Johnson&Johnson

NEWS RELEASE

TREMFYA® (guselkumab) achieves U.S. approval for subcutaneous induction in adults with ulcerative colitis, now the first and only IL-23 inhibitor with a fully subcutaneous regimen

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TREMFYA® offers the flexibility of self-administration from the start of treatment, building on the prior approval of subcutaneous induction in Crohn's disease

TREMFYA® achieved significant rates of clinical remission and endoscopic improvement versus placebo at Week 12 with a subcutaneous induction regimen, consistent with IV induction

Johnson & Johnson is initiating a head-to-head study seeking to demonstrate the superiority of TREMFYA® vs. Skyrizi® (risankizumab) in Crohn's disease, based on the confidence in the clinical profile

HORSHAM, Pa., Sept. 19, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced that the U.S. Food and Drug Administration (FDA) has approved a subcutaneous (SC) induction regimen of TREMFYA® (guselkumab) for the treatment of adults with moderately to severely active ulcerative colitis (UC). With this approval, TREMFYA® is the first and only IL-23 inhibitor to offer both SC and intravenous (IV) induction options for the treatment of UC and Crohn's disease (CD), which combined affect approximately three million Americans.[1] TREMFYA® is the first and only approved fully-human, 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.[2-6]

"Historically, IL-23 inhibitors have required IV infusions at the start of therapy, which can create barriers to starting

treatment or be burdensome for some patients and clinicians," said David T. Rubin, MD, Director, Inflammatory Bowel Disease Center, University of Chicago Medicine and study investigator. "With today's approval, UC patients and providers now have the choice of starting TREMFYA with a self-administered subcutaneous injection, with the same efficacy and safety that were established with IV induction in the prior clinical trials and subsequently seen in our real-world practice."

The UC SC induction approval is based on results from the Phase 3 ASTRO trial, which employed a treat-through design to evaluate the efficacy and safety of TREMFYA® SC induction therapy in adults with moderately to severely active UC who had an inadequate response or intolerance to conventional therapy and advanced therapies. All multiplicity-controlled primary and secondary endpoints demonstrated statistically significant and clinically meaningful improvements with TREMFYA® compared to placebo across all clinical and endoscopic measures: [4,7]

- Early symptomatic response was observed, with TREMFYA® separating from placebo as early as two weeks and sustained through Week 24.
- Significantly greater proportions of patients treated with TREMFYA® 400 mg SC every four weeks (q4w) achieved clinical remission (26% vs. 7%; $p<0.001$) and endoscopic improvement (36% vs. 12%; $p<0.001$) at Week 12 vs. those treated with placebo.
- Results were consistent with the FDA-approved 200mg IV induction regimen, which previously achieved clinical remission (23% vs. 8%; $p<0.001$) and endoscopic improvement (27% vs. 11%; $p<0.001$) vs. those treated with placebo. The efficacy of SC and IV induction was comparable across subgroups with severe or refractory disease and both routes demonstrated a similar time to onset of efficacy.
- Week 24 SC induction followed by SC maintenance data also demonstrated statistically significant and clinically meaningful improvements in clinical remission (100 mg: 34%, 200 mg: 34% vs. 10%; $p<0.001$) and endoscopic improvement (100 mg: 39%, 200 mg: 44% vs. 12%; $p<0.001$) vs. those treated with placebo.

"With today's approval, TREMFYA is the first and only IL-23 inhibitor to offer inflammatory bowel disease patients robust clinical and endoscopic results with a fully subcutaneous regimen, now across both ulcerative colitis and Crohn's disease," said Chris Gasink, MD, Vice President, Medical Affairs, Gastroenterology & Autoantibody, Johnson & Johnson Innovative Medicine. "The initiation of a head-to-head study in Crohn's disease is a further testament to our commitment to advancing the clinical evidence of TREMFYA in IBD."

TREMFYA® dosing in the treatment of moderately to severely active UC:[4]

- The recommended SC induction dosage is 400 mg (given as two consecutive injections of 200 mg each, dispensed in one Induction Pack) at Weeks 0, 4 and 8. TREMFYA® is also available in a 200 mg prefilled syringe. For the IV induction option, 200 mg IV infusions are administered at Weeks 0, 4 and 8.
- Recommended maintenance dosage is either 100 mg administered by SC injection at Week 16, and every 8

weeks thereafter, or 200 mg administered by SC injection at Week 12, and every 4 weeks thereafter. Healthcare providers are instructed to use the lowest effective recommended dosage to maintain therapeutic response.

Johnson & Johnson is committed to supporting access to all its treatments, including offering a patient support program called TREMFYA withMe. Commercially insured adult patients who are prescribed TREMFYA® for UC may be eligible to receive their first induction treatment in as little as 24 hours through TREMFYA withMe.

In September 2024, Johnson & Johnson received FDA **approval** of TREMFYA® (with IV induction) for the treatment of adults with moderately to severely active UC, based on the Phase 3 QUASAR study.[4] In March 2025, TREMFYA® received FDA **approval**, including both SC and IV induction options, for the treatment of adults with moderately to severely active CD.[4] Based on the positive outcomes of clinical programs,[8-10] Johnson & Johnson is initiating the first IL-23 inhibitor head-to-head study seeking to demonstrate the superiority of TREMFYA® vs. Skyrizi® (risankizumab), representing an important next step in Crohn's disease research.

This approval is another important milestone for patients and is emblematic of Johnson & Johnson's continuous commitment to innovating to improve the lives of people living with chronic immune-mediated diseases, including inflammatory bowel disease.

Editor's Notes:

a) CD64+ cells are the predominant source of IL-23 in CD. Cells not expressing CD64 may also contribute to IL-23 production but to a lesser extent.[2,3]
b) "Only" based on approved selective IL-23 inhibitors for moderately to severely active UC and CD as of March 2025.[4-6]
c) Based on in vitro studies in an inflammatory monocyte model.[2]
d) Moderately to severely active UC was defined as a modified Mayo score (mMS) between 5 and 9 and an centrally reviewed endoscopy (ES) score of 2 or 3.[4]
e) Symptomatic response is defined as a decrease in the symptomatic Mayo score (a combination of Mayo stool frequency and Mayo rectal bleeding subscores) by at least 30% and 1 point from the baseline.[4]
f) Clinical remission is 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 endoscopy subscore of 0, or 1 with no friability present on the endoscopy.[4]
g) Endoscopic improvement is defined an endoscopy subscore of 0, or 1 with no friability present on the endoscopy.[4]
h) David Rubin 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 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 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.[7]

ABOUT THE QUASAR PROGRAM (**NCT04033445**)

QUASAR is a randomized, double-blind, placebo-controlled, parallel group, multicenter Phase 2b/3 program designed to evaluate the efficacy and safety of TREMFYA®, a selective IL-23 inhibitor, in adult patients with moderately to severely active ulcerative colitis who had an inadequate response or intolerance to conventional therapy (e.g., thiopurines or corticosteroids), prior biologics and/or JAK inhibitors (i.e., tumor necrosis factor-alpha antagonists, vedolizumab, or tofacitinib). QUASAR included a Phase 2b dose-ranging induction study, a confirmatory Phase 3 induction study, and a Phase 3 maintenance study. Efficacy, safety, pharmacokinetics, immunogenicity, and biomarkers are assessed at specified time points. The most common adverse reactions (>2%) in patients with UC who received TREMFYA® and at a higher rate of placebo in the induction study were respiratory tract infections. The most common adverse reactions (>3%) in patients with UC who received TREMFYA® and at a higher rate of placebo in the maintenance study were injection site reactions, arthralgia, and upper respiratory tract infection.[10]

ABOUT THE GRAVITI STUDY (**NCT05197049**)

GRAVITI is a randomized, double-blind, placebo-controlled Phase 3 study to evaluate guselkumab SC induction therapy (400 mg at Weeks 0, 4, and 8) in patients with moderately to severely active Crohn's disease who experienced an inadequate response or failed to tolerate conventional therapy (i.e., corticosteroids or immunomodulators) or biologic therapy (TNF antagonists or vedolizumab). Patients received guselkumab 400 mg SC q4w (x3) followed by guselkumab 200 mg SC q4w; or guselkumab 400 mg SC q4w (x3) followed by guselkumab 100 mg SC q8w; or placebo. The maintenance doses in GRAVITI (200 mg SC q4w and 100 mg SC q8w) are the same as those evaluated in the Phase 3 GALAXI 2 and GALAXI 3 studies that evaluated the efficacy and safety of IV induction followed by SC maintenance therapy in patients with moderate to severely active Crohn's disease. Similar to GALAXI, GRAVITI employed a treat-through design, in which patients were randomized to guselkumab at Week 0 and remained on that regimen throughout the study, regardless of clinical response status at the end of induction.

Participants randomized to placebo were able to receive guselkumab (400 mg SC q4w x3 ➔ 100 mg SC q8w) if rescue criteria were met at Week 16.[8]

ABOUT THE GALAXI PROGRAM (**NCT03466411**)

GALAXI is a randomized, double-blind, placebo-controlled, active-controlled (ustekinumab), global, multicenter Phase 2/3 program designed to evaluate the efficacy and safety of guselkumab in participants with moderately to severely active Crohn's disease with inadequate response/intolerance to conventional therapies (corticosteroids or immunomodulators) and/or biologics (TNF antagonists or vedolizumab). GALAXI includes a Phase 2 dose-ranging study (GALAXI 1) and two independent, identically designed confirmatory Phase 3 studies (GALAXI 2 and 3). Each GALAXI study employed a treat-through design in which participants remained on the treatment to which they were initially randomized and includes a long-term extension study that will assess clinical, endoscopic, and safety outcomes with guselkumab through a total of five years. Patients received guselkumab 200 mg intravenous induction at Weeks 0, 4 and 8 followed by guselkumab 200 mg subcutaneous maintenance every 4 weeks; or guselkumab 200 mg intravenous induction at Weeks 0, 4 and 8, followed by guselkumab 100 mg subcutaneous maintenance every 8 weeks; or a biologic active control; or placebo. Participants randomized to placebo were able to receive ustekinumab if clinical response was not met at Week 12. Of the 873 individuals pooled across the GALAXI 2 & 3 dataset, 456 (52 percent) had prior history of inadequate response to biologics, 365 (42 percent) were biologic-naïve and 52 (6 percent) were biologic experienced without documented inadequate response or intolerance. The GALAXI 2 and GALAXI 3 studies were the first-ever double-blind registrational head-to-head clinical trials to demonstrate superiority versus ustekinumab in Crohn's disease, showing guselkumab was superior to ustekinumab in all endoscopic-based endpoints when analyzed with pooled data.[9]

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.[11]

ABOUT CROHN'S DISEASE

Crohn's disease is one of the two main forms of inflammatory bowel disease, which affects an estimated three million Americans. Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract with no known cause, but the disease is associated with abnormalities of the immune system that could be triggered by a genetic predisposition, diet, or other environmental factors. Symptoms of Crohn's disease can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever. Currently no cure is available for Crohn's disease.[1]

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 the dual-acting mechanism 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.

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. TREMFYA® is approved in Europe, Canada, and a number of other countries for the treatment of adults with moderately to severely active ulcerative colitis and Crohn's disease.

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**.

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,
- trouble breathing or throat tightness
- chest tightness
- skin rash, hives

mouth, tongue or throat

- 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**, 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, bronchitis, feeling very tired (fatigue), fever (pyrexia), and skin rash.

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 **www.innovativemedicine.jnj.com**.

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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®. 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**, **www.jnj.com**, **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.

[1] Crohn's & Colitis Foundation. Overview of Crohn's disease. Available at: **https://www.crohnscolitisfoundation.org/what-is-crohns-disease/overview**. Accessed September 2025.

[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.

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

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

[7] 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 September 2025.

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[9] National Institutes of Health: **Clinicaltrials.gov**. A study of the efficacy and safety of guselkumab in participants with moderately to severely active Crohn's disease (GALAXI). Identifier: NCT03466411. Available at: **https://clinicaltrials.gov/study/NCT03466411**. Accessed September 2025.

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

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