Johnson&Johnson

NEWS RELEASE

# TREMFYA® (guselkumab) demonstrates impressive results across biologic-naïve and biologic-refractory patients in Crohn's disease and ulcerative colitis

2024-10-10

TREMFYA® is now U.S. FDA-approved for ulcerative colitis and under review for Crohn's disease

TREMFYA® is the only IL-23 inhibitor to demonstrate superiority to ustekinumab in the overall population of patients with Crohn's disease, inclusive of those who are biologic-naïve and biologic-refractory

Ninety percent more biologic-naïve patients and three times more biologic-refractory patients with ulcerative colitis achieved endoscopic remission with TREMFYA®

VIENNA, Austria, Oct. 10, 2024 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced TREMFYA® (guselkumab) data in both Crohn's disease (CD) and ulcerative colitis (UC) showing high rates of endoscopic remission in both biologic-naïve and biologic-refractory patients (including UC patients refractory to JAK inhibitors), indicating a normal appearance of intestinal mucosa.[1,2] These subgroup analyses are from pooled data from the Phase 3 GALAXI 2 & 3 studies of TREMFYA® in adults with moderately to severely active CD and the Phase 3 QUASAR maintenance study of TREMFYA® in adults with moderately to severely active UC. These findings are among 19 Johnson & Johnson abstracts being presented at the United European Gastroenterology (UEG) Week 2024. TREMFYA® is under review for the treatment of adults with moderately to severely active UC and CD by the European Medicines Agency (EMA).

"These results show the potential of TREMFYA to offer a differentiated treatment option for patients with CD and UC, including those starting on a biologic for the first time, and those who have failed prior biologics and traditionally have been less likely to respond to other therapies," stated Esi Lamousé-Smith, M.D., Ph.D., Vice

President, Gastroenterology Disease Area Lead, Immunology, Johnson & Johnson Innovative Medicine. "TREMFYA builds upon our nearly three decades of leadership in IBD therapy and focused innovation in the IL-23 pathway to address the needs of people living with ulcerative colitis and delivering meaningful improvements in symptoms and the potential for sustained remission."

## Endoscopic remission in biologic-naïve patients

In the pooled Phase 3 GALAXI 2 & 3 dataset, TREMFYA® demonstrated greater rates of endoscopic remission compared to ustekinumab at Week 48 in biologic-naïve patients with CD. Endoscopic remission was achieved in 44% of patients treated with TREMFYA® 100 mg every eight weeks (q8w) subcutaneous (SC) injection and 46.1% of patients treated with TREMFYA® 200 mg every four weeks (q4w) SC injection, versus 29.8% of patients treated with ustekinumab.[1]

In the Phase 3 QUASAR study, TREMFYA® demonstrated greater rates of endoscopic remission compared to placebo at Week 44 in biologic/JAK inhibitor-naïve patients with UC. Endoscopic remission was achieved in 38.1% of patients treated with TREMFYA® 100 mg q8w SC injection and 41.7% of patients treated with TREMFYA® 200 mg q4w SC injection, versus 20.4% of patients treated with placebo.[2]

## Endoscopic remission in patients with a history of inadequate response or intolerance to biologics/JAK inhibitors

In the pooled Phase 3 GALAXI 2 & 3 dataset, TREMFYA® demonstrated greater rates of endoscopic remission compared to ustekinumab at Week 48 in biologic-refractory patients with CD. Endoscopic remission was achieved in 28.1% of patients treated with TREMFYA® 100 mg q8w SC injection and 28.6% of patients treated with TREMFYA® 200 mg q4w SC injection, versus 20.5% of patients treated with ustekinumab.[1]

In the Phase 3 QUASAR study, TREMFYA® demonstrated greater rates of endoscopic remission compared to placebo at Week 44 in biologic/JAK inhibitor-refractory patients with UC. Endoscopic remission was achieved in 31.2% of patients treated with TREMFYA® 100 mg q8w SC injection and 23.9% of patients treated with TREMFYA® 200 mg q4w SC injection, versus 8% of patients treated with placebo.[2]

Results from these studies reinforce the well-established safety profile of TREMFYA® including in the treatment of patients with UC and CD.

For a full list of abstracts presented please click **here.**

TREMFYA® received U.S. Food and Drug Administration (FDA) approval in September 2024 for the treatment of adults with moderately to severely active 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 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).[1] 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.[1] 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 THE QUASAR STUDY (**NCT04033445**)

QUASAR is a randomized, double-blind, placebo-controlled, parallel group, multicenter, Phase 2b/3 program designed to evaluate the efficacy and safety of guselkumab 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).[4] 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 guselkumab 200 mg or placebo by intravenous infusion at Week 0, Week 4, and Week 8. In the maintenance study, patients received a subcutaneous maintenance regimen of either TREMFYA 100 mg every 8 weeks, guselkumab 200 mg every 4 weeks, or placebo. Efficacy, safety, pharmacokinetics, immunogenicity, and biomarkers are assessed at specified time points. Of the 568 individuals included in the QUASAR maintenance study, 240 (42.3 percent) had a history of inadequate response or intolerance to biologics or JAK inhibitors, 309 (54.4 percent) were biologic/JAK inhibitor naïve, and 19 (3.3 percent) were

biologic/JAK inhibitor experienced without documented inadequate response or intolerance.[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.[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.

## 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.[8] 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. People with UC also have increased rates of depression.[6]

## 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.[9]

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:

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- 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 STELARA® (ustekinumab)

STELARA® (ustekinumab), a human interleukin (IL)-12 and IL-23 antagonist, is a prescription medicine approved in the United States to treat:

- adults and children 6 years and older with moderate to severe 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 and older with active psoriatic arthritis.
- adults 18 years and older with moderately to severely active Crohn's disease.
- adults 18 years and older with moderately to severely active ulcerative colitis.[10]

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to STELARA®.

## 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. While taking STELARA®, some people have serious infections, which may require hospitalization, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses.

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

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

## Before starting STELARA®, tell your doctor 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 doctor 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 doctor 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 doctor if you have any new skin growths.

## Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is a rare condition that affects the brain and can cause death. The cause of PRES is not known. If PRES is found early and treated, most people recover. Tell your doctor right away if you have any new or worsening medical problems including: headache, seizures, confusion, and vision problems.

## Serious Allergic Reactions

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

### 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 doctor right away if you develop shortness of breath or a cough that doesn't go away during treatment with STELARA®.

## Before receiving STELARA®, tell your doctor about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed above for serious infections, cancers, or PRES.
- ever had an allergic reaction to STELARA® or any of its ingredients. Ask your doctor 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 take STELARA® should not receive live vaccines. Tell your doctor 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 not receive 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 doctor should decide if you will receive STELARA® if you are breastfeeding or plan to breastfeed. It is thought that STELARA® passes into your breast milk.
- talk to your doctor about the best way to feed your baby if you receive STELARA®.

**Tell your doctor 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 doctor and pharmacist when you get a new medicine.

## When prescribed STELARA®:

- Use STELARA® exactly as your doctor tells you to.

- STELARA® is intended for use under the guidance and supervision of your doctor. In children 6 years and older, it is recommended that STELARA® be administered by a healthcare provider. If your doctor decides that you or a caregiver may give your injections of STELARA® at home, you should receive training on the right way to prepare and inject STELARA®. Your doctor will determine the right dose of STELARA® for you, the amount for each injection, and how often you should receive it. Do not try to inject STELARA® yourself until you or your caregiver have been shown how to inject STELARA® by your doctor or nurse.

Common side effects of STELARA® include: nasal congestion, sore throat, and runny nose, upper respiratory infections, fever, headache, tiredness, itching, nausea and vomiting, 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 click to 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 **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.janssen.com/johnson-johnson-innovative-medicine**. 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.

Source: Johnson & Johnson

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[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.
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