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News Release

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New TREMFYA® (guselkumab) Post-Hoc Analysis Reveals Active Psoriatic Arthritis Patients with Early Efficacy Had Meaningful Long-Term Improvement in Health-Related Quality of Life

Post-hoc analysis of DISCOVER-2 Phase 3 data suggests active psoriatic arthritis patients with week 8 response to guselkumab showed greater improvements in health-related quality of life at week 100, compared to patients without early response

Additional post-hoc analyses show treatment with guselkumab demonstrated improvements of fatigue (FACIT-F scale) at week 8, demonstrating clinically meaningful and durable long-term improvements, with nearly a third maintaining normative levels through week 100

BEERSE, BELGIUM, November 10, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced a new post-hoc analysis of the Phase 3 DISCOVER-2 study that shows early (week 8) clinical improvements[a] of most measures (joint and skin disease, enthesitis and dactylitis) in adult patients with active psoriatic arthritis (PsA) treated with TREMFYA® (guselkumab) were associated with improvements in health-related quality of life (HRQoL) (measured by EQ-5D)[b] from year one (week 52) through year two (week 100).[1] Rates of adverse events (AEs) were comparable among treatment groups.[1] Guselkumab is the first fully human selective interleukin (IL)-23 inhibitor therapy approved in the EU for adults with active PsA and adults with moderate to severe plaque psoriasis (Pso).[2]

People with active PsA can experience both physical and mental health challenges that can interfere with their daily lives and impact their work and relationships.[3] Additionally, some patients experience fatigue – a burdensome symptom that often can be underestimated and underreported.[3]

In a separate post-hoc analysis of DISCOVER-2, clinically meaningful improvements in fatigue (measured by Functional Assessment of Chronic Illness Therapy – Fatigue [FACIT-F])[c] observed at one year in guselkumab-treated patients were enhanced through two years, resulting in greater proportions of patients achieving normative FACIT-F levels.[4]

"Patients with active psoriatic arthritis may struggle engaging in everyday tasks as a result of health-related quality of life symptoms often associated with the disease," said Philip J. Mease[d], M.D., Swedish Medical Center/Providence St. Joseph Health and University of Washington in Seattle, Washington. "In these analyses, we see that achieving early clinical strides in distinct symptom domains may demonstrate future gains in health-related quality of life and fatigue improvement, which underscores the important role this therapy plays in the management of the multiple and complex symptoms of active psoriatic arthritis."

These new analyses of DISCOVER-2 data presented at the 2022 American College of Rheumatology (ACR) Convergence meeting, taking place in Philadelphia, PA and virtually, November 10-14, 2022, show:

Improvements in Health-Related Quality of Life Through Two Years

In DISCOVER-2 biologic-naïve patients with active PsA who were randomised to guselkumab:[1]

- Early (week 8) response in distinct active PsA domains differentially impacted specific components of HRQoL (e.g. EQ-5D, SF-36, DLQI)[b,e] over two years.
- Statistically significant improvements in overall and physical HRQoL were observed among early clinical responders across several active PsA domains including joint and skin disease, enthesitis, and dactylitis.
- Despite differences in HRQoL observed among early clinical responders and non-early responders, non-early responders also saw benefit in long-term HRQoL with guselkumab.

Clinically Meaningful Improvements in Fatigue Through Two Years

In DISCOVER-2 patients with active PsA and elevated measures of fatigue:[4]

- Guselkumab provided statistically significant benefit over placebo for reducing fatigue as early as week 8 (nominal P-values).
- FACIT-F scores continued to improve between week 24 and week 52 in guselkumab-treated patient groups.
- The clinically meaningful improvements in fatigue seen at week 52 in guselkumab-treated patients were further enhanced through week 100, resulting in greater proportions of patients achieving normative FACIT-F levels.
- Improvement of ≥2 points in FACIT-F by week 8 predicted clinically meaningful improvement of ≥4 points at week 100.
- Early targets in FACIT-F levels achieved at 8 weeks of guselkumab treatment were identified as a potential predictor of later response.

"The burden of active psoriatic arthritis on a patient's quality of life makes the task of effectively managing the debilitating symptoms of this disease all the more urgent

and challenging," said Terence Rooney, M.D., Vice President, Rheumatology and Maternal-Fetal Immunology Disease Area Leader, Janssen Research & Development, LLC. "These analyses from DISCOVER-2 provide patients and physicians with critical insights as they consider the most appropriate treatment option to manage physical symptoms and help improve overall well-being."

Editor's Notes:

a. Early (week 8) clinical improvement was defined as any of the following:
    - ≥20% improvement in swollen joint count (SJC), tender joint count (TJC), patient pain visual analogue scale (VAS), patient skin VAS, Health Assessment Questionnaire-Disability Index (HAQ-DI)[1]
    - ≥4-point improvement in FACIT-F measure[1]
    - Minimal clinically important improvement in clinical Disease Activity in PsA (cDAPSA, ≥5.7) composite score[1]
    - Change (reduction) in the Leeds enthesitis index (LEI) or dactylitis severity score (DSS)[1]
b. EQ-5D is a preference-based HRQoL measure with one question for each of the five dimensions that include mobility, self-care, usual activities, pain/discomfort and anxiety/depression.[5]
c. FACIT-F Scale: measured on a 4-point Likert scale (4 = not at all fatigued to 0 = very much fatigued).[6]
d. Dr Mease is a paid consultant for Janssen. He has not been compensated for any media work.
e. Dermatology Life Quality Index (DLQI) is a self-administered questionnaire for patients to score the impact of Pso 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 of Pso on a patient's life, to 21-30, indicating many aspects of their life are severely affected by Pso.[7]
f. The PASI score grades the combination of the amount of surface area covered by Pso plaques in each body region, and the degree of plaque redness, thickness, and scaliness to assess the extent and severity of Pso.[8]

About DISCOVER-2 (NCT03158285; EudraCT 2016-001224-63)[9,10]

DISCOVER-2 is a randomized, double-blind, multicenter Phase 3 study evaluating the efficacy and safety of guselkumab administered by SC injection in biologic-naïve patients with active PsA. DISCOVER-2 evaluated 739 participants who were treated and followed through approximately two years. The study consisted of a screening phase of up to six weeks, a blinded treatment phase of approximately 100 weeks that included a placebo-controlled period from week 0 to week 24 and a blinded active treatment period from week 24 to week 100.[11] It also included a safety follow-up phase through week 112 (i.e., approximately 12 weeks after the last administration of study agent at week 100). Clinical efficacy, radiographic efficacy, health economics, safety, pharmacokinetics, immunogenicity, biomarker, and pharmacogenomics evaluations were performed in the study on a defined schedule.[11]

About Psoriatic Arthritis (PsA)

PsA is a chronic, immune-mediated inflammatory disease characterized by peripheral joint inflammation, enthesitis (pain where the bone, tendon and ligament meet), dactylitis (a type of inflammation in the fingers and toes that can result in a swollen, sausage-like appearance), axial disease, and the skin lesions associated with plaque Pso.[12-14] The disease causes pain, stiffness and swelling in and around the joints; it commonly appears between the ages of 30 and 50, but can develop at any age.[15] Nearly half of patients with PsA experience moderate fatigue and about 30 percent suffer from severe fatigue as measured by the modified fatigue severity scale.[16] In patients with PsA, comorbidities, such as obesity, cardiovascular diseases, anxiety and depression are often present.[17] Studies show up to 30 percent of people with plaque Pso also develop PsA.[15] Although the exact cause of PsA is unknown, genes, the immune system and environmental factors are all believed to play a role in disease onset.[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.[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 injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light), and for the treatment of adult patients with active PsA.[2,19-21]

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 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.

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Janssen Research & Development, LLC; Janssen Biotech, Inc.; and Janssen Scientific Affairs, LLC are 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 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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References

1. McInnes I, *et al.* Early Clinical Improvement as Predictor of Long-term Health-Related Quality of Life in Psoriatic Arthritis Patients Treated with Guselkumab: Post Hoc Analysis Through 2 Years of a Phase 3 Study. Presented at ACR Convergence 2022, Nov. 10-14.
2. European Medicines Agency. TREMFYA Summary of Product Characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/tremfya-epar-product-information_en.pdf. Accessed November 2022.
3. Creaky Joints. Psoriatic Arthritis and Mental Health: The Link to Depression, Anxiety, Fatigue, and More. Available at: https://creakyjoints.org/about-arthritis/psoriatic-arthritis/psa-treatment/psoriatic-arthritis-mental-health/. Accessed November 2022.
4. Gladman D, *et al.* Long-term Efficacy of Guselkumab in Fatigue and Identification of Early Treatment Targets: Post Hoc Analysis Through 2 Years of a Phase 3, Randomized, Double-blind, Placebo-controlled Study Conducted in Biologic-naïve Patients with Active Psoriatic Arthritis. Presented at ACR Convergence 2022, Nov. 10-14.
5. EuroQol Research Foundation. EQ-5D-5L User Guide 2021. September 2019. Available at: https://euroqol.org/wp-content/uploads/2021/01/EQ-5D-5LUserguide-08-0421.pdf. Accessed November 2022.
6. Acaster S, *et al.* Qualitative and quantitative validation of the FACIT-fatigue scale in iron deficiency anemia. *Health Qual Life Outcomes*. 2015;13:60.
7. Finlay AY and Khan GK. Dermatology Life Quality Index (DLQI)-a simple practical measure for routine clinical use. *Clin Exp Dermatol.* 1994;19(3):210-216.
8. Feldman SR and Krueger GG. Psoriasis assessment tools in clinical trials. *Ann Rheum Dis.* 2005;64(Suppl II):ii65-ii68.
9. ClinicalTrials.gov. A Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Participants With Active Psoriatic Arthritis. Identifier: NCT03158285. Available at: https://clinicaltrials.gov/ct2/show/NCT03158285. Accessed November 2022.
10. EUClinicalTrialsRegister.eu. A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Subjects with Active Psoriatic Arthritis. Available at:

https://www.clinicaltrialsregister.eu/ctr-search/trial/2016-001224-63/ES. Accessed November 2022
11. Mease P, *et al.* Guselkumab in biologic-naive patients with active psoriatic arthritis (DISCOVER-2): a double-blind, randomised, placebo-controlled phase 3 trial. *The Lancet*. 2020;395(10230):1126–1136.
12. Belasco J and Wei N. Psoriatic Arthritis: What is Happening at the Joint? *Rheumatol Ther*. 2019;*6*(3):305–315.
13. Donvito T. CreakyJoints: What Is Enthesitis? The Painful Arthritis Symptom You Should Know About. Available at: https://creakyjoints.org/symptoms/what-is-enthesitis/. Accessed November 2022.
14. Donvito T. CreakyJoints: What Is Dactylitis? The 'Sausage Finger' Swelling You Should Know About. Available at: https://creakyjoints.org/symptoms/what-is-dactylitis/. Accessed November 2022.
15. National Psoriasis Foundation. About Psoriatic Arthritis. Available at: https://www.psoriasis.org/about-psoriatic-arthritis/. Accessed November 2022.
16. Husted JA, *et al*. Occurrence and correlates of fatigue in psoriatic arthritis. *Ann Rheum Dis.* 2008;68(10):1553–1558.
17. Haddad A and Zisman D. Comorbidities in Patients with Psoriatic Arthritis. *Rambam Maimonides Med J.* 2017;8(1):e0004.
18. Cassell S and Kavanaugh A. Psoriatic arthritis: Pathogenesis and novel immunomodulatory approaches to treatment. *J Immune Based Therap Vaccines*. 2005;3:6.
19. US Food and Drug Administration. TREMFYA Prescribing Information. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761061s007lbl.pdf. Accessed November 2022.
20. The Canadian Agency for Drugs & Technologies in Health. TREMFYA Prescribing Information. Available at: https://pdf.hres.ca/dpd_pm/00042101.PDF. Accessed November 2022.
21. Japan Pharmaceuticals and Medical Devices Agency. Tremfya Report on the Deliberation Results. Available at: https://www.pmda.go.jp/files/000234741.pdf. Accessed November 2022.