Johnson&Johnson

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For UK medical and trade media only

For immediate release

TREMFYA® (Guselkumab) is the first IL-23 inhibitor to demonstrate robust results with a fully subcutaneous regimen in both induction and maintenance in Crohn's disease

A greater number of patients treated with subcutaneous guselkumab induction and maintenance vs placebo achieved clinical remission and endoscopic response at 48 weeks in the Phase 3 GRAVITI study[1]

Guselkumab shows potential to become the first IL-23 treatment to offer both a subcutaneous and intravenous induction regimen for patients living with Crohn's disease[1]

High Wycombe, UK (29 October 2024) – Johnson & Johnson today announced results from the Phase 3 GRAVITI study of TREMFYA® (guselkumab), the first IL-23 inhibitor, demonstrating robust results in subcutaneous (SC) induction and maintenance therapy. The findings demonstrated significant clinical remission and endoscopic response at 48 weeks vs placebo in adults with moderately to severely active Crohn's disease (CD).[1] These results are among the 14 Johnson & Johnson abstracts presented at the American College of Gastroenterology (ACG) 2024, 25th – 30th October 2024.

"The results from the GRAVITI study indicate that guselkumab has the potential to make a positive difference for individuals with Crohn's disease," said Professor Ailsa Hart, Consultant Gastroenterologist and Director Inflammatory Bowel Disease Research, St Mark's Hospital & Imperial College, London, UK. "Subcutaneous induction therapy with guselkumab could help people living with Crohn's disease to actively manage their symptoms and provides choice and flexibility for them and healthcare providers."

GRAVITI SC Induction Week 12 Results:

- More than half of patients treated with guselkumab (400 mg administered subcutaneously at Weeks 0, 4, and 8) achieved clinical remission versus those in the placebo group (56.1 percent versus 21.4 percent; p<0.001).[1]
- Endoscopic response was achieved in 41.3 percent of patients treated with guselkumab SC induction therapy versus 21.4 percent in the placebo group (p<0.001).[1]
- Greater improvements in clinical remission were seen as early as Week 4 with guselkumab compared with placebo, demonstrating rapid onset of action.[2]

GRAVITI SC Induction Week 48 Results:

- The number of patients achieving clinical remission was more than three times higher with both maintenance doses of guselkumab versus placebo at week 48 (60.0 percent for 100 mg SC every eight weeks (q8w) and 66.1 percent for 200 mg SC every four weeks (q4w) versus 17.1 percent in the placebo group; p<0.001).[1]
- Endoscopic response at week 48 was achieved in 44.3 percent and 51.3 percent of patients in the guselkumab 100 mg SC q8w group and 200 mg SC q4w group respectively, versus 6.8 percent in the placebo group (p<0.001).[1]
- Endoscopic remission was achieved in 30.4 percent and 38.3 percent of patients in the guselkumab 100 mg SC q8w group and 200 mg SC q4w group respectively, versus 6.0 percent in the placebo group.[2]

The co-primary endpoint of clinical remission and endoscopic response at week 12 and all multiplicity-controlled endpoints were met.[1] Safety findings were consistent with the known safety profile of guselkumab in approved indications.[1,a]

"These results show that guselkumab could become the first IL-23 inhibitor to offer both subcutaneous and intravenous induction options," stated Dr. John Fleming, Country Medical Director, UK at Johnson & Johnson Innovative Medicine. "The one-year results of this study suggest that subcutaneous induction with guselkumab is a promising approach to help people with Crohn's disease manage their symptoms and achieve meaningful endoscopic improvements."

Johnson & Johnson submitted a regulatory application seeking the approval of guselkumab for the treatment of adults with moderately to severely active Ulcerative Colitis (UC) and for the treatment of adults with moderately to severely active CD in the United Kingdom.

Editor's Notes:

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

ABOUT THE GRAVITI PROGRAMME (EudraCT 2020-006165-11)

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).[1,3] The maintenance doses in GRAVITI are the same as those evaluated in GALAXI (200 mg SC q4w and 100 mg SC q8w).[1,4] 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)

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).[4,5] GALAXI includes a Phase 2 dose-ranging study (GALAXI 1) and two independent, identically designed confirmatory Phase 3 studies (GALAXI 2 and 3).[4,5] 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.[4,5] Patients received guselkumab 200 mg intravenous induction at Weeks 0, 4 and 8 followed by guselkumab 200 mg subcutaneous maintenance every 4 weeks; or guselkumab 200 mg intravenous induction at Weeks 0, 4 and 8, followed by guselkumab 100 mg subcutaneous maintenance every 8 weeks; or a biologic active control; or placebo.[4] Participants randomised to placebo were able to receive ustekinumab if clinical response was not met at Week 12.[5] Of the 873 individuals pooled across the GALAXI 2 & 3 dataset, 456 (52 percent) had prior history of inadequate response to biologics, 365 (41.8 percent) were biologic-naïve and 52 (6 percent) were biologic experienced without documented inadequate response or intolerance.[4]

ABOUT CROHN'S DISEASE

Crohn's disease is one of the two main forms of inflammatory bowel disease, which affects over 500,000 people across the UK.[6] 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.[7] Symptoms of Crohn's disease can vary, but often include abdominal pain and tenderness, frequent diarrhea, rectal bleeding, weight loss, and fever.[8] Currently no cure is available for Crohn's disease.[9]

ABOUT GUSELKUMAB

Developed by Johnson & Johnson, Guselkumab is the first approved 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.[10,11] IL-23 is an important driver of the pathogenesis of inflammatory diseases.[12] Johnson & Johnson maintains exclusive worldwide marketing rights to Guselkumab.

Report an Adverse Event. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at https://yellowcard.mhra.gov.uk/. By reporting side effects, you can help provide more information on the safety of this medicine.

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.

The marketing authorisation holder for TREMFYA® (Guselkumab) in the UK is:

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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 www.janssen.com/uk/ or at https://www.janssen.com/johnson-johnson-innovative-medicine. Follow us at www.linkedin.com/company/jnjinnovativemedicineuk/. 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 guselkumab. 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., Janssen-Cilag International NV 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., Janssen-Cilag International NV nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

Source: Johnson & Johnson

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[1] Panaccione, R, et al. Efficacy and Safety of Subcutaneous Guselkumab Induction Therapy in Patients With Moderately to Severely Active Crohn's Disease: Results Through Week 48 From the Phase 3 GRAVITI Study. Presentation at American College of Gastroenterology (ACG) 2024.

[2] Panaccione, R, et al. Efficacy and Safety of Subcutaneous Guselkumab Induction Therapy in Patients With Moderately to Severely Active Crohn's Disease: Results Through Week 48 From the Phase 3 GRAVITI Study. Presented at American College of Gastroenterology conference, October 25-30. Poster OP72.

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