Johnson&Johnson

NEWS RELEASE

# Johnson & Johnson seeks U.S. FDA approval for subcutaneous induction regimen of TREMFYA® (guselkumab) in ulcerative colitis, a first for an IL-23 inhibitor

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Following recent U.S. FDA approval of TREMFYA® for adults with moderately to severely active ulcerative colitis (UC), this submission underscores its potential to be the only IL-23 inhibitor that offers choice of subcutaneous or intravenous induction in UC

Submission is supported by the Phase 3 ASTRO study, which achieved the primary endpoint of clinical remission at Week 12 and met all secondary endpoints in adults with moderately to severely active UC

SPRING HOUSE, Pa., Nov. 22, 2024 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced the submission of a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) seeking approval of a subcutaneous (SC) induction regimen of TREMFYA® (guselkumab) for the treatment of adults with moderately to severely active UC. The filing is supported by data from the Phase 3 ASTRO study of TREMFYA® SC induction therapy in adults with UC and builds upon the recent U.S. approval of TREMFYA® in this indication.

The Phase 3 ASTRO study met its primary endpoint, achieving a statistically significant and clinically meaningful results for clinical remission at Week 12 with a 400 mg SC induction dose of TREMFYA® administered at Weeks 0, 4, and 8. All secondary endpoints, including endoscopic improvement and histologic-endoscopic mucosal improvement (HEMI), were also met. Safety data from ASTRO were consistent with the safety findings from the QUASAR program. Results from the ASTRO study are planned for presentation at upcoming medical meetings.[1]

"With the ASTRO study in UC and the GRAVITI study in Crohn's disease (CD), we are focused on delivering versatility

and options for administration of treatment for people with inflammatory bowel disease (IBD). TREMFYA is the first IL-23 inhibitor to potentially offer a fully SC induction and maintenance regimen, which if approved, can provide choice and simplicity for patients and providers," stated Esi Lamousé-Smith, M.D., Ph.D., Vice President, Gastroenterology Disease Area Lead, Immunology, Johnson & Johnson Innovative Medicine. "The ASTRO results add to the compelling data generated from the QUASAR program in UC and build on the promise of TREMFYA in the treatment of IBD as we look to transform outcomes for patients."

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.[2,3,4,5,6]

TREMFYA® received U.S. FDA **approval** in September 2024 for the treatment of adult patients with moderately to severely active UC and is currently administered via an IV induction regimen, followed by a SC maintenance regimen. The approval was supported by data from the Phase 3 QUASAR study evaluating the efficacy and safety of TREMFYA® in adults with moderately to severely active UC.[7]

An application seeking approval of TREMFYA® for the treatment of adults with moderately to severely active CD has been submitted in the U.S., and applications seeking approval for both CD and UC have been submitted in Europe.

## ABOUT THE ASTRO STUDY (**NCT05528510**)

ASTRO is a randomized, double-blind, placebo-controlled, parallel-group, multicenter, treat-through Phase 3 study 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 q4w; or TREMFYA® 400 mg SC induction at Weeks 0, 4 and 8, followed by TREMFYA® 100 mg SC q8w; or placebo. The maintenance doses in ASTRO (200 mg SC q4w and 100 mg SC q8w) are the same as those evaluated in the Phase 3 QUASAR program that established the efficacy and safety of IV induction followed by SC maintenance therapy in patients with moderate to severely active UC.[8]

## 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® 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 JAK inhibitors (tofacitinib). QUASAR included a Phase 2b

dose-ranging induction study, a confirmatory Phase 3 induction study, and a Phase 3 randomized withdrawal maintenance study. In the induction study, patients received either TREMFYA® 200 mg or placebo by IV infusion at Weeks 0, 4, and 8. In the maintenance study, patients received a SC maintenance regimen of either TREMFYA® 200 mg q4w, TREMFYA® 100 mg q8w, or placebo.[9]

## ABOUT THE GRAVITI STUDY (**NCT05197049**)

GRAVITI is a randomized, double-blind, placebo-controlled, treat-through Phase 3 study 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 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 TREMFYA® 400 mg SC at Weeks 0, 4, and 8 followed by TREMFYA® 200 mg SC q4w; or TREMFYA® 400 mg SC at Weeks 0, 4, and 8 followed by TREMFYA® 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).[10]

## 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.[12] 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.[13]

## 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.[2]

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:

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- 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 **https://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.

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[1] Data on file.

[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

[4] TREMFYA® Prescribing Information. Available at: **https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf** Accessed October 2024.

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

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

[7] TREMFYA® Prescribing Information. Available at: **https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf** Accessed October 2024.

[8] 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 October 2024.

[9] National Institutes of Health: **Clinicaltrials.gov**. A Study of Guselkumab in Participants With Moderately to Severely

Active Ulcerative Colitis (QUASAR). Identifier: NCT04033445. **https://classic.clinicaltrials.gov/ct2/show/NCT04033445**. Accessed October 2024.

[10] 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 October 2024.

[11] Crohn's & Colitis Foundation. What is ulcerative colitis? Available at: **https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis**. Accessed April 2024.

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

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

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