Johnson&Johnson

Media contact:
Sophie Daneau
+33 6 3178 8798

Investor contact:
Raychel Kruper
investor-relations@its.jnj.com

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TREMFYA® (guselkumab) studies underscore its potential to be the first IL-23 inhibitor to offer both intravenous (IV) and subcutaneous (SC) induction for Crohn's disease

In Phase 3 GRAVITI study guselkumab achieves all primary and secondary endpoints

Beerse, Belgium (21 June 2024) – Janssen-Cilag International NV, a Johnson & Johnson company, today announced positive topline results from Week 12 of the Phase 3 GRAVITI study of TREMFYA® (guselkumab) subcutaneous (SC) induction therapy in adult patients with moderately to severely active Crohn's disease.[1] The study met both co-primary endpoints and all secondary endpoints, achieving statistically significant and clinically meaningful outcomes versus placebo for both clinical remission at Week 12 and endoscopic response at Week 12.[2] GRAVITI similarly adds to the results guselkumab demonstrated in Crohn's disease in the pooled analysis from Phase 3 GALAXI 2 and GALAXI 3 studies as recently presented at DDW, the first double-blind registrational head-to-head clinical trials to demonstrate superiority versus ustekinumab in key endoscopic endpoints in Crohn's disease, showing the potential to become the first IL-23 inhibitor to offer both IV or SC induction options.[3,4,5] Safety data from the Phase 3 GRAVITI study were consistent with the well-characterized profile of guselkumab in its approved indications.[2,a]

"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 Leader, Immunology, Janssen-Cilag SaS, a company of Johnson & Johnson. "The Phase 3 GRAVITI results demonstrate that SC induction is efficacious, with clinical benefits comparable to IV induction observed in the GALAXI trials. These findings highlight guselkumab's potential to offer more options and flexibility to both patients and healthcare providers."

Week 24 results from the GRAVITI study are being prepared for presentation at upcoming medical meetings and have been shared with health authorities in planned submissions. A separate Johnson & Johnson study (EudraCT: 2022-000365-41) evaluating the efficacy and safety of guselkumab SC induction therapy in ulcerative colitis is ongoing.[6]

Editor's Notes:

a. Guselkumab is not currently approved for the treatment of ulcerative colitis or Crohn's disease in the EU or the UK.

ABOUT THE GRAVITI PROGRAMME (EudraCT: 2020-006165-11, NCT05197049)
GRAVITI is a randomised, double-blind, placebo-controlled, global, multicentre Phase 3 study to evaluate guselkumab SC induction therapy (400 mg at Weeks 0, 4, and 8) in patients with moderately to severely active Crohn's disease who have had an inadequate response or failed to tolerate conventional therapy (i.e., corticosteroids or immunomodulators) or biologic therapy (TNF antagonists or vedolizumab).[1] The maintenance doses in GRAVITI are the same as those evaluated in GALAXI (200 mg SC q4w and 100 mg SC q8w).[1] The study employed a treat-through design, in which patients are randomised to guselkumab at Week 0 and remain on that regimen throughout the study, regardless of clinical response status at the end of induction.[1] Participants randomised to placebo were able to receive guselkumab (400 mg SC q4w x3 ➔ 100 mg SC q8w) if rescue criteria were met at Week 16.[1]

ABOUT THE GALAXI PROGRAMME (EudraCT: 2017-002195-13, NCT03466411)
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 (corticosteroids or immunomodulators) and/or biologics (TNF antagonists or vedolizumab).[3] GALAXI includes a Phase 2 dose-ranging study (GALAXI 1) and two independent, identically designed confirmatory Phase 3 studies (GALAXI 2 and 3).[3] Each GALAXI study employed a treat-through design in which participants remained on the treatment to which they were initially randomised and includes a long-

term extension study that will assess clinical, endoscopic, and safety outcomes with guselkumab through a total of five years.[3] Participants randomised to placebo were able to receive ustekinumab if clinical response was not met at Week 12.[3]

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.[7,8] 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.[9] Symptoms of Crohn's disease can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever. There is currently no cure for Crohn's disease.[10,11]

ABOUT TREMFYA® (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.[11] IL-23 is an important driver of the pathogenesis of inflammatory diseases.[13]

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 psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying anti-rheumatic drug therapy.[12] Guselkumab is also approved in the U.S.,[14] Canada,[15] Japan[16] 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 PsA.[12]

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).[12]

Please refer to the Summary of Product Characteristics for full prescribing information for guselkumab in Pso and PsA: https://www.ema.europa.eu/en/medicines/human/EPAR/tremfya#.

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/emea or at www.janssen.com/johnson-johnson-innovative-medicine. Follow us on LinkedIn. 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 materialise, 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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