FOR EUROPEAN MEDICAL AND TRADE MEDIA ONLY EXCLUDING UK

News Release

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Janssen Presents Study Results Showing Clinical Efficacy for TREMFYA®▼ (guselkumab) and Long-Term Safety Profile for STELARA® (ustekinumab) for Patients Living with Inflammatory Bowel Disease at Digestive Disease Week® 2022

New data show proportions of patients treated with guselkumab who achieved clinical-biomarker response ranged from 47.5-66.7 percent across dose groups in the Phase 2 GALAXI 1 study

Other data presented demonstrate the long-term safety profile of STELARA® (ustekinumab) in bio-naïve and bio-failure patients living with inflammatory bowel disease

BEERSE, BELGIUM, 24 May, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data from the Phase 2 GALAXI 1 clinical trial of TREMFYA®▼ (guselkumab) in adult patients with moderately to severely

active Crohn's disease (CD), and from three separate long-term pooled analyses of adult patients with ulcerative colitis (UC) and CD treated with STELARA® (ustekinumab).[1,2,3,4] These data are being presented as oral and poster presentations and are among 29 Janssen abstracts presented during the Digestive Disease Week® (DDW) meeting taking place in person and virtually in San Diego, California on May 21-24, 2022.

The GALAXI 1 data showed study participants with an inadequate response or intolerance to conventional therapies and/or biologics treated with guselkumab achieved high levels of clinical-biomarker response[a] (47.5-66.7 percent), endoscopic response[b] (44.3-46 percent), and clinical remission[c] with C-reactive protein (CRP) ≤3 mg/L or faecal calprotectin ≤250 µg/g (39.3-66.7 percent) at 48 weeks across dose groups.[1] Guselkumab is not approved to treat adult patients with CD or UC in Europe.[5]

The ustekinumab pooled analyses of long-term safety data in bio-naïve and bio-failure CD/UC patients treated with ustekinumab demonstrated a favourable safety profile consistent with analyses in the overall inflammatory bowel disease (IBD) population and the established safety profile across approved indications.[2,3] In addition, a ustekinumab pooled safety analysis from 13 total studies across all approved indications (including data up to one year in psoriatic arthritis [PsA], two in UC, and five in CD and plaque psoriasis [Pso]), showed no increased incidence (adjusted for duration of follow up) of malignancy with ustekinumab treatment compared to placebo.[4]

"These new data from the GALAXI 1 study are encouraging as we continue to investigate long-term treatment solutions to address the unmet needs for our patients who live with the burden of moderately to severely active Crohn's disease," said GALAXI 1 presenting study author Remo Panaccione, M.D., Professor of Medicine and Director of the Inflammatory Bowel Disease Unit at the University of Calgary, Alberta, Canada.[d] "The clinical-biomarker response and endoscopic response data from the Phase 2 GALAXI 1 clinical trial build upon the study's clinical

remission outcomes and give us insight into the potential that guselkumab may provide sustained remission."

New GALAXI week 48 analyses (oral presentation #888) show:[1]

- **Clinical-biomarker response:[a]** The proportions of patients treated with guselkumab across dose groups[e] (n=185) who achieved clinical-biomarker response at week 48 ranged from 47.5-66.7 percent.[f,g]
- **Endoscopic response:[b]** The proportions of patients treated with guselkumab achieving endoscopic response ranged from 44.3-46 percent across dose groups[e] (n=185) at week 48.[f]
- **Clinical remission and achieving CRP or faecal calprotectin normalisation:[c]** The proportions of patients treated with guselkumab achieving clinical remission and CRP ≤3 mg/L or faecal calprotectin ≤250 µg/g ranged from 39.3-66.7 percent across dose groups (n=185).[e,f,h]
- **Safety:** Safety results were consistent with the known safety profile of guselkumab in approved indications.

Ustekinumab long-term pooled safety analyses showed:

- **Safety profile similar to placebo in bio-naïve patients:** In a pooled long-term safety analysis of four Phase 2/3 IBD studies, 771 bio-naïve patients[i] received ustekinumab with 1511 patient-years of follow up and 425 bio-naïve patients received placebo with 376 patient-years of follow up.[3] Event rates adjusted per 100 patient-years for adverse events (AEs), serious AEs, infections, serious infections, major adverse cardiac events (MACE), and malignancies were similar between ustekinumab and placebo through up to one year.[3] Rates per 100 patient-years (adjusted for duration of follow up) for AEs, serious AEs, infections, serious infections, and MACE were similar and/or numerically lower for ustekinumab versus placebo through up to five years in bio-naïve patients with CD and up to two years in bio-naïve patients with UC (Poster #Tu1440).[3]
- **Safety profile similar to placebo in bio-failure patients:** In a pooled long-term safety analysis of five Phase 2/3 IBD studies, 1596 bio-failure[j]

patients with 1970 patient-years of follow up received ustekinumab and 847 bio-failure patients with 473 patient-years of follow up received placebo.[2] Event rates per 100 patient-years (adjusted for duration of follow up) for AEs, serious AEs, infections, serious infections, MACE, and malignancies were similar between ustekinumab and placebo through up to five years in bio-failure patients with CD and up to two years in bio-failure patients with UC.[2] The safety profile of ustekinumab was consistent with the established safety profile in IBD and across approved indications (Poster #Tu1438).[2]

- **Malignancy risk comparable to placebo:** In an analysis of pooled long-term safety data from 13 studies across approved indications, including CD and UC, in 2501 placebo-treated patients with 1244 patient-years of follow up and 6710 ustekinumab-treated patients with 13807 patient-years of follow up, ustekinumab showed no increased incidence (adjusted for duration of follow up) of malignancy compared to placebo through up to five years of ustekinumab follow up.[4] Comparisons between the number of malignancies observed for patients treated with ustekinumab compared to expected malignancies based on the National Institutes of Health Surveillance, Epidemiology, and End Results database (SEER),[6,k] which does not include nonmelanoma skin cancer (NMSC) and cervical cancer in situ,[7] resulted in a standard incidence ratio (SIR)[l] of 0.85 (95 percent confidence intervals:[m] 0.65, 1.09) for ustekinumab across approved indications, suggesting no increased malignancy risk with ustekinumab treatment. (Oral presentation #14).[4]

"These data provide validation and underscore our commitment to continuing to innovate for patients with disease where considerable need remains," said Jan Wehkamp, M.D., Ph.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. "Drawing from a two-decade legacy of immunology innovation, we continue to generate new evidence for ustekinumab and are investing deeply in our pipeline to usher in a new era of treatment, leveraging the continued research of pathway science aiming to establish guselkumab as a

trusted therapeutic option for healthcare professionals and people who are living with inflammatory bowel disease."

Editor's Notes:

a. Clinical-biomarker response is defined as clinical response and ≥50 percent reduction from baseline in CRP or faecal calprotectin.[1]
b. Endoscopic response is defined as ≥50 percent improvement from baseline in Simple Endoscopic Score for Crohn's Disease (SES-CD) or SES-CD ≤2. SES-CD score at week 48 was based on all observed segments scored at week 48.[1] Subjects who had insufficient data to calculate the total SES-CD score at week 48 were considered not to be in endoscopic response.[1]
c. Clinical remission is defined as a Crohn's Disease Activity Index (CDAI) score of <150.[1]
d. Dr Panaccione is a paid consultant for Janssen. He has not been compensated for any media work.
e. The GALAXI 1 48-week analyses report the results of 248 patients randomised to guselkumab or ustekinumab: patients receiving guselkumab 200 mg intravenous (IV) were shifted to guselkumab 100 mg subcutaneous (SC) dose every eight weeks (q8w); patients receiving guselkumab at 600 or 1200 mg IV changed to guselkumab 200 mg SC every four weeks (q4w).[1] Please see the 'About GALAXI 1' section below for further details regarding dose and study design.
f. Patients who had a prohibited change in concomitant CD medication, a CD-related surgery, or discontinued study agent due to lack of efficacy, or an AE of worsening CD prior to the designated analysis timepoint were considered not to be in clinical remission, clinical response, clinical-biomarker response, endoscopic response, or clinical remission and CRP concentration ≤3 mg/L or faecal calprotectin concentration ≤250 µg/g from that timepoint onwards. Patients who had discontinued the study agent due to any other reasons prior to the designated analysis timepoint had their observed data used, if available, to determine responder and non-responder status from that timepoint onwards.[1]

g. Patients who had a missing CDAI score or who were missing both CRP and faecal calprotectin values at the designated analysis timepoint were considered not to be in clinical-biomarker response at that timepoint.[1]
h. Patients who had missing CDAI score or who were missing both CRP and faecal calprotectin values at the designated analysis timepoint were considered not to be in clinical remission and CRP concentration ≤3 mg/L or faecal calprotectin concentration ≤250 µg/g at that timepoint.[1]
i. All patients who received ≥1 dose of ustekinumab and were never treated with a biologic were included in the analysis.[3]
j. All patients who received ≥1 dose of ustekinumab and were identified as having a history of prior biologic failure were included in the analysis.[2]
k. The expected number of patients with malignancies is based on the SEER Database (year 2016), adjusted for age, gender, and race. Only patients with race belonging to White, Black or African American, Asian, American Indian/Alaska Native, Native Hawaiian, or other Pacific Islander were included since SEER only contains incidence rates for these populations.[7]
l. Standard incidence ratio is the observed number of patients with malignancy divided by the expected number of patients with malignancy.[8]
m. Confidence intervals are based on an exact method assuming that the observed number of events follows a Poisson distribution.[4]

About GALAXI 1 (NCT03466411; EudraCT 2017-002195-13)[9,10,11]

GALAXI 1 is a double-blind, placebo-controlled, active-reference arm, global, multicentre, treat-through, Phase 2 dose-ranging study evaluating the efficacy and safety of guselkumab in adult participants with moderately to severely active CD with inadequate response/intolerance to conventional therapies (corticosteroids, immunosuppressives) and/or biologics (tumour necrosis factor [TNF] antagonists, vedolizumab).

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 product, ustekinumab, dosed at ~6

mg/kg IV at week 0 and then dosed at 90 mg SC at week 8; or IV placebo. The study was not powered to evaluate differences between treatment groups after the primary endpoint at week 12.

The primary endpoint of the Phase 2 GALAXI 1 study is change from baseline in CDAI scores at week 12.[10] All three induction doses of guselkumab significantly improved CDAI scores from baseline as compared to placebo, with placebo-subtracted Least Squares Mean reductions 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, respectively.[11] 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 (abdominal pain mean daily score ≤1 and mean daily stool frequency score ≤3 and no worsening from baseline), clinical-biomarker response (clinical response and ≥50 percent reduction from baseline in CRP or faecal calprotectin), endoscopic response (≥50 percent improvement from baseline in the SES-CD or SES-CD≤2), and safety in participants treated with guselkumab compared with placebo.[11] Participants may receive treatment through five years.[9]

The 48-week analyses report the results of the 248 patients randomised to guselkumab or ustekinumab.[12] After completing 12 weeks of IV induction 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 q8w; patients receiving guselkumab dosed at 600 mg IV or 1200 mg IV changed to guselkumab 200 mg SC q4w; patients receiving ustekinumab continued with a 90 mg SC dose q8w; in addition to the 248 randomised patients, placebo non-responders began ustekinumab IV followed by ustekinumab SC q8w; and placebo responders continued on a placebo SC q4w.[12]

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) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW is an in-person and virtual meeting from May 21-24, 2022. The meeting showcases more than 5000 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 Crohn's Disease

CD is one of the two main forms of IBD, which affects up to two million people across Europe.[13] 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.[14] Symptoms of CD can vary, but often include abdominal pain and tenderness, frequent diarrhoea, rectal bleeding, weight loss and fever.[15] There is currently no cure for CD.[16]

About Ulcerative Colitis

UC affects up to 2.6 million people in Europe.[13] It is a chronic disease of the large intestine, also known as the colon, in which the lining of the colon becomes inflamed and develops tiny open sores or ulcers, that produce pus and mucus.[17] UC is the result of an abnormal response by the body's immune system.[17] Symptoms vary, but may include loose and more urgent bowel movements, persistent diarrhoea, abdominal pain, bloody stool, loss of appetite, weight loss and fatigue.[18]

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.[5,19] Guselkumab is approved in the EU for the treatment of moderate to severe plaque Pso in adults who are candidates for systemic therapy, and alone or in combination with methotrexate (MTX) 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 antirheumatic drug therapy.[5]

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.[20,21,22]

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).[5]

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▼. This medicinal product is subject to additional monitoring and it is, therefore, important to report any suspected AEs 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)

Ustekinumab is a fully human monoclonal antibody and is the first biologic treatment to selectively inhibit the IL-12 and IL-23 pathways.[23,24] 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.[23] Ustekinumab is also approved for the treatment of adults with moderately to severely active 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.[23] In addition to CD and UC, ustekinumab has been approved for the treatment of two further immune-mediated conditions in the EU: Pso and PsA.[23]

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USTEKINUMAB IMPORTANT SAFETY INFORMATION

The most common adverse events (AEs) (>5%) in controlled periods of clinical studies with ustekinumab were nasopharyngitis and headache.[23] Most were considered to be mild and did not necessitate discontinuation of study treatment.[23] The most serious adverse reaction that has been reported for ustekinumab is serious hypersensitivity reactions, including anaphylaxis.[23] The overall safety profile is similar for adult patients with CD, UC, Pso, and PsA.[23]

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.

Adverse drug reactions (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 & Retina; 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® 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) and STELARA® (ustekinumab) 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 materialize, 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 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 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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