News Release

Media Contact:
Craig Stoltz
Mobile: (215) 986-1975

Investor Contact:
Raychel Kruper
Office: (732) 524-6164

New TREMFYA® (guselkumab) Data Show an Overall Clinical Response Rate of Approximately 80 Percent in a Phase 2b Induction Study of Adults with Moderately to Severely Active Ulcerative Colitis

Previously reported results from QUASAR Induction Study 1 showed clinical response was achieved by approximately 60 percent of patients at week 12

Study results presented at 2022 American College of Gastroenterology Annual Meeting showed that continued treatment with subcutaneous TREMFYA allowed a mean of 52.1 percent of IV TREMFYA week 12 clinical nonresponders to achieve clinical response at week 24

SPRING HOUSE, PENNSYLVANIA, October 24, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data from the Phase 2b QUASAR Induction Study 1 in adults with moderately to severely active ulcerative colitis with inadequate responses to previous treatments. The data presented at the 2022 American College of Gastroenterology (ACG) Annual

Scientific Meeting show an overall clinical response rate of approximately 80 percent in patients who were randomized to TREMFYA® (guselkumab).

Clinical response[a] at weeks 12 or 24 of the study was ultimately achieved by 80.2 percent of patients who were randomized to intravenous (IV) TREMFYA 200 mg arm and by 78.5 percent of patients who were randomized to IV TREMFYA 400 mg arm.[1] A mean of 52.1 percent of patients randomized to IV TREMFYA who did not achieve clinical response at week 12 and continued treatment with subcutaneous (SC) TREMFYA, achieved clinical response at week 24.[1,2] Cumulative efficacy and safety results of the Phase 2b QUASAR Induction Study 1 were among 24 abstracts from Janssen presented at the ACG Annual Scientific Meeting in Charlotte, NC, and virtually from October 21-26. TREMFYA is not approved for the dosages studied or for the treatment of adults with UC in the U.S.[3]

"Despite advances in therapy and numerous treatment options, many patients with moderately to severely active ulcerative colitis still experience inadequate response or intolerance to existing therapies," said presenting study author Bruce E. Sands, M.D., M.S., Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at Mount Sinai Hospital, and the Dr. Burrill B. Crohn Professor of Medicine (Gastroenterology) at the Icahn School of Medicine at Mount Sinai.[b] "The outcomes from the QUASAR study provide insights which may help advance the treatment landscape and are a step forward for the many adult patients who remain in need of adequate treatment options."

In QUASAR Induction Study 1, patients who were not achieving clinical response at week 12 after receiving TREMFYA were switched to SC TREMFYA 200 mg.[1,c] Of the patients in the TREMFYA groups who were not acheiving clinical response at week 12 and were switched to SC TREMFYA 200 mg, 54.3 percent (19/35) and 50.0 percent (19/38) of those who previously received induction IV TREMFYA 200 mg or IV TREMFYA 400 mg, respectively, achieved clinical response at week 24.[1] Patients could enter the QUASAR Maintenance Study at week 12 or week 24 if a clinical response was achieved.

Safety findings at week 24 were consistent both with those at week 12 and with the known safety profile for TREMFYA in approved indications.[1,3,4] No new safety concerns for TREMFYA were identified.[1]

"The week 24 clinical response data from the QUASAR Phase 2b study provide further evidence of TREMFYA's potential as another treatment option for adults with moderately to severely active ulcerative colitis," said Jan Wehkamp, M.D., Ph.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. "We are committed to progressing our research program in ulcerative colitis in an effort to address unmet need in patients still struggling with the debilitating symptoms of this chronic disease."

These data build upon previously reported week 12 outcomes of the QUASAR Induction Study 1 showing that clinical response was achieved by 61.4 percent (62/101) and 60.7 percent (65/107) of patients randomized to IV TREMFYA 200 mg and IV TREMFYA 400 mg, respectively, compared with 27.6 percent (29/105) randomized to placebo ($p<0.001$).[1,4,c]

About QUASAR Induction Study 1 (NCT04033445; EudraCT 2018-004002-25)[2,5]

QUASAR Induction Study 1 is a 12-week, double-blind, randomized, placebo-controlled, multicenter Phase 2b induction dose-ranging study evaluating the efficacy and safety of the investigational use of TREMFYA in 313 adults with moderately to severely active UC with inadequate response/intolerance to conventional therapies (thiopurines or corticosteroids) and/or advanced therapies (TNFα antagonists, vedolizumab, or tofacitinib). Approximately 50 percent of patients enrolled in the study had a prior inadequate response or intolerance to advanced UC therapy.[1,2]

Participants had to have a baseline modified Mayo score[a] of 5 to 9 (inclusive), with a Mayo rectal bleeding subscore ≥1 and a Mayo endoscopy subscore ≥2 obtained during central review of video endoscopy.[1,4,6]

Participants were randomized equally into three groups receiving treatment at weeks 0, 4 and 8 with either TREMFYA IV dosed at 200 or 400 mg, or matched placebo.[1] Patients who were not in clinical response to IV induction at week 12 received TREMFYA treatment (placebo IV to TREMFYA IV 200 mg; TREMFYA IV 200 mg to TREMFYA SC 200 mg; TREMFYA IV 400mg to TREMFYA SC 200 mg) at weeks 12, 16, and 20 and were evaluated at week 24. Matching IV or SC placebo was administered to maintain the blind.[1] Patients who achieved clinical response at either weeks 12 or 24 entered the Phase 3 maintenance study.[1]

Editor's Note:

a. Clinical response is defined as a decrease from induction 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.[1] Modified Mayo score is a three-component (stool frequency, rectal bleeding, and endoscopy subscores) Mayo score without the physician's global assessment.[6]
b. Dr. Sands is a paid consultant for Janssen, and was a member of the steering committee for the QUASAR study. He has not been compensated for any media work.
c. Please see the 'About QUASAR Induction Study 1' section for further details regarding the study design.

About Ulcerative Colitis

Inflammatory bowel disease (IBD), which includes Crohn's disease and UC, affects as many as 1.6 million people in the United States.[7] 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.[8] It is the result of the immune system's overactive response.[8] Symptoms vary, but

may include loose and more urgent bowel movements, persistent diarrhea, abdominal pain, bloody stool, loss of appetite, weight loss and fatigue.[9]

About TREMFYA® (guselkumab)[3]

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.[3,10] TREMFYA is approved in the U.S., Canada, Japan, and a number of other countries worldwide for the treatment of adults with moderate to severe plaque psoriasis (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 psoriatic arthritis (PsA).[3,11,12] 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.[13]

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

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:
  - 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/JanssenGlobal.

Janssen Research & Development, LLC is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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® (guselkumab) product development. 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, any of the other Janssen Pharmaceutical Companies 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 2, 2022, 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 the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.*

# # #

References

1. Sands, BE, *et al.* QUASAR Induction Study 1 Cumulative Response to Guselkumab in Patients With Moderately to Severely Active Ulcerative Colitis (Abstract #A0395). Presented at ACG Annual Scientific Meeting, October 21-26.
2. National Institutes of Health: Clinicaltrials.gov. A Study of Guselkumab in Participants With Moderately to Severely Active Ulcerative Colitis (QUASAR). Identifier: NCT04033445. Available at: https://www.clinicaltrials.gov/ct2/show/record/NCT04033445. Accessed September 2022.
3. TREMFYA® Prescribing Information. Available at: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf. Accessed September 2022.
4. Dignass A, et al. The Efficacy and Safety of Guselkumab Induction Therapy in Patients With Moderately to Severely Active Ulcerative Colitis: Phase 2b QUASAR Study Results Through Week 12 (OP23). Presented at the 2022 ECCO Congress, February 16-19, 2022.
5. EU Clinical Trials Register. A Phase 2b/3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Ulcerative Colitis. EudraCT: 2018-004002-25. Available at: https://www.clinicaltrialsregister.eu/ctr-search/trial/2018-004002-25/ES. Accessed September 2022.
6. Naegeli, *et al.* Full, Partial, and Modified Permutations of the Mayo Score: Characterizing Clinical and Patient-Reported Outcomes in Ulcerative Colitis Patients. *Crohn's and Colitis 360*: 2021; 3; 1-8.

7. Crohn's & Colitis Foundation of America. The Facts About Inflammatory Bowel Diseases. Available at https://www.crohnscolitisfoundation.org/sites/default/files/2019-02/Updated%20IBD%20Factbook.pdf. Accessed September 2022.
8. Crohn's & Colitis Foundation. What is Ulcerative Colitis? Available at: https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis. Accessed September 2022.
9. Crohn's & Colitis Foundation. Signs and Symptoms of Ulcerative Colitis. Available at: https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis/symptoms. Accessed September 2022.
10. McInnes, IB, *et al.* Long-Term Efficacy and Safety of Guselkumab, a Monoclonal Antibody Specific to the p19 Subunit of Interleukin-23, Through Two Years: Results From a Phase III, Randomized, Double-Blind, Placebo-Controlled Study Conducted in Biologic-Naive Patients With Active Psoriatic Arthritis. Arthritis & Rheumatology (2021).
11. The Canadian Agency for Drugs & Technologies in Health. TREMFYA Prescribing Information. Available at: https://pdf.hres.ca/dpd_pm/00042101.PDF. Accessed September 2022.
12. Japan Pharmaceuticals and Medical Devices Agency. Tremfya Report on the Deliberation Results. Available at: https://www.pmda.go.jp/files/000234741.pdf. Accessed September 2022.
13. European Medicines Agency. TREMFYA Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/tremfya-epar-product-information_en.pdf. Accessed September 2022.