Johnson&Johnson

NEWS RELEASE

Johnson & Johnson study shows TREMFYA® (guselkumab) is the first and only IL-23 inhibitor to demonstrate efficacy in perianal fistulizing Crohn's disease

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TREMFYA® demonstrated significantly higher rates of combined fistula remission – complete external closure of draining fistulas and absence of fluid collection on MRI – compared to placebo at Week 24

First study of its kind in 20 years for this debilitating manifestation of Crohn's disease presented as late-breaking data at Digestive Disease Week 2026

CHICAGO, May 5, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced results from the Phase 3 FUZION study evaluating TREMFYA® (guselkumab) in adults with active perianal fistulizing Crohn's disease (CD). At Week 24, TREMFYA demonstrated significantly higher rates of combined fistula remission, a highly stringent endpoint defined as complete external closure of draining fistulas and absence of fluid collection on MRI, compared to placebo.[1] Remission in patients with this complicated manifestation remains difficult to achieve, and this is the first randomized control trial of an approved therapy in inflammatory bowel disease (IBD) that demonstrates efficacy in adults with active perianal fistulizing Crohn's disease in 20 years. These late-breaking data are among the 32 company-sponsored abstracts at Digestive Disease Week (DDW) 2026.

Key findings from the FUZION study

TREMFYA met the primary endpoint of combined fistula remission at Week 24, defined as complete closure of all external fistula openings with no drainage, without development of new fistulas and no evidence of underlying fluid collections on MRI.[a] Combined fistula remission was achieved by 28.3% of patients receiving TREMFYA 100 mg every 8 weeks (q8w) and 27.0% of patients receiving TREMFYA 200 mg every 4 weeks (q4w), compared with 10.3% for

placebo.

The treatment differences versus placebo were statistically significant for both the 100 mg q8w and 200 mg q4w dosing regimens (p=0.007 and p=0.013, respectively). Adverse events through 24 weeks were consistent with the known safety profile of TREMFYA in CD.

"The pain, swelling and persistent drainage associated with perianal fistulizing Crohn's disease can be profoundly disruptive to patients' daily lives," said Laurent Peyrin-Biroulet, MD, PhD, study investigator.[b] "Achieving durable fistula closure without repeated surgical interventions remains a significant unmet need. The results from the FUZION study demonstrate the ability of TREMFYA to achieve combined fistula remission, which is an exciting step forward for patients, expanding what's possible for managing this debilitating and chronic condition."

"It has been more than two decades since a highly rigorous study has been dedicated to perianal fistulizing Crohn's disease, a very difficult-to-treat and complex manifestation of this already challenging condition," said Ludovic de Beaucoudrey, PhD, J&J Innovative Medicine Vice President, Immunology, Global Medical Affairs, Gastroenterology and Autoantibody. "Building on decades of experience in immunology, Johnson & Johnson continues to address areas of significant unmet need, and the FUZION study reflects our commitment to delivering meaningful, evidence-based advances for patients and the healthcare providers who care for them."

Addressing a significant unmet need in perianal fistulizing Crohn's disease

A fistula is an abnormal connection or tunnel that develops between the intestine and another organ or the skin, typically arising when inflammation causes ulceration in the intestinal wall or surrounding tissue. Over time, these ulcers may penetrate the full thickness of the bowel, forming a channel that allows infected material to drain. Perianal fistulizing Crohn's disease affects nearly 25% of patients with CD and represents a severe, often debilitating manifestation of the disease that has profound impacts on a person's physical and mental health.[2,3] It is characterized by pain, swelling, persistent drainage, recurrent abscesses, and a frequent need for surgical intervention.

As another example of this commitment for evidence-based advances for CD patients and providers, Johnson & Johnson is also initiating the CHARGE study, the first head-to-head study of IL-23 inhibitors in IBD, which will evaluate TREMFYA compared to risankizumab in treatment of Crohn's disease. Trial sites are now open for patient enrollment. For more information, visit **ClinicalTrials.gov**.

With the addition of the results from the breakthrough Phase 2b DUET studies in CD and UC, Johnson & Johnson products were featured in three late-breaking abstracts at DDW.[4,5] For a full list of all Johnson & Johnson data being presented at DDW visit: **https://www.jnj.com/innovativemedicine/immunology/gastroenterology**.

Editor's Notes:

a. Defined as >2cm of the perianal fistulas in at least two of three dimensions, confirmed by a blinded central review of the MRI results.
b. Dr. Laurent Peyrin-Biroulet is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

About the FUZION study (NCT05347095)

FUZION is a randomized, placebo-controlled, double-blind, multicenter, Phase 3 study designed to evaluate the efficacy and safety of TREMFYA in adults with perianal fistulizing Crohn's disease. Patients enrolled in the study had one or more active draining perianal fistulas confirmed by blinded central MRI review, CD Activity Index [CDAI] <350, and inadequate response to oral corticosteroids, azathioprine, 6-mercaptopurine, methotrexate, or up to 2 advanced therapy classes. Patients were randomized 2:2:1 to receive TREMFYA 200 mg intravenous (IV) induction at Weeks 0, 4, 8 weeks followed by TREMFYA 100 mg subcutaneous (SC) induction every 8 weeks (q8w); or TREMFYA 200 mg IV infusion in at Weeks 0, 4, 8 weeks followed by TREMFYA 200 mg SC every 4 weeks (q4w); or placebo.[6]

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 and an estimated four million people across Europe.[7,8] 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.[9] 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.[10]

About TREMFYA (guselkumab)

Developed by Johnson & Johnson, TREMFYA is the first 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 and children 6 years and older who also weigh at least 88 pounds (40 kg) 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 and children 6 years and older who also weigh at least 88 pounds (40 kg) 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, 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**.

TREMFYA 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 diarrhea or stomach pain
o shortness of breath

o weight loss
o cough
o warm, red, or painful skin or sores on your body different from your psoriasis
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.

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: 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**, **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] Laurent Peyrin-Biroulet, et al. Guselkumab for Perianal Fistulizing Crohn's Disease: Week 24 Results from the Phase 3, Randomized, Double-blind, Placebo-Controlled, Multicenter FUZION Study. (Abstract 1058b) Presented at Digestive Disease Week (DDW) May 2-5, 2026

[2] Sulak A., et al. Where Are We and Where to Next?—The Future of Perianal Crohn's Disease Management, Journal of Clinical Medicine, Volume 12, Issue 19, October 2023, 6379, **https://doi.org/10.3390/jcm12196379**.

[3] Spinelli A, Yanai H, Girardi P, Milicevic S, Carvello M, Maroli A, Avedano L. The Impact of Crohn's Perianal Fistula on Quality of Life: Results of an International Patient Survey. Crohns Colitis 360. 2023 Jul 25;5(3):otad036. doi: 10.1093/crocol/otad036. PMID: 37529012; PMCID: PMC10390083.

[4] Sands BE, et al. Efficacy And Safety Of The First Co-Antibody Therapy, Jnj-78934804, In Patients With Moderately To Severely Active Crohn's Disease Refractory To Systemic Therapies. (Abstract 979f) Presented at Digestive Disease Week (DDW) May 2-5, 2026.

[5] Maria T. Abreu, et al. Efficacy And Safety Of The First Co-Antibody Therapy, Jnj-78934804, In Patients With Moderately To Severely Active Ulcerative Colitis Refractory To Systemic Therapies. (Abstract 1058d) Presented at Digestive Disease Week (DDW) May 2-5, 2026.

[6] National Institutes of Health: **Clinicaltrials.gov**. A Study of Guselkumab in Participants With Fistulizing, Perianal Crohn's Disease (FUZION CD). Identifier: NCT05347095. **https://clinicaltrials.gov/study/NCT05347095?tab=researcher**. Accessed March 2026.

[7] Crohn's & Colitis Foundation. Overview of Crohn's disease. Available at: **https://www.crohnscolitisfoundation.org/what-is-crohns-disease/overview**. Accessed February 2026.

[8] Ng SC, et al. Worldwide incidence and prevalence of inflammatory bowel disease in the 21st century: a systematic

review of population-based studies. The Lancet. 2017;390:2769-78.

[9] Crohn's & Colitis Foundation. What is Crohn's disease? Available at: https://**www.crohnscolitisfoundation.org/what-is-crohns-disease/causes**. Accessed March 2026.

[10] Crohn's & Colitis Foundation. Signs and symptoms of Crohn's disease. Available at **https://www.crohnscolitisfoundation.org/patientsandcaregivers/what-is-crohns-disease/symptoms**. Accessed March 2026.

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