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For immediate release

TREMFYA® (guselkumab) QUASAR Maintenance Study in UC met its primary endpoint and all major secondary endpoints, including highly statistically significant rates of endoscopic remission

Washington, D.C. (May 20, 2024) – Johnson & Johnson today announced the first data from the Phase 3 QUASAR Maintenance Study (Abstract #759) that showed 50.0 percent (p<0.001) of patients with moderately to severely active ulcerative colitis[a] (UC) receiving subcutaneous (SC) TREMFYA® (guselkumab) 200 mg every four weeks (q4w) and 45.2 percent (p<0.001) of patients receiving SC TREMFYA® 100 mg every eight weeks (q8w) achieved the primary endpoint of clinical remission[b] at Week 44 compared to placebo (18.9 percent).[1] In additional analyses of patients who were in clinical remission, 67 percent and 71 percent, respectively, were also in endoscopic remission at Week 44 (Mayo endoscopic subscore [MES]= 0), indicating they had normal appearance of intestinal mucosa.[2]

“These data suggest the potential of guselkumab to provide durable, clinical remission and improve important high-bar endpoints such as endoscopic remission to the point of normalization and histologic remission, which represent the kind of progress needed in new treatments for this inflammatory bowel disease," said David T. Rubin, M.D., Chief, Section of Gastroenterology, Hepatology and Nutrition, University of Chicago and lead study investigator.[f] “The clinical results measured at Week 44 in the QUASAR Maintenance Study suggest that treatment with guselkumab is a promising therapy to help ulcerative colitis patients with challenging symptoms that impact their daily lives.”

Both TREMFYA® treatment groups also met all nine major secondary endpoints with high statistical significance and clinically meaningful improvements versus placebo. A summary of select secondary endpoints from the 44-week Maintenance Study include:[1]

Percentage of patients achieving secondary endpoints by treatment group			
Secondary endpoints	**Phase 3 QUASAR Maintenance Study treatment groups**		
	SC TREMFYA® 200mg q4w	**SC TREMFYA® 100mg q8w**	**Placebo (TREMFYA® withdrawal)**
Endoscopic remission (normalization, MES=0)	33.7% (p<0.001)	34.6% (p<0.001)	15.3%
Endoscopic improvement[g]	51.6% (p<0.001)	49.5% (p<0.001)	18.9 %
Clinical response[h]	74.7% (p<0.001)	77.7% (p<0.001)	43.2%
Histo-endoscopic mucosal improvement	47.9% (p<0.001)	43.6% (p<0.001)	16.8%

The proportion of patients with more than one adverse event (AE) was similar across treatment groups: SC TREMFYA® 200mg q4w, 70.0 percent; SC TREMFYA® 100mg q8w, 64.5 percent; placebo, 68.2 percent.[1] The most common AEs in the combined TREMFYA® group compared to placebo were COVID-19 (11.2 percent vs. 14.1 percent), UC (11.2 percent vs. 29.7 percent) and joint pain (6.1 percent vs. 6.8 percent), respectively.[1] The safety results were consistent to the safety profile of TREMFYA® in the approved indications of moderate to severe plaque psoriasis (PsO) and active psoriatic arthritis (PsA).[1,e]

“The Phase 3 QUASAR Maintenance Study continues to demonstrate the promise of TREMFYA to unlock potential treatment options for patients living with ulcerative colitis who continue to experience debilitating symptoms despite the availability of

treatments today," said David Lee, M.D., Ph.D., Global Therapeutic Area Head, Immunology, Johnson & Johnson. "These findings underscore our commitment to elevate the standard of care in ulcerative colitis and strengthen our resolve to advance inflammatory bowel disease science."

These data are among 28 oral and poster presentations that Johnson & Johnson is presenting at Digestive Disease Week 2024, highlighting the company's commitment and leadership in advancing the science of inflammatory bowel disease.

This year, Johnson & Johnson submitted regulatory applications seeking the approval of TREMFYA® for the treatment of adults with moderately to severely active UC in countries or regions including the United States and Europe.

Editor's Notes:

a. Baseline modified score of 5 to 9 with a Mayo rectal bleeding subscore of ≥ 1 and a Mayo endoscopy subscore ≥ 2 based on central review.[1]

b. Clinical remission was defined as a Mayo stool frequency subscore of 0 or 1 and not increased from induction baseline, a Mayo rectal bleeding subscore of 0, and a Mayo endoscopy subscore of 0 or 1 with no friability present on the endoscopy.[1]

c. Endoscopic remission (normalization) was defined as a MES of 0.[1]

d. Histologic-endoscopic mucosal improvement was 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 per Geboes grading system) and endoscopic improvement.[1]

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

f. Dr. Rubin is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

g. Endoscopic improvement was defined as an endoscopy subscore of 0 or 1 with no friability present on the endoscopy.[1]

h. Clinical response was 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]

ABOUT THE QUASAR PROGRAM (NCT04033445)

QUASAR is a randomized, double-blind, placebo-controlled, parallel group, multicenter, seamless Phase 2b/3 program designed to evaluate the efficacy and safety of guselkumab, a selective IL-23 inhibitor, in adult patients with moderately to severely active ulcerative colitis who experienced an inadequate response or who demonstrate intolerance to conventional therapy (e.g., thiopurines or corticosteroids), other biologics and/or JAK inhibitors (i.e., tumor necrosis factor [TNF]-alpha antagonists, vedolizumab, or tofacitinib).[3] QUASAR includes a Phase 2b dose-ranging induction study, a confirmatory Phase 3 induction study, a Phase 3 randomized withdrawal maintenance study, and a long-term extension study through a total of 5 years. Efficacy, safety, pharmacokinetics, immunogenicity, and biomarkers are assessed at specified time points.[2]

In the Phase 3 randomized withdrawal QUASAR Maintenance Study, adult patients who demonstrated a clinical response to 12 weeks of TREMFYA® IV induction in the Phase 2 and Phase 3 induction studies were randomized 1:1:1 to three treatment groups: SC TREMFYA® 200 mg q4w, TREMFYA® 100 mg q8w or placebo (TREMFYA® withdrawal).[1] The major secondary endpoints included corticosteroid-free clinical remission, maintenance of clinical remission, clinical response, symptomatic remission, endoscopic improvement, histo-endoscopic mucosal improvement, endoscopic normalization, Inflammatory Bowel Disease Questionnaire (IBDQ) remission, and fatigue response at Week 44 (56 weeks after initiation of treatment).[1]

ABOUT ULCERATIVE COLITIS

Ulcerative colitis 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.[4] 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. UC patients also have increased rates of depression.[3]

ABOUT TREMFYA® (guselkumab)

Developed by Johnson & Johnson, TREMFYA® is the first approved fully-human dual-acting monoclonal antibody that blocks IL-23 by binding to the p19 subunit of IL-23 and binding to CD64, a receptor on cells that produce IL-23.[5] IL-23 is an important driver of the pathogenesis of inflammatory diseases.[4] 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.[6,7,8,9]

TREMFYA® is approved in the U.S. 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.[4,10] 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.[11]

Johnson & Johnson maintains exclusive worldwide marketing rights to TREMFYA®.

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:
    - 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 use 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 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 and Janssen Biotech, Inc. 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. 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. 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] Rubin, D et al. The efficacy and safety of guselkumab as maintenance therapy in patients with moderately to severely active ulcerative colitis: Results from the Phase 3 QUASAR Maintenance Study. Oral presentation (Abstract #759) at the Digestive Disease Week (DDW) 2024. April 2024.
[2] Rubin, D et al. The Efficacy and Safety of Guselkumab as Maintenance Therapy in Patients with Moderately to Severely Active Ulcerative Colitis: Results from the Phase 3 Quasar Maintenance Study. Presented at DDW 2024, May 18-May 21.
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