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News Release

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The Majority of Adults with Moderately to Severely Active Crohn's Disease in a Phase 2 Study Achieved Clinical Remission and Corticosteroid-Free Remission Through 48 Weeks with TREMFYA®▼ (guselkumab)

New long-term data show proportions of patients achieving clinical remission ranged from 57.4-73 percent across three guselkumab dose groups in the Phase 2 GALAXI 1 study

The majority of patients in clinical remission were also in corticosteroid-free remission with rates ranging from 55.7-71.4 percent

BEERSE, BELGIUM, 18 February, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new results from the Phase 2 GALAXI 1 clinical trial showing the majority (57.4-73 percent) of adults with moderately to severely active Crohn's disease (CD) who were treated with TREMFYA®▼ (guselkumab) achieved clinical remission (Crohn's Disease Activity Index [CDAI]<150)[a] at week 48.[1] The week 48 results also show the majority (55.7-71.4 percent) of patients who achieved clinical remission with guselkumab were free of corticosteroid treatment.[1,b] Guselkumab is not currently approved for the treatment of

adults with CD in the EU.[2] These data are being presented today as an oral presentation (OP24) at the 17th Congress of the European Crohn's and Colitis Organisation (ECCO), taking place virtually from 16-19 February.[1]

"These 48-week GALAXI 1 data represent a major step in the development of guselkumab," said presenting study author Professor Silvio Danese, Director, Gastroenterology and Endoscopy, IRCCS Ospedale San Raffaele and University Vita-Salute San Raffaele, Milan, Italy.[c] "Further, remission was achievable for patients in this study without corticosteroids, which is important to note as avoidance of long-term steroid use is an important consideration when treating these patients."

Week 48 results show:[d]

- **Clinical remission:[a]** 63.9 percent of patients treated with guselkumab 200 mg intravenous (IV)/100 mg subcutaneous (SC), 73 percent treated with guselkumab 600 mg IV/200 mg SC and 57.4 percent treated with guselkumab 1200 mg IV/200 mg SC achieved clinical remission.[1,a] With ustekinumab, which was used as a reference arm, 58.7 percent of patients achieved clinical remission.[1] The study was not powered to evaluate differences between treatment groups.[1]
- **Corticosteroid-free clinical remission:[b]** 59 percent of patients treated with guselkumab 200 mg IV/100 mg SC, 71.4 percent treated with guselkumab 600 mg IV/200 mg SC, and 55.7 percent treated with guselkumab 1200 mg IV/200 mg SC, achieved corticosteroid-free clinical remission[b] (CDAI<150 and no corticosteroid therapy at week 48). The proportion of patients in the ustekinumab group was 58.7 percent.[1]
- **Patient-Reported Outcome (PRO)-2 remission:[e]** 57.4 percent of patients treated with guselkumab 200 mg IV/100 mg SC, 69.8 percent treated with guselkumab 600 mg IV/200 mg SC, and 50.8 treated with guselkumab 1200 mg IV/200 mg SC achieved PRO-2 remission.[1,e] The proportion of patients in the ustekinumab group was 46 percent.[1]

All guselkumab dose groups during the 48-week treatment period in GALAXI 1 had

comparable safety data, consistent with the known safety profile for guselkumab in approved indications.[1] Key safety event rates were similar among the three dosing groups.[1] In the guselkumab 200 mg IV/100 mg SC, 600 mg IV/200 mg SC, 1200 mg IV/200 mg SC and ustekinumab groups, adverse events (AEs) occurred in 71.2 percent, 80.8 percent, 69.9 percent, and 84.5 percent, respectively.[1] Serious adverse events (SAEs) occurred in 8.2 percent, 6.8 percent, 6.8 percent, and 12.7 percent, respectively.[1] No opportunistic infections, cases of tuberculosis, or deaths were reported in any group.[1] Infections[f] occurred in 34.2 percent, 41.1 percent, 34.2 percent, and 36.6 percent, respectively.[1] Serious infections occurred in 2.7 percent, 2.7 percent, 1.4 percent, and 1.4 percent, respectively.[1]

"With a life-long progressive condition like Crohn's disease, it's critical to investigate potential new treatment options with the understanding that remission is the ultimate goal," said Jan Wehkamp, M.D., Ph.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. "These new data underscore Janssen's continued commitment to investigating pathway science with guselkumab in the development of additional therapies that can potentially address the multifaceted nature of immune-mediated diseases like Crohn's disease."

Janssen previously announced results from the 12-week interim analysis and top-line 48-week data from the GALAXI Phase 2 study.[3,4]

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Editor's Notes:

a. Clinical remission is defined as a CDAI score of <150.[1]
b. Corticosteroid-free clinical remission is defined as a CDAI score <150 at week 48 and not receiving corticosteroids at week 48.[1]
c. Professor Danese is a paid consultant for Janssen. He has not been compensated for any media work.
d. Please see the 'About GALAXI 1' section below for further details regarding the

study design.

e. PRO-2 remission is defined as the unweighted CDAI component of daily average abdominal pain (AP) score ≤1 and the unweighted CDAI component of daily average stool frequency (SF) ≤3, and no worsening of AP or SF from baseline.[1]
f. Infections as assessed by the investigator.

About GALAXI 1 (NCT03466411; EudraCT 2017-002195-13)[5,6]

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).

Participants were randomised equally into five treatment arms, including treatment with guselkumab dosed at 200, 600 or 1200 mg IV at weeks 0, 4 and 8, respectively; or treatment with the reference arm, ustekinumab, dosed at ~6 mg/kg IV at week 0 and then dosed at 90 mg SC at week 8; or IV placebo. Comparison with placebo was not conducted beyond week 12.

The primary endpoint of the Phase 2 GALAXI 1 study is change from baseline in CDAI scores at week 12.[7] All three induction doses of guselkumab significantly improved CDAI scores from baseline as compared to placebo, with placebo-subtracted Least Squares Mean changes of 124.2 ($p<0.001$), 102.7 ($p<0.001$), and 108.7 ($p<0.001$) for the 200 mg IV, 600 mg IV, and 1200 mg IV groups, every four weeks, respectively.[7] Additional key outcomes evaluated at week 12 include clinical remission (CDAI<150), clinical response (decrease from baseline in CDAI ≥100 or CDAI<150), PRO-2 remission (AP mean daily score ≤1 and mean daily stool frequency score ≤3), clinical biomarker response (clinical response and ≥50 percent reduction from baseline in C-reactive protein or faecal calprotectin), endoscopic response (≥50 percent improvement from baseline in the SES-CD), and safety in

participants treated with guselkumab compared with placebo.[7] Participants may receive treatment through five years.

The 48-week analyses report the results of the 248 patients in the maintenance phase.[1] After completing 12 weeks of therapy, patients transitioned to their long-term maintenance treatments as follows: patients receiving guselkumab 200 mg IV were shifted to guselkumab 100 mg SC dose every eight weeks; patients receiving guselkumab dosed at 600 mg IV or 1200 mg IV changed to guselkumab 200 mg SC every four weeks; patients receiving ustekinumab continued with a 90 mg SC dose every eight weeks; placebo non-responders began ustekinumab IV followed by ustekinumab SC every eight weeks; and placebo responders continued on a placebo SC every four weeks.[1]

About Crohn's Disease

CD is one of the two main forms of inflammatory bowel disease, which affects up to two million people across Europe.[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.[10] There is currently no cure for CD.[11]

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.[2] 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 (DMARD).[2] 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.

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).[2]

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

ADRs should be reported▼. This medicinal product is subject to additional monitoring and it is, therefore, important to report any suspected ADRs related to this medicinal product. 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 STELARA® (ustekinumab)[12]

Ustekinumab is a fully human monoclonal antibody and is the first biologic treatment to selectively inhibit the IL-12 and IL-23 pathways.[12,13] In the EU, ustekinumab is approved for the treatment of adult patients with moderate to severe CD who have

had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNF-α antagonist, or have medical contraindications to such therapies.[12,13] Ustekinumab is also approved for the treatment of adults with moderately to severely active ulcerative colitis (UC) who have had an inadequate response with, or lost response to, or were intolerant to either conventional therapy or a biologic, or have medical contraindications to such therapies.[12]

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

USTEKINUMAB IMPORTANT SAFETY INFORMATION

The most common adverse events (AEs) (>5%) in controlled periods of clinical studies with ustekinumab were nasopharyngitis and headache.[12] Most were considered to be mild and did not necessitate discontinuation of study treatment.[12] The most serious adverse reaction that has been reported for ustekinumab is serious hypersensitivity reactions, including anaphylaxis.[12] The overall safety profile is similar for adult patients with CD, UC, Pso, and PsA.[12]

Please refer to the Summary of Product Characteristics for full prescribing information for ustekinumab: https://www.ema.europa.eu/en/documents/product-information/stelara-epar-product-information_en.pdf.

ADRs should be reported.

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, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com/EMEA.

Follow us at www.twitter.com/JanssenEMEA.

Janssen-Cilag International NV, the marketing authorisation holder for TREMFYA® and STELARA® in the EU, and Janssen Research & Development, LLC are each part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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® (guselkumab) product development. 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, any of the other Janssen Pharmaceutical Companies 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 2, 2022, 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 the Janssen Pharmaceutical Companies 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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