Johnson&Johnson

NEWS RELEASE

TREMFYA® (guselkumab) positioned to become the first and only IL-23 inhibitor to offer subcutaneous induction in ulcerative colitis as demonstrated in new data through 24 weeks

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TREMFYA® subcutaneous induction demonstrates significant rates of clinical remission and endoscopic improvement at Week 24 in ulcerative colitis

Findings build on recent FDA-approval of both routes of administration for induction therapy with TREMFYA® in Crohn's disease

SAN DIEGO, May 5, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new data from the Phase 3 ASTRO study evaluating TREMFYA® (guselkumab) subcutaneous (SC) induction therapy in adults with moderately to severely active ulcerative colitis (UC). The ASTRO Week 24 data build on the Week 12 SC induction data that showed statistically significant and clinically meaningful improvements compared to placebo across all clinical and endoscopic measures consistent with the U.S. Food and Drug Administration (FDA)-approved intravenous (IV) induction regimen evaluated in this population, in the Phase 3 QUASAR study.[1,2] TREMFYA® is the first and only IL-23 inhibitor to demonstrate robust results with a fully SC regimen. These findings are among 24 abstracts highlighting the Company's research being presented at Digestive Disease Week (DDW) 2025.

Data at Week 24 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 statistically significant and clinically meaningful improvements across all clinical and endoscopic measures compared with patients receiving placebo.[1]

At Week 24:	TREMFYA® 100 mg q8w	TREMFYA® 200 mg q4w	Placebo
Clinical remission (P<0.001)[a]	35.3 %	36.4 %	9.4 %
Symptomatic remission (P<0.001)[b]	54.7 %	50.0 %	25.2 %
Endoscopic improvement (P<0.001)[c]	40.3 %	45.0 %	12.2 %
Clinical response (P<0.001)[d]	63.3 %	61.4 %	30.9 %

"Data from the ASTRO study demonstrate that subcutaneous induction treatment with TREMFYA provides clinically meaningful remission in patients with ulcerative colitis, similar to the effects seen with intravenous induction," said Millie Long, M.D., MPH, Professor of Gastroenterology and Hepatology at the University of North Carolina at Chapel Hill and study investigator.[e] "The availability of both subcutaneous and intravenous induction options would offer physicians and patients greater flexibility in their treatment approach."

Furthermore, at Week 24, in prespecified analyses of subpopulations defined by prior advanced therapy treatment status, TREMFYA® demonstrated statistically significant results across 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®.[1]

"These results highlight the potential of TREMFYA to redefine ulcerative colitis care with a fully subcutaneous induction and maintenance regimen that offers a convenient option with meaningful clinical and endoscopic improvements," said Esi Lamousé-Smith, MD, PhD, Vice President, Gastroenterology Disease Area Lead, Immunology, Johnson & Johnson Innovative Medicine. "Our goal is to reshape UC care and empower prescribers with a differentiated and effective treatment that offers the option of patient self-administration from day one."

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.[3,4,5,6,7]

TREMFYA® received FDA **approval** in September 2024 for the treatment of adult patients with moderately to severely active UC and is currently administered via an IV induction regimen, followed by a SC maintenance regimen. In November 2024, a supplemental Biologics License Application (sBLA) **was submitted** to the FDA seeking approval of a SC induction regimen of TREMFYA® for the treatment of adults with moderately to severely active UC. TREMFYA® was also **approved** by the FDA in March 2025 for SC and IV induction options for the treatment of adults with moderately to severely active Crohn's disease (CD).

For a full list of all data being presented at DDW visit: **https://innovativemedicine.jnj.com/our-innovation/focus-areas/immunology/gastroenterology/gastroenterology-newsroom**

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. Symptomatic remission per Mayo score is 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).
c. Endoscopic improvement was defined as an endoscopy subscore of 0 or 1 with no friability present on the endoscopy.
d. Clinical response is defined as decrease from baseline in the modified Mayo score by greater than or equal to (>=) 30 percent (%) and >=2 points, with either a >=1-point decrease from baseline in the rectal bleeding subscore or a rectal bleeding subscore of 0 or 1.
e. Dr. Long is a paid consultant for Johnson & Johnson. She 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 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.[8]

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.[9]

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.[5]

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. In addition, TREMFYA ® is approved in Europe, Japan and Brazil for the treatment of adult patients with moderately to severely active UC and in Brazil and China for the treatment of adults with moderately to severely active CD.

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 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:

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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**, 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 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** 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] 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.

[2] Long M, et al. Efficacy And Safety Of Subcutaneous Guselkumab Induction Therapy In Patients With Ulcerative Colitis: Results Through Week 24 From The Phase 3 Astro Study. Oral presentation (#4241895) at Digestive Disease Week 2025. May 2025.

[3] 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.

[4] 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.

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

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

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

[8] 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.

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

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