Johnson&Johnson

NEWS RELEASE

TREMFYA® (guselkumab) is the first and only IL-23 inhibitor to demonstrate robust results with a fully subcutaneous regimen in both induction and maintenance in Crohn's disease

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A greater number of patients treated with subcutaneous TREMFYA® induction and maintenance achieved clinical and endoscopic remission at 48 weeks in the Phase 3 GRAVITI study versus placebo

TREMFYA® could become the first IL-23 treatment to offer both a subcutaneous and intravenous (IV) induction regimen for patients living with Crohn's disease (CD), pending FDA approval

PHILADELPHIA, Oct. 28, 2024 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced results from the Phase 3 GRAVITI study of TREMFYA® (guselkumab), the first and only IL-23 inhibitor, demonstrating robust results in subcutaneous (SC) induction and maintenance therapy. The findings demonstrated significant clinical remission and endoscopic response at 48 weeks in adults with moderately to severely active CD.[1] These results are among the 14 Johnson & Johnson abstracts presented at the American College of Gastroenterology (ACG) 2024, October 25-30.

"The GRAVITI results show that induction treatment with subcutaneous guselkumab is as rapid and robust as we have seen with the IV induction, which could offer a welcome new option for Crohn's disease treatment," stated Remo Panaccione, MD, FRCPC, Study Investigator and Professor of Medicine and the Director of the Inflammatory Bowel Disease Unit at the University of Calgary. "The one-year results of this study suggest that SC induction with guselkumab is a promising approach to help people with CD manage their symptoms and achieve meaningful endoscopic improvements."

GRAVITI SC Induction Week 12 Results:

- More than half of patients treated with TREMFYA® (400 mg administered subcutaneously at Weeks 0, 4, and 8) achieved clinical remission versus those in the placebo group (56.1 percent versus 21.4 percent).[1]
- Endoscopic response was achieved in 41.3 percent of patients treated with TREMFYA® SC induction therapy versus 21.4 percent in the placebo group.[1]
- Greater improvements in clinical remission were seen as early as Week 4 with TREMFYA® compared with placebo, demonstrating rapid onset of action.[1]

GRAVITI SC Induction Week 48 Results:

- The rate of clinical remission was more than three times higher with both maintenance doses of TREMFYA® versus placebo (60.0 percent for 100 mg SC every eight weeks (q8w) and 66.1 percent for 200 mg SC every four weeks (q4w) versus 17.1 percent.[1]
- Endoscopic response was achieved in 44.3 percent and 51.3 percent of patients in the TREMFYA® 100 mg SC q8w group and 200 mg SC q4w group respectively versus 6.8 percent in the placebo group.[1]
- Endoscopic remission was achieved in 30.4 percent and 38.3 percent of patients in the TREMFYA® 100 mg SC q8w group and 200 mg SC q4w group respectively versus 6.0 percent in the placebo group.[1]

"These results show that TREMFYA has the potential to become the only IL-23 inhibitor to offer both SC and IV induction options for Crohn's disease, and, if approved, will offer choice and flexibility for people living with CD," stated Esi Lamousé-Smith, M.D., Ph.D., Vice President, Gastroenterology Disease Area Lead, Immunology, Johnson & Johnson Innovative Medicine. "The convenience of self-administration from the start of treatment is part of our commitment to delivering innovative therapeutic solutions to people with Crohn's disease."

The results reinforced the well-established safety profile of TREMFYA®.

TREMFYA® received U.S. Food and Drug Administration (FDA) approval in September 2024 for the treatment of adults with moderately to severely active ulcerative colitis (UC) and an application for the treatment of moderately to severely active CD is currently under FDA review. Regulatory applications seeking approval of TREMFYA® for the treatment of adults with moderately to severely active UC and for the treatment of adults with moderately to severely active CD have been submitted in Europe.

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).[2] 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.2 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.[2]

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).[3] GALAXI includes a Phase 2 dose-ranging study (GALAXI 1) and two independent, identically designed confirmatory Phase 3 studies (GALAXI 2 and 3).[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 (41.8 percent) were biologic-naïve and 52 (6 percent) were biologic experienced without documented inadequate response or intolerance.[4] 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 CD. Data from GALAXI 2 & 3 showed guselkumab was superior to ustekinumab in all pooled endoscopic endpoints.

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.[5,6] 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.[7]

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.[8]

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 cell 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.

TREMFYA® is approved 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.

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® (guselkumab)?

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, mouth, tongue, or throat
    - trouble breathing or throat tightness
    - chest tightness
    - skin rash, hives
    - 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:

- fever, sweats, or chills
- muscle aches
- weight loss
- cough
- warm, red, or painful skin or sores on your body different from your psoriasis
- diarrhea or stomach pain
- shortness of breath
- blood in your phlegm (mucus)
- burning when you urinate or urinating more often than normal

Do not take 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, 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 in a 100 mg/mL prefilled syringe and One-Press patient-controlled injector for subcutaneous injection, a 200 mg/2 mL prefilled syringe and prefilled pen (TREMFYA® PEN) for subcutaneous injection, and 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**. Follow us at **@JNJInnovMed**. Janssen Research & Development, LLC, Janssen Biotech, Inc. and Janssen-Cilag International NV are Johnson & Johnson companies.

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 Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen-Cilag International NV and/or 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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. None of Janssen Research & Development, LLC, Janssen Biotech, Inc., Janssen-Cilag International NV nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

[1]Panaccione, R, et al. Efficacy and Safety of Subcutaneous Guselkumab Induction Therapy in Patients With Moderately to Severely Active Crohn's Disease: Results Through Week 48 From the Phase 3 GRAVITI Study. Oral presentation (OP72) at American College of Gastroenterology (ACG) 2024.

[2]National Institutes of Health: **Clinicaltrials.gov**. A study of guselkumab subcutaneous therapy in participants with moderately to severely active Crohn's disease (GRAVITI). Identifier: NCT05197049. Available at: **https://classic.clinicaltrials.gov/ct2/show/NCT05197049**. Accessed September 2024.

[3]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 2024.

[4]Danese S, et al. Week 48 efficacy of guselkumab and ustekinumab in Crohn's disease based on prior response/exposure to biologic therapy: Results from the GALAXI 2 & 3 Phase 3 Studies. Poster presentation

(Abstract MP672) at United European Gastroenterology Week (UEGW) 2024. October 2024.

[5]Crohn's & Colitis Foundation. Overview of Crohn's disease. Available at: **https://www.crohnscolitisfoundation.org/what-is-crohns-disease/overview**. Accessed September 2024.

[6]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.

[7]Crohn's & Colitis Foundation. What is Crohn's disease? Available at: **https://www.crohnscolitisfoundation.org/what-is-crohns-disease/causes**. Accessed September 2024.

[8]Crohn's & Colitis Foundation. Signs and symptoms of Crohn's disease. Available at **https://www.crohnscolitisfoundation.org/patientsandcaregivers/what-is-crohns-disease/symptoms**. Accessed September 2024.

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