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News Release

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TREMFYA® (guselkumab) Maintains Key Efficacy Endpoints Through Three Years for Adults with Moderately to Severely Active Crohn's Disease in a Phase 2 Study

Key efficacy endpoints of the long-term extension GALAXI study included clinical remission, patient-reported outcome remission, and endoscopic response

BEERSE, BELGIUM, October 16, 2023 – Janssen Pharmaceuticals, Inc., a Johnson & Johnson Company, today announced new data from the long-term extension (LTE) of the GALAXI Phase 2 study demonstrating the durable clinical and endoscopic efficacy of guselkumab, a selective IL-23 p19 inhibitor, in patients with moderate-to-severe Crohn's disease (CD), now through a total of three years.[1] Rates of clinical remission and endoscopic response were maintained through three years. The safety profile of guselkumab was consistent with that of its currently approved indications.[1] These data are among Janssen's 17 oral and poster presentations at the United European Gastroenterology (UEGW) Week 2023 taking place in Copenhagen, Denmark, 14-17 October, 2023.

"The results from the GALAXI long-term extension strengthen our confidence in guselkumab's potential for patients with moderate-to-severe Crohn's disease," said study author Anita Afzali, M.D., Division of Digestive Diseases, University of Cincinnati College of Medicine, Cincinnati, OH.[a] "These insights are especially helpful to physicians, as research continues investigating the efficacy and safety profile of guselkumab for its use as a potential treatment option for their patients in need of lasting relief."

After completing the Week 48 Phase 2 GALAXI study, patients continued in the LTE to receive one of three maintenance regimens that were randomly assigned to the following treatment arms:[1]

- Guselkumab 100 mg subcutaneous (SC) every eight weeks (q8w)[1]
- Guselkumab 200 mg SC every four weeks (q4w)[1]
- Ustekinumab 90 mg SC q8w[1]

A summary of data from the GALAXI LTE at three years for all randomised patients is as follows:

Endpoint	Combined guselkumab[b]	Ustekinumab
Clinical remission[c]	54.1 percent (100/185)[1]	46.0 percent (29/63)[1]
PRO-2 remission[d]	51.4 percent (95/185)[1]	39.7 percent (25/63)[1]
Endoscopic response[e]	34.7 percent (61/176)[1]	19.4 percent (12/62)[1]

Both guselkumab treatment arms demonstrated similar benefits in this study.[1] The study was not designed to evaluate efficacy differences between individual guselkumab doses or guselkumab versus ustekinumab.

Most infections were not serious and did not result in discontinuation, while incidence rates of serious adverse events (SAEs) and serious infections were generally low.[1] Most infections were mild to moderate in severity and resolved without discontinuation of treatment (65.8 versus 3.3 events per 100 patient-years).[2]

"Establishing the long-term efficacy and safety profile of guselkumab is an important step as we work to bring relief and remission to the millions of people worldwide living with Crohn's disease," said Jan Wehkamp, MD, Ph.D., Vice President, Gastroenterology Disease Area Leader at Janssen. "We remain committed to researching and developing novel therapies, and to deepening our understanding of the interleukin (IL)-23 pathway with the goal of offering patients a range of treatment options that best fit their needs."

Further research is currently being conducted on guselkumab for the treatment of patients with inflammatory bowel disease, which includes Phase 3 studies that are fully recruited and ongoing.[3]

Guselkumab is not approved for the treatment of adults living with CD in the European Union (EU).[4]

Editor's Notes:

a. Dr. Anita Afzali is a paid consultant for Janssen. She has not been compensated for any media work.
b. Combined guselkumab group includes the pooled 100 mg SC q8w and the 200 mg SC q4w data.[1]
c. Clinical remission is defined as a Crohn's Disease Activity Index (CDAI) score of <150 (primary efficacy analysis set (nonresponder imputation)).[1]
d. PRO-2 remission is defined as an abdominal pain (AP) mean daily score ≤1 and mean daily stool frequency (SF) score ≤3 and no worsening of AP or SF from baseline (primary efficacy analysis set (nonresponder imputation)).[1]
e. 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]

About GALAXI 1 Long-Term Extension (NCT03466411; EudraCT 2017-002195-13)

GALAXI 1 is a double-blind, placebo-controlled, active-controlled, global, multicentre, Phase 2 dose-ranging study evaluating the efficacy and safety of guselkumab in participants with moderately to severely active CD with inadequate response/intolerance to conventional therapies (corticosteroids, immunosuppressives and/or biologics (TNF antagonists, vedolizumab).[5,6] The GALAXI 1 long-term extension study is assessing clinical, endoscopic, and safety outcomes through 5 years in patients receiving maintenance therapy with guselkumab.[5,6]

Upon completing the treat-through Week 48 Phase 2 study, patients who were deemed by the investigator to be benefitting from treatment were continued in the LTE with 1 of 3 previously assigned maintenance regimens: guselkumab dosed at 100 mg subcutaneous (SC) every 8 weeks, guselkumab dosed at 200 mg SC every 4 weeks (q4w), or ustekinumab dosed at 90 mg SC q8w. [5,6]

Key efficacy endpoints assessed at Week 144 included CD Activity Index (CDAI) clinical remission, patient-reported outcome (PRO)-2 remission, and endoscopic response.[1,6] Safety analyses included all treated patients. The Phase 2 study was not designed to evaluate efficacy differences between individual guselkumab doses or between guselkumab and ustekinumab.[4,6]

About Crohn's Disease (CD)

CD is one of the two main forms of inflammatory bowel disease (IBD), which affects an estimated three million Americans and an estimated two million people across Europe.[7,8] CD 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 CD can vary, but often include abdominal pain and tenderness, frequent diarrhoea, rectal bleeding, weight loss, and fever. There is currently no cure for CD.[9]

About TREMFYA® (guselkumab)

Developed by Janssen, guselkumab is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of interleukin (IL)-23 and inhibits its interaction with the IL-23 receptor.[4,11] 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 alone or in combination with methotrexate (MTX) 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 antirheumatic drug therapy.[4] It is also approved in the U.S., Canada, Japan and a number of other countries worldwide for the treatment of adults with moderate to severe plaque Pso who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light), and for the treatment of adult patients with active PsA.[11,12,13]

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to TREMFYA®.

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).[4]

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-epar-product-information_en.pdf

ADRs should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play

or Apple App Store. ADRs should also be reported to Janssen-Cilag Ltd on +44 (0) 1494 567447.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism & Retina, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com/EMEA.

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Janssen-Cilag International NV, the marketing authorisation holder for TREMFYA® in the EU, and Janssen Research & Development, LLC 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 product development of TREMFYA® (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, Jansen-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 behaviour 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 January 1, 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. Neither Janssen Research Development, LLC, Jansen-Cilag International NV nor Johnson & Johnson undertake to update any forward-looking statement as a result of new information or future events or developments.

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