Johnson&Johnson

NEWS RELEASE

TREMFYA® (guselkumab), the first and only IL-23 inhibitor with a fully subcutaneous treatment regimen, demonstrates durable remission in Crohn's disease at two years

2025-10-27

Clinical remission rates were over 85% for both TREMFYA® maintenance doses at 96 weeks in both the Phase 3 GRAVITI and GALAXI studies

TREMFYA® is the only IL-23 inhibitor to demonstrate durable endoscopic and clinical remission with a fully subcutaneous regimen in moderately to severely active Crohn's disease

PHOENIX, Oct. 27, 2025 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced new 96-week data from the long-term extensions (LTE) of the Phase 3 GRAVITI, GALAXI 2 and GALAXI 3 studies, which show the durability of TREMFYA® (guselkumab) in adults with moderately to severely active Crohn's disease (CD) at two years.[1] These findings are among 23 Johnson & Johnson abstracts being presented at the 2025 American College of Gastroenterology Annual Scientific Meeting (ACG).

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.[2 3 4 5 6]

At Week 96, patients treated with TREMFYA® 400 mg subcutaneous (SC) induction (GRAVITI) or 200 mg intravenous (IV) induction (GALAXI) followed by SC maintenance dose regimens of either 100 mg every eight weeks (q8w) or 200 mg every four weeks (q4w) show high rates of long-term clinical remission, endoscopic response, endoscopic

remission, and deep remission.

At Week 96 (as observed)*:	TREMFYA® 100 mg q8w	TREMFYA® 200 mg q4w
Clinical remission[a]		
GRAVITI	92.0%	93.4%
GALAXI 2, 3 (pooled)	86.7%	87.1%
Endoscopic response[b]		
GRAVITI	65.0%	65.1%
GALAXI 2, 3 (pooled)	73.6%	70.7%
Endoscopic remission[c]		
GRAVITI	41.5%	46.0%
GALAXI 2, 3 (pooled)	56.3%	56.6%
Deep remission[d]		
GRAVITI	38.7%	44.1%
GALAXI 2, 3 (pooled)	51.2%	49.0%

*The as observed analysis set included participants who entered the LTE, received ≥1 partial or complete study drug dose during the LTE, remained on treatment, and had data available at Week 96; participants who had a dose adjustment (GALAXI only) were not included at Week 96.

Safety data through 96 weeks in the LTE periods of the GALAXI and GRAVITI studies were consistent with the well-established safety profile of TREMFYA®.

"Crohn's disease is a chronic condition that can greatly impact a patient's quality of life," said David Rubin, MD, Director of the Inflammatory Bowel Disease Center at the University of Chicago.[e] "These results show that guselkumab can provide endoscopic remission through either SC or IV induction, allowing people with moderate to severely active Crohn's disease to manage their condition with greater independence and confidence."

The GRAVITI study evaluated TREMFYA® SC induction and maintenance therapy versus placebo.[7] The GALAXI 2 and 3 studies evaluated TREMFYA® IV induction and SC maintenance therapy versus placebo and STELARA® (ustekinumab).[8] Previously presented pooled data from the GALAXI clinical program showed TREMFYA® was superior to STELARA® for all endoscopic endpoints at Week 48, the only IL-23 inhibitor to achieve this in a double-blinded registrational program.[9]

"As the only IL-23 inhibitor approved for both subcutaneous SC and IV induction in Crohn's disease and now also in ulcerative colitis, TREMFYA provides patients and their providers with meaningful choices in how they begin treatment with proven long-term benefits," said Esi Lamousé-Smith, MD, PhD, Vice President, Gastroenterology Disease Area Lead, Immunology, Johnson & Johnson Innovative Medicine. "These results underscore our legacy of delivering innovations that address the diverse needs of people living with IBD, while continuing to provide treatment options that deliver deep and sustained remission over time."

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

For a full list of all Johnson & Johnson data being presented at ACG visit:
https://www.jnj.com/innovativemedicine/immunology/gastroenterology

Editor's Notes:

a. Clinical remission was defined as a CDAI score <150.
b. Endoscopic response was defined as a ≥50% improvement in SES-CD (GALAXI/GRAVITI) or an SES-CD ≤2 (GALAXI only).
c. Endoscopic remission was defined as an SES-CD ≤4, with a ≥2-point reduction and no subscore >1 on any subcomponent.
d. Deep remission was defined as achieving both clinical remission and endoscopic remission, as defined above.
e. Dr. David Rubin is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

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 are randomized to guselkumab at Week 0 and remain 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. The GRAVITI study includes a long-term extension (LTE) period starting at Week 24, during which clinical and endoscopic endpoints will be assessed through a total of two years, and safety outcomes with guselkumab treatment through a total of five years. Participants entered the LTE period receiving the same maintenance treatment they received prior to the LTE.[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 and includes a long-term extension period that will assess clinical, endoscopic, and safety outcomes with guselkumab treatment 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 ustekinumab; or placebo. Participants randomized to placebo were able to receive ustekinumab if clinical response was not met at Week 12. Participants entered the LTE period receiving the same maintenance treatment they received prior to the LTE. Between Weeks 52 and 80, participants who were not in clinical response dose-escalated or "sham" adjusted to 200 mg SC every 4 weeks.[8]

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.[10] [11] 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.[12] 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.[13]

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**.

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 diarrhea or stomach pain

o muscle aches

o weight loss

o cough

o warm, red, or painful skin or sores on your body different from your psoriasis

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.

WHAT IS STELARA® (ustekinumab)?

STELARA® is a prescription medicine used to treat:

- adults and children 6 years of age and older with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
- adults and children 6 years of age and older with active psoriatic arthritis.

- adults with moderately to severely active Crohn's disease.
- adults with moderately to severely active ulcerative colitis.

IMPORTANT SAFETY INFORMATION

STELARA® is a prescription medicine that affects your immune system. STELARA® can increase your chance of having serious side effects, including:

Serious Infections

STELARA® may lower your ability to fight infections and may increase your risk of infections. Some people have serious infections during treatment with STELARA®, which may require hospitalization, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses.

- Your healthcare provider should check you for TB before starting STELARA® and watch you closely for signs and symptoms of TB during treatment with STELARA®.
- If your healthcare provider feels that you are at risk for TB, you may be treated for TB before and during treatment with STELARA®.

You should not start STELARA® if you have any kind of infection unless your healthcare provider says it is okay.

Before starting STELARA ® , tell your healthcare provider if you:

- think you have an infection or have symptoms of an infection such as:

- fever, sweats, or chills
- muscle aches
- cough
- shortness of breath
- blood in phlegm
- weight loss
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- burning when you urinate or urinate more often than normal
- feel very tired

- are being treated for an infection or have any open cuts.
- get a lot of infections or have infections that keep coming back.
- have TB or have been in close contact with someone with TB.

After starting STELARA ® , call your healthcare provider right away if you have any symptoms of an infection

(see above). These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications. STELARA® can make you more likely to get infections or make an infection that you have worse.

People who have a genetic problem where the body does not make any of the proteins interleukin 12 (IL-12) and interleukin 23 (IL-23) are at a higher risk for certain serious infections that can spread throughout the body and cause death. People who take STELARA® may also be more likely to get these infections.

Cancers

STELARA® may decrease the activity of your immune system and increase your risk for certain types of cancer. Tell your healthcare provider if you have ever had any type of cancer. Some people who had risk factors for skin cancer developed certain types of skin cancers while receiving STELARA®. Tell your healthcare provider if you have any new skin growths.

Serious Allergic Reactions

Serious allergic reactions can occur. Stop using STELARA® and get medical help right away if you get any symptoms of a serious allergic reaction such as: feeling faint, swelling of your face, eyelids, tongue, or throat, chest tightness, or skin rash.

Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is a rare condition that affects the brain and can cause death. Tell your healthcare provider right away if you get any symptoms of PRES during treatment with STELARA®, including: headache, seizures, confusion, and vision problems.

Lung Inflammation

Cases of lung inflammation have happened in some people who receive STELARA® and may be serious. These lung problems may need to be treated in a hospital. Tell your healthcare provider right away if you develop shortness of breath or a cough that doesn't go away during treatment with STELARA®.

Before you use or receive STELARA ® , tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed above for serious infections or cancers.
- ever had an allergic reaction to STELARA® or any of its ingredients. Ask your healthcare provider if you are not sure.
- are allergic to latex. The needle cover on the prefilled syringe contains latex.
- have recently received or are scheduled to receive an immunization (vaccine). People who are being treated

with STELARA® should avoid receiving live vaccines. Tell your healthcare provider if anyone in your house needs a live vaccine. The viruses used in some types of live vaccines can spread to people with a weakened immune system and can cause serious problems. You should avoid receiving the BCG vaccine during the one year before receiving STELARA® or one year after you stop receiving STELARA®.

- have any new or changing lesions within psoriasis areas or on normal skin.
- are receiving or have received allergy shots, especially for serious allergic reactions.
- receive or have received phototherapy for your psoriasis.
- are pregnant or plan to become pregnant. It is not known if STELARA® can harm your unborn baby. You and your healthcare provider should decide if you will receive STELARA®.
- are breastfeeding or plan to breastfeed. STELARA® can pass into your breast milk.
- talk to your healthcare provider about the best way to feed your baby if you receive STELARA®.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

When prescribed STELARA ® :

- Use STELARA® exactly as your healthcare provider tells you to. The healthcare provider will determine the right dose of STELARA®, the amount for each injection, and how often it should be given. Be sure to keep all scheduled follow-up appointments.
- STELARA® is intended for use under the guidance and supervision of your healthcare provider. In children, it is recommended that STELARA® be administered by a healthcare provider. If your healthcare provider decides that you or a caregiver may give your injections of STELARA® at home, you or a caregiver should receive training on the right way to prepare and inject STELARA®. Do not try to inject STELARA® until you have been shown how to inject STELARA® by a healthcare provider.

Common side effects of STELARA ® include: nasal congestion, sore throat, and runny nose, upper respiratory infections, fever, headache, tiredness, itching, nausea and vomiting, influenza, redness at the injection site, vaginal yeast infections, urinary tract infections, sinus infection, bronchitis, diarrhea, stomach pain, and joint pain. These are not all of the possible side effects with STELARA®. Tell your doctor about any side effect that you experience. Ask your doctor or pharmacist for more information.

Please read the full **Prescribing Information** and **Medication Guide** for STELARA® and discuss any questions you have with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **https://www.fda.gov/medwatch** or call **1-800-FDA-1088**.

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 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.

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