

Johnson & Johnson announces new data showing TREMFYA® (guselkumab) is the only IL-23 to deliver durable fistula remission through 48 weeks in Crohn's disease with perianal fistula

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- TREMFYA maintained combined fistula remission through Week 48 across both maintenance dose regimens, including an increase from 28% at Week 24 to 35% at Week 48 in the 100 mg dose group
- These findings build on the Phase 3 clinical program, demonstrating efficacy in a dedicated, randomized, placebo-controlled trial in patients with this debilitating and challenging manifestation of Crohn's disease

SPRING HOUSE, Pa., Oct. 19, 2026 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced one-year results from the Phase 3 FUZION study showing TREMFYA® (guselkumab) maintained or improved fistula remission through 48 weeks in adults with Crohn's disease (CD).¹ The findings build on the previously reported Week 24 results and further support the use of TREMFYA in one of the most difficult-to-treat manifestations of CD². The late-breaking findings are being presented at the 2026 United European Gastroenterology Week (UEG Week).

Key findings from the Phase 3 study in Crohn's disease with perianal fistula

Combined fistula remission^a, which incorporates both clinical and radiologic assessment, was maintained or improved in both TREMFYA maintenance regimens through Week 48. Among patients receiving TREMFYA 100 mg every 8 weeks (q8w), combined fistula remission further increased from 28% at Week 24 to 35% at Week 48. Similar findings were observed for rates of clinically assessed fistula remission.^b

Results among patients receiving TREMFYA 200 mg every 4 weeks (q4w) remained consistent through Week 48. More than 90% of all randomized patients, which included both bio-naïve and bio-experienced patients, completed

treatment through Week 48.

"Perianal fistula remain one of the most debilitating complications of Crohn's disease, where achieving durable disease control beyond symptom improvement is a challenge," said Laurent Peyrin-Biroulet, MD, PhD, study investigator.^c "The latest findings from the FUZION study, which is the first of its kind in 20 years, shows that patients treated with TREMFYA maintained or improved upon the clinical benefits observed at Week 24, providing encouraging evidence for its use in this patient population."

Safety findings through Week 48 were consistent with the well-established safety profile of TREMFYA in Crohn's disease.

The 48-week findings reinforce the previously shared **Week 24 results from FUZION**, which showed that in the overall study population at Week 24, 28% of patients receiving TREMFYA 100 mg q8w and 27% receiving TREMFYA 200 mg q4w achieved combined fistula remission compared with 10% receiving placebo, making TREMFYA the only IL-23 inhibitor to demonstrate efficacy in a dedicated, randomized, placebo-controlled trial in patients with Crohn's disease with perianal fistula.²

"These one-year findings expand the evidence for TREMFYA in perianal fistulizing Crohn's disease where long-term treatment options remain limited," said David M. Lee, M.D., Ph.D., Global Immunology Therapeutic Area Head, Johnson & Johnson. "Building on our longstanding expertise in immune-mediated diseases, we are committed to studying TREMFYA across the full spectrum of moderately to severely active Crohn's disease and generating evidence that may transform outcomes for patients, including those facing some of its most challenging complications."

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. Combined fistula remission was 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.
- b. Clinically assessed fistula remission was defined as: 100% closure of all treated external openings without development of new fistulas or abscesses and without any drainage by external openings, occurring spontaneously or after gentle finger compression.
- c. 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 Crohn's disease with perianal fistula. 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.³

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.^{4,5} 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.⁶ Symptoms of Crohn's disease can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever. Some patients may also develop fistulas, abnormal connections between the intestine and other organs or tissues, which can be associated with pain, drainage, infection, and substantial impairment in quality of life. Currently no cure is available for Crohn's disease.⁷

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:

- 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:

- 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.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 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.

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