News Release

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New Phase 2b Data Show the Majority of Adults with Moderately to Severely Active Ulcerative Colitis Achieved Clinical Response with TREMFYA® (guselkumab) at 12 Weeks

Data from the Phase 2b QUASAR Induction Study 1 showed approximately 60 percent of patients achieved the primary endpoint of clinical response, and approximately 30 percent of patients showed endoscopic improvement with TREMFYA treatment compared with placebo

Results also showed a greater proportion of TREMFYA-treated patients achieved clinical remission and other major secondary endpoints at week 12 compared with placebo

SPRING HOUSE, PENNSYLVANIA, February 18, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced results from the Phase 2b QUASAR Induction Study 1. Results showed a significantly greater proportion of adults with moderately to severely active ulcerative colitis (UC) who previously had an inadequate response or intolerance to conventional therapies and/or selected advanced therapies and were treated with TREMFYA® (guselkumab) achieved clinical response[a] at week 12, the study's primary endpoint (intravenous [IV]

TREMFYA 200 mg: 61.4 percent [62/101] and IV TREMFYA 400 mg: 60.7 percent [65/107]) compared with placebo (27.6 percent [29/105]).[1] Safety data at week 12 were consistent with the safety profile for TREMFYA in approved indications.[1,2] TREMFYA is not currently approved for the treatment of adults with UC in the U.S.[2]

These new efficacy and safety data are the first reported on the investigational use of TREMFYA for moderately to severely active UC in an analysis of 313 patients enrolled in the QUASAR clinical program.[3] These findings were presented today as an oral presentation (OP23) at the 17th Congress of the European Crohn's and Colitis Organisation (ECCO) taking place virtually from February 16-19.[1]

"Despite available treatment options, there are patients with moderately to severely active ulcerative colitis who are still in need of additional therapeutic approaches due to inadequate response or intolerance to their current treatment," said presenting study author Axel Dignass, M.D., Ph.D., Head of the Department of Medicine and Professor of Medicine and Gastroenterology at the Agaplesion Markus Hospital, Goethe University in Frankfurt, Germany.[b] "Results from the QUASAR study show both IV induction doses of TREMFYA achieved clinical responses in patients with moderately to severely active ulcerative colitis at rates greater than placebo."

In the study, the primary endpoint of the 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,c] Major secondary endpoints in the QUASAR study include clinical remission,[d] symptomatic remission,[e] endoscopic improvement,[f] histo-endoscopic mucosal improvement[g] and endoscopic normalization[h] at week 12.[1,c]

Results from the five secondary endpoints showed:[1,c]

- **Clinical remission rates[d]** were achieved in 25.7 and 25.2 percent of patients in the 200 and 400 mg TREMFYA groups, respectively, compared with 9.5 percent in the placebo group.

- **Symptomatic remission rates**[e] were achieved in 50.5 and 47.7 percent of patients in the respective 200 and 400 mg TREMFYA groups compared with 20.0 percent in the placebo group.
- **Endoscopic improvement rates**[f] were achieved in 30.7 and 30.8 percent of patients in the respective 200 and 400 mg TREMFYA groups compared with 12.4 percent in the placebo group.
- **Histo-endoscopic mucosal improvement rates**[g] were achieved in 19.8 and 27.1 percent of patients in the respective 200 and 400 mg TREMFYA groups compared with 8.6 percent in the placebo group.
- **Endoscopic normalization rates**[h] were achieved in 17.8 and 14 percent of patients in the respective 200 and 400 mg TREMFYA groups compared with 6.7 percent in the placebo group.

Safety findings for both TREMFYA dose groups were consistent with the known safety profile for TREMFYA in approved indications.[1,2] The proportions of patients reporting adverse events (AEs), serious AEs, and AEs leading to discontinuation in both TREMFYA dose groups were not greater compared with placebo.[1] No serious infections, cases of malignancy or death were reported for TREMFYA.[1]

"Data from the Phase 2b QUASAR study provide the initial evidence in the development of TREMFYA as a potential treatment for adult patients 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 look forward to advancing this important research in the ongoing QUASAR Phase 3 induction and maintenance studies as we continue in our commitment to develop therapeutic options for patients with debilitating diseases like ulcerative colitis."

Phase 3 clinical trials evaluating TREMFYA for the treatment of adults with moderately to severely active UC are ongoing and enrolling participants. Learn more through the Janssen Global Trial Finder.

Editor's Notes:

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.[4]
b. Professor Dignass is a paid consultant for Janssen. He has not been compensated for any media work.
c. Please see the 'About QUASAR Induction Study 1' section below for further details regarding the study design.
d. Clinical remission is defined as a stool frequency subscore of 0 or 1, a rectal bleeding score of 0, and an endoscopy subscore of 0 or 1 with no friability present on the endoscopy, where the stool frequency subscore has not increased from induction baseline.[1]
e. Symptomatic remission is defined as a stool frequency subscore of 0 or 1 and a rectal bleeding subscore of 0, where the stool frequency subscore has not increased from induction baseline.[1]
f. Endoscopic improvement is defined as an endoscopy subscore of 0 or 1 with no friability present on the endoscopy.[1]
g. Histo-endoscopic mucosal improvement is defined as achieving a combination of histologic improvement (neutrophil infiltration in <5 percent of crypts, no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system) and endoscopic improvement.[1]
h. Endoscopic normalization is defined as an endoscopy subscore of 0.[1]

About QUASAR Induction Study 1 (NCT04033445; EudraCT 2018-004002-25)[3,5]

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 TREMFYA in 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).

Participants had to have a baseline modified Mayo score 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.

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]

About Ulcerative Colitis

In the United States, about one million people are affected by UC.[6] 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.[7] It is the result of an abnormal response by the body's immune system.[7] Symptoms vary but may include loose and more urgent bowel movements, persistent diarrhea, abdominal pain, bloody stool, loss of appetite, weight loss, and fatigue.[8]

About TREMFYA® (guselkumab)[2]

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. 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 may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light), and for the treatment of adult patients with active psoriatic arthritis (PsA). It is also approved in the European Union for the treatment of moderate to severe plaque PsO in adults who are candidates for systemic therapy, and alone or in combination with methotrexate (MTX) 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

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, 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 a 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.

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References

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