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For immediate release

TREMFYA® (guselkumab) demonstrates superior efficacy versus STELARA® (ustekinumab) in first Phase 3 pooled data from two double-blind, placebo and active-controlled studies in Crohn's disease

Data featured in late-breaking oral presentation at Digestive Disease Week (DDW) 2024, taking place in Washington DC from May 18-21, showed guselkumab successfully met the co-primary endpoints for both doses compared to ustekinumab in Phase 3 studies (GALAXI 2 and 3) while also meeting major secondary endpoints

Beerse, Belgium (May 21, 2024) – Johnson & Johnson today announced results from two identically-designed Phase 3 studies (GALAXI 2 and 3) evaluating the efficacy and safety of guselkumab, an IL-23 inhibitor, versus placebo and ustekinumab, in adult patients with moderately to severely active Crohn's disease (CD).[1a] Data from the GALAXI 2 and 3 studies showed that both dose regimens of guselkumab (200 mg intravenous [IV] induction dose at Weeks 0, 4, and 8, followed by 100 mg subcutaneous [SC] every 8 weeks [q8w] or 200 mg SC every 4 weeks [q4w]) met the co-primary endpoints compared to placebo in each individual study, establishing a new highly rigorous standard for efficacy in CD treatment.[1,b] In addition, at Week 48, both dose regimens of guselkumab demonstrated statistically significant and clinically meaningful differences of efficacy compared to ustekinumab on multiple endoscopic endpoints in pooled analyses of GALAXI 2 and 3.[1] These results represent the first double-blind study of guselkumab to demonstrate superiority versus ustekinumab in CD, and were featured as a late-breaking oral presentation (Abstract #1057b) at Digestive Disease Week (DDW) 2024.[1]

The GALAXI 2 (n=508) and GALAXI 3 (n=513) studies were two independent, identically-designed, 48-week confirmatory Phase 3 studies, both with ongoing long-term extension studies, which included patients with moderately to severely active CD who had failed or were intolerant to conventional therapy (immunomodulators or corticosteroids) or biologic therapy (tumor necrosis factor [TNF] antagonists or vedolizumab).[1] Both studies employed a treat-through design in which patients in the active treatment arms remained on the therapy to which they were initially randomised, regardless of clinical response at Week 12, with the exception of non-responders in the placebo arm, who crossed over to blinded ustekinumab treatment. In each trial, the co-primary endpoints were clinical response at Week 12 and clinical remission at Week 48, and clinical response at Week 12 and endoscopic response at Week 48, comparing each guselkumab dose regimen to placebo.[1] Pooled analyses of both trials comparing guselkumab to ustekinumab were pre-specified for major secondary endpoints.[1]

In the pooled analyses from the 48-week, randomised, double-blind studies, both guselkumab dose regimens demonstrated statistical superiority to ustekinumab across four major secondary endpoints.[1] Guselkumab was superior to ustekinumab for the objective endpoints at Week 48 of endoscopic response[1,c] (guselkumab 100mg SC q8w vs ustekinumab Δ10.6 percent; 95 percent Confidence Interval [CI], 2.7–18.5; p<0.009, guselkumab 200mg SC q4w vs ustekinumab Δ15.6 percent; 95 percent CI, 7.9–23.4; p<0.001) and the more rigorous endpoint of endoscopic remission[1,d] (Δ12.3 percent; 95 percent CI, 4.9–19.7; p<0.001, Δ8.5 percent; 95 percent CI, 1.1–15.9; p<0.024).[1] Furthermore, guselkumab was superior to ustekinumab with endpoints that included both symptom-based and endoscopic outcomes in the same participants: clinical remission[1,e] and endoscopic response (Δ13.6 percent; 95 percent CI, 5.9–21.3; p<0.001, Δ7.8 percent; 95 percent CI, 0.1–15.6; p<0.049) and deep remission[1,f] at Week 48 (Δ11.3 percent; 95 percent CI, 4.2–18.5; p<0.002, Δ7.4 percent; 95 percent CI, 0.3–14.6; p<0.040).[1]

"These results are promising for those who continue to experience persistent and debilitating symptoms and offer the possibility of guselkumab as a future-first advanced therapy or after failure of other advanced therapies that may deliver the lasting remission patients deserve to relieve the burden of disease," said Remo Panaccione, M.D., Professor of Medicine,

University of Calgary and lead study investigator.[g] "The GALAXI programme demonstrates the potential of guselkumab and this targeted IL-23 approach for rapid and sustained efficacy in the treatment of Crohn's disease."

In the GALAXI programme, the safety profile for both guselkumab regimens were consistent with the known safety profile of guselkumab's currently approved indications.[1] Through Week 48, the number of patients with ≥1 adverse events (AE), ≥1 serious AEs, and AEs leading to discontinuation were similar across patients who received guselkumab, placebo, or ustekinumab.[1] The proportions of patients with serious infections and AEs of interest were low; in GALAXI 2, serious infections were 0.7 percent for guselkumab 100mg SC q8w and 1.4 percent for guselkumab 200 mg SC q4w; in GALAXI 3, serious infections were 0.0 percent for guselkumab 100mg SC q8w and 0.8 percent for guselkumab 200 mg SC q4w.[1]

"Nearly two million people in Europe experience the persistent and debilitating symptoms of Crohn's disease," said Ludovic de Beaucoudrey, PhD, Senior Director, Therapeutic Area Lead, Immunology, Janssen-Cilag Limited, a company of Johnson & Johnson. "Our Phase 3 GALAXI programme comprises two rigorous independent studies that demonstrate guselkumab's potential for individuals living with moderately to severely active Crohn's disease, where considerable needs remain, and highlight our commitment to inflammatory bowel disease."

Key results versus ustekinumab from the Phase 3 GALAXI programme:

Patients in the Phase 3 GALAXI 2 (n=508) and GALAXI 3 (n=513) studies were assigned 2:2:2:1 to:[1]

- Guselkumab 200mg intravenous (IV) q4w (Weeks 0, 4, and 8) to 200mg SC q4w
- Guselkumab 200mg IV q4w (Weeks 0, 4, and 8) to 100mg SC q8w
- Ustekinumab ~6mg/kg IV (1x) to 90mg SC q8w
- Placebo

A summary of data from the 48-week pooled analyses is as follows:[1]

Endpoint	Guselkumab 100mg SC q8w (vs. ustekinumab)	Guselkumab 200mg SC q4w (vs. ustekinumab)	Ustekinumab
Endoscopic response Week 48	47.9 percent (p=.009)	52.7 percent (p<.001)	37.1 percent
Endoscopic remission Week 48	33.2 percent (p=.024)	37.2 percent (p<.001)	24.7 percent
Clinical remission and endoscopic response Week 48	41.6 percent (p=.049)	47.3 percent (p<.001)	33.7 percent
Deep remission Week 48	29.7 percent (p=.040)	33.8 percent (p<.002)	22.3 percent
Clinical remission Week 48	65.4 percent (p=.512)	70.3 percent (p=.058)	62.9 percent

On 1 May 2024, Janssen-Cilag International NV, a Johnson & Johnson company, submitted applications to the European Medicines Agency (EMA) seeking to expand the Marketing Authorisation Application for guselkumab to include the treatment of adult patients with moderately to severely active ulcerative colitis (UC) and moderately to severely active CD. Additionally, on March 11, 2024, Johnson & Johnson submitted a supplemental Biologics License Application to the U.S. Food and Drug Administration (FDA) seeking approval of guselkumab for the treatment of adults with moderately to severely active UC.

Editor's Notes:

a. Guselkumab is not currently approved to treat Crohn's disease.
b. The results from the Phase 3 GALAXI studies described in this release are based on the global endpoints
c. Endoscopic response is defined as ≥50 percent improvement from baseline in the Simple Endoscopic Score in Crohn's disease (SES-CD) (primary efficacy analysis set (nonresponder imputation)).[1]
d. Endoscopic remission is defined as an endoscopy subscore of 0.[1]
e. Clinical remission is defined as a Crohn's Disease Activity Index (CDAI) score of <150 (primary efficacy analysis set (nonresponder imputation)).[1]

f. Deep remission endpoint consists of clinical remission and endoscopic remission together.[1]
g. Dr. Panaccione is a paid consultant for Johnson & Johnson. He has not been compensated for any media work.

ABOUT THE GALAXI PROGRAMME (EudraCT 2017-002195-13)

GALAXI is a randomised, double-blind, placebo-controlled, active-controlled (ustekinumab), global, multicentre Phase 2/3 programme designed to evaluate the efficacy and safety of guselkumab in participants with moderately to severely active Crohn's disease with inadequate response/intolerance to conventional therapies (immunomodulators, corticosteroids) and/or biologics (TNF antagonists, vedolizumab).[2] GALAXI includes a Phase 2 dose-ranging study (GALAXI 1) and two independent, identically designed confirmatory Phase 3 studies (GALAXI 2 and 3).[2] Each GALAXI study employed a treat-through design in which participants remained on the treatment to which they were initially randomised, reflecting real-world clinical practice, and includes a long-term extension study that will assess clinical, endoscopic, and safety outcomes with guselkumab through a total of five years.[2]

ABOUT CROHN'S DISEASE

Crohn's disease is one of the two main forms of inflammatory bowel disease, which affects nearly 2 million people across Europe.[3] Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract with no known cause, but the disease is associated with abnormalities of the immune system that could be triggered by a genetic predisposition, diet, or other environmental factors.[4] Symptoms of Crohn's disease can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever.[5] There is currently no cure for Crohn's disease.[6]

ABOUT GUSELKUMAB

Developed by Johnson & Johnson, guselkumab is the first approved fully-human monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor.[7] IL-23 is an important driver of the pathogenesis of inflammatory diseases.[8]

Guselkumab is approved in the EU for the treatment of moderate to severe plaque psoriasis (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 anti-rheumatic drug therapy.[7] Guselkumab is also approved in the U.S., [9] Canada,[10] Japan[11] and a number of other countries for the treatment of adults with moderate-to-severe 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).

Johnson & Johnson maintains exclusive worldwide marketing rights to guselkumab.

GUSELKUMAB IMPORTANT SAFETY INFORMATION

In controlled periods of clinical studies with guselkumab, adverse drug reactions (ADRs) that consisted of respiratory tract infections were very common (≥10 percent); increased transaminases, headache, diarrhoea, arthralgia, and injection site reactions were common (≥1 to <10 percent); and herpes simplex infections, tinea infections, gastroenteritis, decreased neutrophil count, hypersensitivity, anaphylaxis, urticaria and rash were uncommon ADRs (≥0.1 percent to <1 percent).[7]

Please refer to the Summary of Product Characteristics for full prescribing information for guselkumab in Pso and PsA: https://www.ema.europa.eu/en/documents/product-information/tremfya-eparproduct-information_en.pdf.

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 taking place in Washington DC 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. More information can be found at www.ddw.org.

ABOUT JOHNSON & JOHNSON

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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 www.janssen.com/EMEA or at https://www.janssen.com/johnson-johnson-innovative-medicine. Follow us at J&J Innovative Medicine Europe, Middle East & Africa (EMEA). Janssen-Cilag International NV, 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] Panaccione, R et al. Efficacy and safety of guselkumab therapy in patients with moderately to severely active Crohn's disease: Results of the GALAXI 2 & 3 Phase 3 studies. Oral presentation (Abstract #1057b) at the Digestive Disease Week (DDW) 2024. May 2024.
[2] 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.
[3] 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.
[4] Crohn's & Colitis Foundation. What is Crohn's disease? Available at: https://www.crohnscolitisfoundation.org/what-is-crohns-disease/causes. Accessed May 2024.
[5] Crohn's & Colitis Foundation. Signs and Symptoms of Crohn's Disease. Available at: https://www.crohnscolitisfoundation.org/what-is-crohns-disease/symptoms. Accessed May 2024.
[6] NHS. Overview Crohn's disease. Available at: https://www.nhs.uk/conditions/crohns-disease/. Accessed May 2024.
[7] EU SmPC: European Medicines Agency. TREMFYA Summary of Product Characteristics. Last updated July 2022. Available at: https://www.ema.europa.eu/en/documents/product-information/tremfya-epar-productinformation_en.pdf. Accessed May 2024.
[8] 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.
[9] TREMFYA® Prescribing Information. Available at: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/TREMFYA-pi.pdf. Accessed May 2024.
[10] The Canadian Agency for Drugs & Technologies in Health. TREMFYA Prescribing Information. Available at: https://pdf.hres.ca/dpd_pm/00042101.pdf. Accessed May 2024.
[11] Japan Pharmaceuticals and Medical Devices Agency. Tremfya Report on the Deliberation Results. Available at: https://www.pmda.go.jp/files/000234741.pdf. Accessed May 2024.

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