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News Release

Media Contact:
Kevin Veninga
Mobile: +31 6 1526 8214
Email: kveninga@its.jnj.com

Investor Contact:
Raychel Kruper
Office: +1 (732) 524-6164

TREMFYA®▼ (guselkumab) Demonstrates Higher Rates of Complete Skin Clearance with Earlier Treatment in Adults with Moderate to Severe Plaque Psoriasis in Phase 3b GUIDE Study

GUIDE week 28 data demonstrate psoriasis patients treated with guselkumab ≤2 years after disease onset (versus >2 years) are more likely to achieve super-responder[a] status (complete skin clearance[b] at week 20 through week 28)

Late-breaking week 68 data suggest these super responders could maintain long-term disease control (low disease activity) with an extended dose interval

Beerse, Belgium, 8 September 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data for TREMFYA®▼(guselkumab) from the ongoing Phase 3b GUIDE study, which is designed to understand the impact of early intervention and potential dosing interval flexibility on the long-term disease course in adult patients with moderate to severe plaque psoriasis (Pso). These new data demonstrated that "super responders"[a] to guselkumab who received every-16-

week dosing[b] maintained disease control (absolute Psoriasis Area and Severity Index [PASI] score <3) at a rate that was non-inferior to the approved every-eight-week dosing interval (92.6 percent vs 91.9 percent, P=0.001), meeting the study's week 68 primary endpoint.[1] 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]

Data from the GUIDE, VOYAGE 1 and VOYAGE 2 studies, among others, comprise the 38 abstracts that are being presented by Janssen at the European Academy of Dermatology and Venereology (EADV) 31st Congress taking place virtually and in-person in Milan September 7-10, 2022.

"Currently, patients with psoriasis can face a long and complicated treatment journey as they try and find the regimen that works best for them and their lives," Kilian Eyerich, M.D., Professor and Medical Director, Department of Dermatology, Medical Center – University of Freiburg in Breisgau, Germany.[e] "These new results suggest patients who receive treatment soon after disease onset may see higher rates of psoriasis clearance and in the future we hope that dosing-interval flexibility could be a consideration that would allow this patient population to have a therapy strategy tailored to them. As we continue to analyse and understand the data from GUIDE, we hope to understand clinical outcomes from different patients with varying underlying immunological changes that may help inform individualised guselkumab therapeutic strategies in the future."

These data build on previous analyses showing that adults living with moderate to severe plaque Pso who initiate treatment with guselkumab less than or equal to two years (versus more than two years) from onset of signs and symptoms are more likely to achieve super-responder status (odds ratio [OR]=1.58; 95 percent confidence interval [CI]: 1.16-2.14) after controlling for differences in baseline characteristics.[3] Additionally, the use of prior biologics (OR=0.47; 95 percent CI: 0.28-0.78), each year of age (OR=0.98; 95 percent CI: 0.97-0.99) and each kg/m^2 increase in BMI (OR=0.95; 95 percent CI: 0.93-0.98) decreased the odds of being a

super responder.[3] Super responders are defined as GUIDE trial participants who received on-label guselkumab treatment until week 20 and responded with PASI =0[d] at both weeks 20 and 28.[1]

"Psoriasis can cause difficult and painful symptoms for patients and present in varied manifestations," said Lloyd Miller, M.D., Ph.D., Vice President, Immunodermatology Disease Area Stronghold, Janssen Research & Development, LLC. "We are dedicated to investigating and understanding the pathways of disease to help develop effective therapies and optimize our existing therapies to mitigate patient burdens by improving symptoms and the outcomes associated with the underlying disease."

New analyses from the five-year VOYAGE 1 and VOYAGE 2 trial data show:

- The high levels of health-related quality of life (HRQoL), defined as Dermatology Life Quality Index (DLQI) score of 0 or 1,[f] achieved in patients with complete or almost complete skin clearance[c] are sustained at a consistent level (range of 87.1-95.5 percent for those patients achieving PASI 100) measured approximately every 24 weeks from week 100 through week 252 of treatment with guselkumab.[4]
- Clear skin responses were consistently maintained through five years in guselkumab-treated patients with baseline scalp or nail Pso, regardless of the severity of scalp or nail Pso at baseline.[5]
- In a post hoc analysis of pooled data, the majority of guselkumab-treated patients with moderate to severe Pso achieved either >90 percent improvement in PASI (>77.8 percent across head, trunk, upper extremities, lower extremities) or 100 percent improvement in PASI (>70.2 percent across head, trunk, upper extremities, lower extremities). These data were durable and remained consistent through week 252.[6]

Editor's Notes:

a. Super responders are defined as GUIDE trial participants who receive on-label guselkumab treatment until week 20 and respond with a Psoriasis Area and Severity Index (PASI) score of 0[d] at both weeks 20 and 28.[1]

b. Guselkumab q16w dosing is not an approved dosing regimen in EMEA. Guselkumab is administered as a 100 mg subcutaneous injection once every 8 weeks, after starter doses at weeks 0 and 4.[2]
c. Complete skin clearance is defined as an absolute Psoriasis Area and Severity Index (PASI)[d] score of 0.[1]
d. The Psoriasis Area and Severity Index (PASI) score grades the amount of surface area covered by Pso plaques in each body region, and the degree of plaque redness, thickness, and scaliness.[7]
e. Prof. Dr. Eyerich is a paid consultant for Janssen. He has not been compensated for any media work.
f. Dermatology Life Quality Index (DLQI) is a self-administered questionnaire for patients to score the impact of psoriasis on their quality of life. The higher the score, the more quality of life is affected. Scores may range from 0-1, indicating no effect on a patient's life, to 21-30, indicating extremely high effect on patient's life.[8]

About GUIDE (NCT03818035 EudraCT 2018-001238-16)[9,10]

GUIDE is a Phase 3b, multicentre, randomised, double-blind study to evaluate further therapeutic strategies for guselkumab. A total of 880 patients with moderate to severe plaque Pso were enrolled. The study aimed to determine whether super responders (SRs) receiving guselkumab treatment maintained control of disease until week 68 with a prolonged treatment interval of guselkumab 100 mg every 16 weeks. The primary endpoint is the proportion of SRs maintaining an absolute PASI <3 at week 68. In part one of GUIDE, patients who received guselkumab treatment until week 20 and maintained PASI 0 from weeks 20 through 28 were classified as SRs. In part two, SRs were randomly assigned at week 28 to continue guselkumab every 8 or 16 weeks until the primary endpoint was assessed. In part three, patients who meet this endpoint stopped treatment and will be followed through week 220; patients will be re-treated if their PASI score worsens to greater than 5.

Guselkumab treatment was well tolerated and no new safety signals were identified. In part one of the study, nasopharyngitis was the most common Treatment Emergent

Adverse Event (TEAE) experienced by patients (24.3 percent, 214/880). Nasopharyngitis was also the most reported Adverse Event across study groups in part two. In the SR group, of those who received 8-week dosing, 17.6 percent (26/148) reported nasopharyngitis, compared to 15.4 percent (23/149) who received 16-week dosing. Amongst the non-SR group, 18.5 percent (97/525) reported nasopharyngitis with 8-week dosing.[1]

About VOYAGE 1 (NCT02207231 EudraCT 2014-000719-15)[11,12]

This Phase 3, randomised, double-blind, placebo and active comparator-controlled trial with 837 patients was designed to evaluate the efficacy and safety of guselkumab compared with placebo and adalimumab in adults with moderate to severe plaque Pso. Patients were randomised to receive subcutaneous (SC) injections of guselkumab 100 mg at weeks 0, 4 and 12, followed by every eight week (q8w) dosing; placebo at weeks 0, 4 and 12, followed by crossover to guselkumab 100 mg q8w at week 16; or adalimumab 80 mg (n= 334) at week 0, followed by 40 mg at week 1, then dosing every two weeks (q2w) through week 47, with crossover to guselkumab q8w at week 52.[13]

The co-primary endpoints of the study were the proportions of patients receiving guselkumab versus patients receiving placebo achieving Investigator's Global Assessment (IGA) 0/1 (clear/almost clear skin) (85 percent vs 3 percent [P<0.001 vs placebo]) and PASI 90 (73 percent vs 7 percent [P<0.001 vs placebo]) at week 16.[13] Secondary endpoints were assessed at weeks 16, 24, and 48, with safety monitoring throughout the study. Through week 48, non-responder imputation (NRI) rules were used for missing data (after the application of treatment failure rules [TFR]).

During the open-label extension period, which started at week 52, all patients continued open-label treatment with guselkumab through week 252. Efficacy assessments included proportions of patients achieving PASI 90, PASI 100, IGA 0/1, and IGA 0 (clear skin). Efficacy was analysed using prespecified TFR for the primary

analysis, while NRI and as observed (OBS) methodology were also used for secondary analyses.

About VOYAGE 2 (NCT02207244 EudraCT 2014-000720-18)[14,15]

This Phase 3, randomised, double-blind, placebo and active comparator-controlled trial was designed to evaluate the efficacy and safety of guselkumab compared with placebo and adalimumab in adults with moderate to severe plaque Pso. Patients (N=992) were randomised to receive SC injections of guselkumab 100 mg (n=496) at weeks 0, 4 and q8w thereafter; placebo (n=248) at weeks 0, 4, and 12 followed by crossover to guselkumab 100 mg at week 16; or adalimumab 80 mg (n=248) at week 0, 40 mg at week 1, then 40 mg q2w until week 23.[16] Weeks 28-72 incorporated a randomised withdrawal study design. During the open-label period (weeks 76-252), all patients received guselkumab 100 mg q8w. Physician- and patient-reported outcomes were assessed. Efficacy was analysed using pre-specified treatment failure rules (patients discontinuing due to lack of efficacy, worsening of Pso, or use of a prohibited treatment were considered non-responders). Data were combined for patients randomised to guselkumab and for those originally randomised to placebo who later crossed over to guselkumab at week 16. Patients were treated and followed for up to 264 weeks.

Co-primary endpoints of the study were proportions of patients receiving guselkumab versus placebo achieving IGA 0/1 (clear/almost clear) (84 vs 9 percent, respectively [P<0.001 vs placebo]) and PASI 90 (70 vs 2 percent, respectively [P<0.001 versus placebo]) at week 16.[16] Additional efficacy assessments included proportions of patients achieving PASI 75, and PASI 100 responses, as well as IGA score of 0, Dermatology Life Quality Index (DLQI) score of 0/1, Psoriasis Signs and Symptoms Diary (PSSD) score of 0, SF-36, the Hospital Anxiety and Depression Scale (HADs), and the Work Limitations Questionnaire (WLQ). Efficacy was analysed using pre-specified treatment failure rules, non-responder imputation, and as observed methodology.

About Plaque Psoriasis (Pso)

Plaque Pso is an immune-mediated disease resulting in overproduction of skin cells, which causes inflamed, scaly plaques that may be itchy or painful.[17] It is estimated that more than 125 million people worldwide live with the disease.[18] Nearly one-quarter of all people with plaque Pso have cases that are considered moderate to severe.[18] Living with plaque Pso can be a challenge and impact life beyond a person's physical health, including emotional health, relationships, and handling the stressors of life.[19]

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 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.[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 systemic therapy (injections or pills) or phototherapy (treatment using ultraviolet light), and for the treatment of adult patients with active PsA.[20,22] Guselkumab is being investigated in Phase 3 clinical trials in both adults with moderately to severely active Crohn's disease (EudraCT 2017-002195-13) and adults with moderately to severely active ulcerative colitis (EudraCT 2018-004002-25).[23,24]

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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 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 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 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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