News Release

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New Phase 3 TREMFYA® (guselkumab) Results in Ulcerative Colitis Show a 77 Percent Overall Clinical Response Rate and Early Symptom Improvement

Data from the QUASAR induction study of adults with moderate to severely active ulcerative colitis show clinically meaningful results at Weeks 12 or 24

Additional data show symptomatic response as early as one week after the first induction dose, with symptomatic improvements increasing through Week 12

SPRING HOUSE, PENNSYLVANIA, October 23, 2023 – Janssen Pharmaceuticals, Inc., a Johnson & Johnson Company, today announced new data from the QUASAR Phase 3 Induction Study demonstrating the efficacy and safety profile of TREMFYA® (guselkumab), a selective IL-23 p19 inhibitor, in patients with moderately to severely active ulcerative colitis (UC) through 24 weeks.[1] High rates of clinical response[a] were observed at Weeks 12 or 24, with no new safety signals observed compared to the safety profile of TREMFYA in its approved indications.[1] Symptomatic response[b] and improvements in patient-reported outcomes of rectal bleeding and absolute stool number were observed as early as one week after a single IV induction dose, with symptomatic response evident in more than two-thirds of patients at Week 12.[2] These

data are among Janssen's 20 oral and poster presentations at the American College of Gastroenterology (ACG) Annual Scientific Meeting, taking place in Vancouver, Canada, October 20-25, 2023.

"Ulcerative colitis is a complex immune-mediated disease that can cause a wide range of often-debilitating symptoms," said study author Jessica R. Allegretti, M.D., Medical Director, Crohn's and Colitis Center at the Brigham and Women's Hospital, Boston, MA, USA.[c] "Results from the QUASAR studies support the potential of TREMFYA as a durable and fast-acting treatment option."

QUASAR Cumulative Clinical Response Results Through Week 24:

- At Week 12, clinical response was achieved by a significantly higher percentage of TREMFYA-treated patients (61.5 percent [259/421]) versus placebo (27.9 percent [78/280]).[1]
- Among TREMFYA-treated patients who were not in clinical response to IV induction therapy at Week 12 and who then received subcutaneous treatment for an additional 12 weeks, 55 percent (66/120) achieved clinical response at Week 24.[1]
- Cumulative clinical response at Week 12 or 24 was achieved by 77.2 percent (325/421) of patients randomized to TREMFYA at baseline.[1] Patients with or without a history of inadequate response/intolerance to biologics and Janus kinase (JAK) inhibitors benefited from continued treatment with subcutaneous TREMFYA through Week 24.[1]

QUASAR Cumulative Safety Results Through Week 24:

- Safety findings through the final safety visit were consistent with Week 12 results; no new safety signals were identified.[1]
- The most frequent adverse events among TREMFYA-treated patients (n=586) were COVID-19 (7.2 percent), anemia (5.1 percent), and worsening UC (4.6 percent).[1]

QUASAR Early Symptomatic Response Data: Week 1 Through Week 12:

- As early as Week 1 and increasing through Week 12, greater symptomatic improvements were seen in patients treated with TREMFYA compared with placebo with treatment differences for TREMFYA versus placebo evident across outcomes.[2]

Percentage of Patients Achieving Early Symptomatic Response[2,b]		
	TREMFYA-treated patients	Placebo-treated patients
Week 1 (p<0.01)	28.3 percent	18.9 percent
Week 2 (p<0.01)	34.0 percent	23.6 percent
Week 4 (p<0.01)	53.2 percent	30.0 percent
Week 8 (p<0.01)	66.0 percent	39.6 percent
Week 12 (p<0.01)	71.7 percent	35.0 percent

Percentage of Patients with Stool Frequency Subscores of 0 or 1[2,d]		
	TREMFYA-treated patients	Placebo-treated patients
Week 2 (p<0.05)	26.1 percent	18.2 percent
Week 4 (p<0.001)	41.3 percent	25.4 percent
Week 8 (p<0.001)	53.4 percent	29.6 percent
Week 12 (p<0.001)	60.1 percent	31.8 percent

Percentage of Patients with Rectal Bleeding Subscores of 0[2,e]		
	TREMFYA-treated patients	Placebo-treated patients
Week 2 (p<0.110)	24.2 percent	19.3 percent
Week 4 (p<0.001)	36.8 percent	22.9 percent
Week 8 (p<0.001)	55.8 percent	33.2 percent
Week 12 (p<0.001)	64.6 percent	28.6 percent

"TREMFYA continues to show that it has the potential to provide people living with ulcerative colitis with early, clinically meaningful results," said Jan Wehkamp, MD, PhD, Vice President, Gastroenterology Disease Area Leader at Janssen (recently renamed "Johnson & Johnson Innovative Medicines"). "We are committed to ongoing research of TREMFYA in inflammatory bowel disease to give those living with the condition and providers more treatment options that fit their needs and help them achieve remission."

Further research is currently being conducted on TREMFYA for the treatment of patients with inflammatory bowel disease, which includes Phase 3 studies that are fully recruited and ongoing.[2]

TREMFYA is not approved for the treatment of adults living with UC in the U.S.

Editor's Notes:

a. Clinical response was defined as a decrease from baseline in the modified Mayo score by ≥30 percent and ≥2 points, with either a ≥1-point decrease from baseline in the rectal bleeding subscore or a rectal bleeding subscore of 0 or 1.[2]
b. Symptomatic response was defined as a decrease from induction baseline in the symptomatic Mayo score (sum of the stool frequency and the rectal bleeding subscores) by ≥30 percent and ≥1 point, with either a ≥1 point decrease from baseline in the rectal bleeding subscore or a rectal bleeding subscore of 0 or 1.[2]
c. Dr. Allegretti is a paid consultant for Janssen. She has not been compensated for any media work.
d. A stool frequency subscore of 0 or 1 is indicative of normalization or near normalization of bowel habits.[2]
e. Rectal bleeding subscores of 0 is indicative of resolution of rectal bleeding.[2]

About the QUASAR Study (NCT04033445; EudraCT 2018-004002-25)

The QUASAR study is designed to evaluate the efficacy and safety of TREMFYA in the treatment of moderately to severely active UC. Overall, the study evaluates long-term TREMFYA treatment.[4,5] Efficacy, safety, pharmacokinetics, immunogenicity, and biomarkers are assessed at specified time points.[4,5] The QUASAR Phase 3 Induction Study is a randomized, double-blind, placebo-controlled, parallel-group, multicenter study to evaluate the efficacy and safety of TREMFYA, a selective IL-23 p19 inhibitor, as induction therapy in patients with moderately to severely active UC who had an inadequate response or intolerance to conventional (i.e., thiopurines or corticosteroids) and/or advanced therapies (i.e., tumor necrosis factor-alpha antagonists, vedolizumab or tofacitinib).[4,5]

About Ulcerative Colitis (UC)

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.[6] It is the result of the immune system's overactive response.[6] Symptoms vary, but may include loose and more urgent bowel movements, persistent diarrhea, abdominal pain, bloody stool, loss of appetite, weight loss and fatigue.[6]

About TREMFYA® (guselkumab)[7]

Developed by Janssen, TREMFYA is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of interleukin (IL)-23 and inhibits its interaction with the IL-23 receptor.9 IL-23 is an important driver of the pathogenesis of inflammatory diseases such IBD, plaque psoriasis (PsO), and psoriatic arthritis (PsA). TREMFYA is approved in the U.S., Canada, Japan and a number of other countries for the treatment of adults with moderate to severe plaque PsO who are candidates for injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light) and for the treatment of adult patients with active PsA. It is also approved in the EU for the treatment of moderate to severe plaque PsO in adults who are candidates for systemic therapy and for the treatment of active

PsA in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug therapy.

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

IMPORTANT SAFETY INFORMATION[7]

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:
  - 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.
- 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: upper respiratory 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.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism &

Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JJInnovMed and www.twitter.com/JanssenUS.

Janssen Research & Development, LLC; Janssen Biotech, Inc.; and Janssen Scientific Affairs, LLC 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 product development of TREMFYA® (guselkumab). 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.; and Janssen Scientific Affairs, LLC 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 January 1, 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, or on request from Johnson & Johnson. Neither Janssen Research & Development, Janssen Biotech, Inc.; and Janssen Scientific Affairs, LLC nor Johnson & Johnson undertake to update any forward-looking statement as a result of new information or future events or developments.

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References

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