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For immediate release

Data from the Phase 3 QUASAR Maintenance Study demonstrates guselkumab achieves the primary endpoint and all nine major secondary endpoints, including endoscopic normalisation and histo-endoscopic mucosal improvement

Data from this study support the TREMFYA® Regulatory Application submitted to the European Medicines Agency and the supplemental Biologics License Application (sBLA) currently under review by U.S. Food and Drug Administration (FDA)

High Wycombe, UK (21 May 2024) – Johnson & Johnson today announced the first data from the Phase 3 QUASAR Maintenance Study, a ramdomised-withdrawl, double-blind, placebo (PBO)-controlled study that demonstrated the efficacy and and safety profile of TREMFYA® (guselkumab) through 44 weeks in adult patients with moderately to severely active ulcerative colitis[a] (UC).[1] Both guselkumab maintenance groups achieved the primary endpoint, clinical remission[b], at Week 44 and all nine major secondary endpoints with statistical significance.[1] Results from the Maintenance Study showed 45.2 percent of patients (N=188) receiving subcutaneous (SC) guselkumab 100 mg every eight weeks (q8w) and 50.0 percent of patients (N=190) receiving SC guselkumab 200 mg every four weeks (q4w) achieved clinical remission at Week 44 compared to placebo (18.9 percent, N=190).[1] Safety results were consistent with the known profile.[1]

A summary of secondary endpoints from the 44-week Maintenance Study include:[1]

Percentage of patients achieving secondary endpooints by treatment group			
Secondary endpoints	**Phase 3 QUASAR Maintenance Study treatment groups**		
	SC guselkumab 100mg q8w (N=188)	**SC guselkumab 200mg q4w (N=190)**	**Placebo (guselkumab withdrawal) (N=190)**
Endoscopic normalisation[c]	34.6 percent (Δ =18.5, p<0.001)	33.7 percent (Δ=16.8, p<0.001)	15.3 percent
Endoscopic improvement[d]	49.5 percent (Δ=29.5, p<0.001)	51.6 percent (Δ=31.1, p<0.001)	18.9 percent
Clinical response[e]	77.7 percent (Δ=33.6, p<0.001)	74.7 percent (Δ=30.7, p<0.001)	43.2 percent
Histo-endoscopic mucosal improvement[f]	43.6 percent (Δ=25.7, p<0.001)	47.9 percent (Δ=29.6, p<0.001)	16.8 percent
Corticosteroid-free clinical remission	45.2 percent (Δ=25.7, p<0.001)	48.9 percent (Δ=29.0, p<0.001)	18.4 percent
Maintenance of clinical remission	60.6 percent (Δ=25.9, p=0.004)	72.5 percent (Δ=38.4, p<0.001)	33.9 percent
Symptomatric remission	70.2 percent (Δ=31.9, p<0.001)	68.9 percent (Δ=30.5, p<0.001)	37.4 percent
IBDQ remission	64.4 percent (Δ=26.3, p<0.001)	64.2 percent (Δ=25.9, p<0.001)	37.4 percent
Fatigue response at Wk44	50.5 percent (Δ=20.1, p<0.001)	43.2 percent (Δ=12.6, p=0.009)	29.5 percent

“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 normalisation and histo-endoscopic mucosal improvement, 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.[9] “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.”

The proportion of patients with more than one adverse event (AE) was similar across treatment groups: guselkumab 100mg q8w, 64.5 percent; guselkumab 200mg q4w, 70.0 percent; placebo, 68.2 percent.[1] The most common AEs in the combined guselkumab group compared to placebo were COVID-19 (11.2 percent vs. 14.1 percent), UC (11.21 percent vs. 29.7 percent) and joint pain (6.1 percent vs. 6.8 percent), respectively.[1]

"The Phase 3 QUASAR Maintenance Study reaffirms the potential in offering new avenues for patients enduring the challenges of ulcerative colitis, even in the face of existing treatments," comments Ludovic de Beaucoudrey, PhD, Senior Director, Therapeutic Area Lead, Immunology, Janssen-Cilag Limited, a company of Johnson & Johnson. "As many as two million people suffer with ulcerative colitis in Europe,[2] and these findings highlight our dedication to enhancing patient care standards and driving forward the field of IBD research, ensuring that innovative solutions continue to evolve."

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

Footnotes:

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.

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.

c. Endoscopic remission (normalisation) was defined as an endoscopy subscore of 0.

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

e. Clinical response was defined as a decrease from induction baseline in the modified Mayo score by ≥30% 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.

f. Histologic-endoscopic mucosal improvement was defined as achieving a combination of histologic improvement and endoscopic improvement.

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

ABOUT THE QUASAR PROGRAMME (EudraCT 2018-004002-25)

QUASAR is a randomised, double-blind, placebo-controlled, parallel group, multicentre, seamless Phase 2b/3 programme 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 Induction Study 1 (Phase 2b Induction Dose-ranging Study), a Induction Study 2 (Phase 3 Induction Study), a Maintenance Study (Phase 3 Maintenance Study) and a long-term extension (LTE) of the Maintenance Study and receive up to approximately another five years of treatment. Efficacy, safety, pharmacokinetics, immunogenicity, and biomarkers are assessed at specified time points.[3]

In the Phase 3 randomised withdrawal QUASAR Maintenance Study, adult patients who demonstrated a clinical response to guselkumab IV induction in the Phase 2 and Phase 3 induction studies at Week 12 were randomised 1:1:1 to three treatment groups: SC guselkumab 200 mg q4w, guselkumab 100 mg q8w or placebo (guselkumab withdrawal).[1] The primary endpoint was clinical remission at Week 44.[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 normalisation, Inflammatory Bowel Disease Questionnaire (IBDQ) remission, and fatigue response at Week 44.[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. 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 diarrhoea, abdominal pain, loss of appetite, weight loss, and fatigue. Ulcerative colitis patients also have increased rates of depression.[5]

ABOUT GUSELKUMAB

Developed by Johnson & Johnson, guselkumab is a fully-human 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.[6] IL-23 is an important driver of the pathogenesis of inflammatory diseases.[7]

Johnson & Johnson maintains exclusive worldwide marketing rights to guselkumab.

Adverse events should be reported. ▼ This medicinal product is subject to additional monitoring, and it is therefore important to report any suspected adverse events related to this medicinal product. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Janssen-Cilag Limited, a Johnson & Johnson company on 01494 567447 or at dsafety@its.jnj.com.

Janssen-Cilag International NV, the marketing authorisation holder for TREMFYA®▼ (guselkumab) in the EU, Janssen-Cilag Limited and Janssen-Cilag GmbH, are a Johnson & Johnson company.

ABOUT DDW

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and online meeting from May 18-21, 2024. The meeting showcases more than 4,400 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology.

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.

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 at the Digestive Disease Week (DDW) 2024. April 2024.

[2] Ng SC, et al. Worldwide incidence and prevalence of inflammatory bowel disease in the 21st century: a systematic review of population-based studies. The Lancet. 2017;390:2769-78.

[3] 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 (QUASAR). Identifier: EudraCT 2018-004002-25. https://www.clinicaltrialsregister.eu/ctr-search/search?query=2018-004002-25. Accessed May 2024.

[4] Crohn's & Colitis Foundation. What is ulcerative colitis? Available at: https://www.crohnscolitisfoundation.org/what-is-ulcerative-colitis. Accessed May 2024.

[5] MedicalNewsToday. Ulcerative colitis and mental health: What's the link? Available at: https://www.medicalnewstoday.com/articles/ulcerative-colitis-and-mental-health-link. Accessed May 2024.

[6] emc: Electronic medicines compendium. TREMFYA 100mg solution for injection in pre-filled pen. Last Updated August 2022.Available at: https://www.medicines.org.uk/emc/medicine/34321. Accessed May 2024.

[7] Schinocca, C. et al. Role of the IL-23/IL-17 pathway in rheumatic diseases: an overview. Frontiers in immunology. 2021 Feb 22;12:321. Available at: https://doi.org/10.3389/fimmu.2021.637829. Accessed May 2024.