustained clinical and endoscopic outcomes with a fully subcutaneous regimen through 48 weeks in ulcerative colitis

2025-10-07

Patients treated with subcutaneous TREMFYA® achieved clinically meaningful results in both clinical remission (36.7%) and endoscopic remission (25.9%) at Week 48 in the Phase 3 ASTRO study

Clinical and endoscopic outcomes were demonstrated across both biologic-naïve and biologic-refractory subgroups

TREMFYA® is the only IL-23 inhibitor with a fully subcutaneous regimen, following recent FDA approval of SC induction in adults with ulcerative colitis

SPRING HOUSE, Pa., Oct. 7, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new 48-week data from the Phase 3 ASTRO study evaluating TREMFYA® (guselkumab) subcutaneous (SC) induction and maintenance therapy in adults with moderately to severely active ulcerative colitis (UC). These data show clinically meaningful rates of clinical and endoscopic remission, making TREMFYA® the first and only IL-23 inhibitor to demonstrate robust results with a fully SC regimen.<sup>1</sup> The findings are among 20 Johnson & Johnson abstracts being presented at the United European Gastroenterology (UEG) Week 2025.

TREMFYA® is the first and only approved, dual-acting monoclonal antibody 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 UC. Findings are based on in vitro studies.<sup>2,3,4,5,6</sup>

The ASTRO Week 48 data build on the previously reported Week 12 SC induction data, which showed statistically significant and clinically meaningful improvements compared to placebo across all clinical and endoscopic measures.<sup>7</sup> Data through Week 48 show patients treated with TREMFYA® 400 mg SC induction followed by SC maintenance dose regimens of either 100 mg every eight weeks (q8w) or 200 mg every four weeks (q4w) demonstrated clinically meaningful improvements across all clinical and endoscopic measures compared with patients receiving placebo (all nominal  $p < 0.001$ ).<sup>1</sup>

At Week 48:	TREMFYA® 100 mg q8w	TREMFYA® 200 mg q4w	Placebo
Clinical remission <sup>a</sup>	36.7 %	42.9 %	7.2 %
Endoscopic improvement <sup>b</sup>	44.6 %	47.1 %	11.5 %
Endoscopic remission <sup>c</sup>	25.9 %	26.4 %	5 %
Symptomatic remission <sup>d</sup>	47.5 %	53.6 %	14.4 %

Furthermore, in prespecified analyses of subpopulations defined by prior advanced therapy treatment status, TREMFYA® demonstrated clinically meaningful results across all endpoints in both biologic and JAK inhibitor-naïve and biologic and JAK inhibitor-refractory patients. Safety data from the ASTRO study were consistent with the well-established safety profile of TREMFYA®.<sup>1</sup>

"For many patients, having a subcutaneous induction option is an important step forward—offering the flexibility of at-home administration after proper training without compromising efficacy," said Prof. Silvio Danese, IRCCS Ospedale San Raffaele and University VitaSalute San Raffaele in Milan, Italy and study investigator.<sup>e</sup> "These results show that a fully subcutaneous regimen of guselkumab can deliver meaningful clinical and endoscopic benefits that are sustained for a full year, supporting long-term disease control in ulcerative colitis."

"These results reflect our unwavering commitment to advancing the science that delivers both meaningful outcomes and more choices for healthcare providers and their patients," said Esi Lamoussé-Smith, MD, PhD, Vice President, Gastroenterology Disease Area Lead, Immunology, Johnson & Johnson Innovative Medicine. "TREMFYA is the only IL-23 inhibitor to offer a subcutaneous induction option in both Crohn's disease and ulcerative colitis, the latter of which was recently approved by the U.S. FDA and supported by findings from the ASTRO study. This latest development offers patients and providers the choice of starting treatment for UC with a self-administered subcutaneous injection, with the same efficacy and safety that were established with IV induction."

TREMFYA® has received U.S. Food and Drug Administration (FDA) and European Commission (EC) approval for both SC and IV induction options for the treatment of adults with moderately to severely active Crohn's disease and U.S.

FDA approval for both SC and IV induction options for the treatment of adults with moderately to severely active ulcerative colitis. TREMFYA® is approved by the EC for the treatment of adult patients with moderately to severely active ulcerative colitis and is currently administered via an IV induction regimen, followed by a SC maintenance regimen.

For a full list of all Johnson & Johnson data being presented at UEG Week visit:

<https://www.jnj.com/innovativemedicine/immunology/gastroenterology>

Editor's Notes:

---

- a. Clinical remission was defined as a Mayo stool frequency subscore of 0 or 1 and not increased from baseline, a Mayo rectal bleeding subscore of 0, and a Mayo endoscopic subscore of 0 or 1 with no friability present on the endoscopy.
- b. Endoscopic improvement was defined as an endoscopy subscore of 0 or 1 with no friability present on the endoscopy.
- c. Endoscopic remission (normalization) was defined as a Mayo endoscopic subscore (MES) of 0.
- d. Symptomatic remission per Mayo score was defined as a stool frequency subscore of 0 (normal number of stools) or 1 (1 to 2 stools more than normal) and a rectal bleeding subscore of 0 (no blood seen).
- e. Prof. Danese is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

## ABOUT THE ASTRO STUDY (NCT05528510)

ASTRO is a randomized, double-blind, placebo-controlled, parallel-group, multicenter, treat-through Phase 3 study designed to evaluate the efficacy and safety of TREMFYA® SC induction therapy (400 mg at Weeks 0, 4, and 8) in adults with moderately to severely active ulcerative colitis (UC) who had an inadequate response or intolerance to conventional therapy (e.g., thiopurines or corticosteroids), prior biologics (TNF antagonists or vedolizumab) and/or ozanimod or approved JAK inhibitors. Patients (n = 418) were randomized 1:1:1 to receive TREMFYA® 400 mg SC induction at Weeks 0, 4 and 8 followed by TREMFYA® 200 mg SC every 4 weeks (q4w); or TREMFYA® 400 mg SC induction at Weeks 0, 4 and 8, followed by TREMFYA® 100 mg SC every 8 weeks (q8w); or placebo. The maintenance dose regimens in ASTRO (200 mg SC q4w and 100 mg SC q8w) are the same as those evaluated in the Phase 3 QUASAR program which established the efficacy and safety profile of IV induction followed by SC maintenance therapy in patients with moderate to severely active UC.<sup>8</sup>

## ABOUT ULCERATIVE COLITIS

Ulcerative colitis (UC) is a chronic disease of the large intestine, also known as the colon, in which the lining of the colon becomes inflamed and develops tiny open sores, or ulcers, that produce pus and mucus. It is the result of the immune system's overactive response. Symptoms vary but may typically include loose and more urgent bowel movements, rectal bleeding or bloody stool, persistent diarrhea, abdominal pain, loss of appetite, weight loss, and fatigue.<sup>9</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 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.<sup>5</sup>

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 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).

## 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

o trouble breathing or throat tightness

pressure)  
o swelling of your face, eyelids, lips, mouth, tongue  
or throat

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®. 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®.
- 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](http://www.mothertobaby.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® 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](http://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](http://www.innovativemedicine.jnj.com)

Follow us at [@JNJInnovMed](https://twitter.com/JNJInnovMed).

## Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding 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: 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](http://www.sec.gov), [www.jnj.com](http://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:

<sup>1</sup> Allegretti JR, et al. Efficacy and safety of subcutaneous guselkumab induction and maintenance therapy in patients with ulcerative colitis: results through week 48 from the phase 3 ASTRO study. Oral presentation OP203 at United European Gastroenterology (UEG) Week 2025. October 2025.

<sup>2</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>3</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>4</sup> TREMFYA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.

<sup>5</sup> Skyrizi® [Prescribing Information]. North Chicago, IL: AbbVie, Inc.

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

<sup>7</sup> Peyrin-Biroulet, et al. Efficacy and safety of subcutaneous guselkumab induction therapy in patients with Ulcerative Colitis: Results through week 12 from the phase 3 ASTRO study. Results from the Phase 3 ASTRO study. Oral presentation (#OP10) at the 20th Congress of the European Crohn's and Colitis Organization (ECCO). February 2025.

<sup>8</sup> National Institutes of Health: **Clinicaltrials.gov**. A Study of Guselkumab Therapy in Participants With Moderately to Severely Active Ulcerative Colitis (ASTRO). Identifier: NCT05528510. **<https://clinicaltrials.gov/study/NCT05528510?term=astro&intr=guselkumab&rank=1>**. Accessed March 2025.

<sup>9</sup> Crohn's & Colitis Foundation. What is ulcerative colitis? Available at: **<https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis>**. Accessed March 2025

---

Media contact:  
Craig Stoltz  
**[cstoltz@its.jnj.com](mailto:cstoltz@its.jnj.com)**

Investor contact:  
Lauren Johnson  
**[investor-relations@its.jnj.com](mailto:investor-relations@its.jnj.com)**

View original content to download multimedia:**<https://www.prnewswire.com/news-releases/tremfya-guselkumab-is-first-and-only-il-23-inhibitor-to-demonstrate-sustained-clinical-and-endoscopic-outcomes-with-a-fully-subcutaneous-regimen-through-48-weeks-in-ulcerative-colitis-302576330.html>**

SOURCE Johnson & Johnson