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News Release

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TREMFYA® (guselkumab) Real-World Data Analyses Were Associated With Greater Treatment Persistence Than IL-17s in Both Bio-naïve and Bio-experienced Patients Living With Moderate to Severe Plaque Psoriasis

Additional post-hoc analysis of guselkumab showed improvements in scalp psoriasis and quality-of-life measures at week 48

BEERSE, BELGIUM, 17 March 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data, showing that initiation of TREMFYA® (guselkumab) was associated with greater treatment persistence[a] compared to secukinumab or ixekizumab in bio-naïve and bio-experienced patients[b] living with moderate to severe plaque psoriasis (Pso), based on pairwise analyses[c] of real-world data.[1,2,3] Additionally, in a post-hoc analysis of Phase 3 VOYAGE 2 clinical trial results, guselkumab demonstrated durable clinical efficacy, itch relief and quality-of-life improvements in patients living with scalp Pso.[4] Guselkumab is the first and only fully human selective interleukin (IL)-23 inhibitor therapy approved in the EU for adults with moderate to severe plaque Pso.[3] These study results are among 14

company-sponsored abstracts being presented by Janssen at the 2023 American Academy of Dermatology (AAD) Annual Meeting, taking place 17-21 March.

Analysis of real-world data from the IBM MarketScan Research Databases from 13 July 2017 to 1 May 2021 showed guselkumab was associated with greater persistence (i.e., longer median time to index treatment discontinuation) compared to secukinumab and ixekizumab among bio-naïve patients:[1]

- The guselkumab cohort showed 2.20 times (at 12 months) and 2.28 times (at 18 months) longer persistence versus the secukinumab cohort, and 1.84 times (at 12 months) and 1.86 times (at 18 months) longer persistence versus the ixekizumab cohort.[1]
- 2,202 and 2,772 patients were identified for pairwise analysis of the guselkumab versus secukinumab cohorts, and 2,241 and 2,007 patients for pairwise analysis of the guselkumab versus ixekizumab cohorts, respectively.[1]

Analysis of real-world data from the IBM MarketScan Research Databases from 13 July 2017 to 1 May 2021 showed guselkumab was associated with greater persistence compared to secukinumab and ixekizumab among bio-experienced patients:[2]

- The guselkumab cohort showed 2.00 times (at 12 months) and 2.04 times (at 18 months) longer persistence versus the secukinumab cohort, and 1.76 times (at 12 months) and 1.67 times (at 18 months) longer persistence versus the ixekizumab cohort.[2]
- 1,314 and 3,294 patients were identified for pairwise analysis of the guselkumab and secukinumab cohorts, and 1,564 and 2,667 patients for pairwise analysis of the guselkumab and ixekizumab cohorts, respectively.[2]

"These persistency real-world results potentially indicate that guselkumab is associated with better long-term control of the symptoms associated with Pso compared with secukinumab and ixekizumab, irrespective of whether patients were bio-naïve or bio-experienced," said Steven Feldman, M.D., Ph.D., dermatologist at

the Wake Forest University School of Medicine.[d] "Increasing our understanding of real-world data can improve clinical practice, leading to benefits for our patients. These critical insights help us make better treatment decisions for, and with, our patients living with Pso."

In a post-hoc analysis[e] of the Phase 3 VOYAGE 2 clinical trial, which compared guselkumab with placebo and with adalimumab in patients with moderate to severe plaque Pso, guselkumab demonstrated durable clinical efficacy, changes in mean Psoriasis Symptoms and Signs Diary (PSSD) itch scores[f] and quality-of-life improvements in adult patients with scalp Pso:[4]

- Among guselkumab responders (patients achieving at least 90 percent improvement from baseline in Psoriasis Area and Severity Index [PASI 90] score)[4,g] remaining on treatment, mean scalp-specific Investigator Global Assessment (ss-IGA)[h] score rapidly improved from 2.9 at week 0 to 0.2 at week 24, and 0.3 at week 48.[4]
- Changes in mean PSSD itch scores and Dermatology Life Quality Index scores paralleled changes in mean ss-IGA scores for all cohorts.[4]

"These new data underscore Janssen's commitment to provide efficacious and long-lasting treatments for people living with Pso, which may also proactively contribute to their overall well-being," said Lloyd Miller, M.D., Ph.D., Vice President, Immunodermatology Disease Area Stronghold, Janssen Research & Development, LLC. "Up to 80 percent of people living with Pso have scalp involvement, and it significantly impacts quality of life.[5] These results continue to show the important role guselkumab plays in the management of moderate to severe plaque Pso, including difficult-to-treat areas such as the scalp."

Editor's Notes:

a. Persistence was defined based on gaps between days of treatment supply over twice the labelled dosing interval: >120 days for guselkumab or >60 days for secukinumab/ixekizumab.[1,2]

b. Adults with moderate to severe plaque Pso initiated (index date) on guselkumab, secukinumab, or ixekizumab between 13 July 2017 and 1 May 2021 were identified in the IBM MarketScan Research Databases. Bio-naïve patients had no claims for biologics 12 months pre-index date.[1] Bio-experienced patients had ≥1 claim for a biologic other than guselkumab, secukinumab, and ixekizumab 12 months pre-index date.[2]
c. These analyses compared real-world persistence between pairs of patients from each cohort. Cohorts were balanced for potential confounders using entropy balancing, and persistence was compared using Cox proportional hazard models (guselkumab versus secukinumab, guselkumab versus ixekizumab).[1,2] Results may not be generalised to the uninsured or patients with non-commercial insurance. Prescription fills do not guarantee the medication was taken as prescribed. Results may be subject to residual confounding.[1,2]
d. Dr. Steven Feldman is a paid consultant for Janssen. He has not been compensated for any media work.
e. This post-hoc analysis explored scalp responses as measured by ss-IGA during guselkumab treatment and withdrawal in patients with scalp involvement (as indicated at screening) who were randomised to guselkumab 100 mg at week 0 and week 4, then every 8 weeks. At week 28, PASI 90 responders were re-randomised to continue (n=159) or discontinue (n=164) guselkumab; non-responders continued guselkumab (n=84).[4]
f. The PSSD is a validated patient-reported outcome tool used to assess symptoms and signs of moderate to severe plaque Pso.[6] PSSD itch scores were not scalp-specific.
g. The PASI score grades the amount of surface area on each body region that is covered by Pso plaques and the severity of plaques for their redness, thickness, and scaliness.[7]
h. ss-IGA assesses scalp Pso lesions for degree of redness, thickness, and scaling on a 5-point scale, with 0 indicating absence of disease and 4 indicating severe disease.[8]

About VOYAGE 2 (NCT02207244; EudraCT 2014-000720-18)[9,10]

This Phase 3, randomised, double-blind, placebo and active comparator-controlled clinical trial was designed to evaluate the efficacy and safety of guselkumab compared with placebo and adalimumab in adults with moderate to severe plaque Pso.[9] Patients (N=992) were randomised to receive subcutaneous injections of guselkumab 100 mg (n=496) at weeks 0, 4, and every 8 weeks (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 every 2 weeks (q2w) until week 23.[11] Weeks 28-72 incorporated a randomised withdrawal study design.[11] During the open-label period (weeks 76-252), all patients received guselkumab 100 mg q8w.[9] Physician- and patient-reported outcomes were assessed.[11] 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).[11] Data were combined for patients randomised to guselkumab and for those originally randomised to placebo who later crossed over to guselkumab at week 16.[11] Patients were treated and followed for up to 264 weeks.[9]

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.[11] 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 score of 0/1, PSSD score of 0, SF-36, the Hospital Anxiety and Depression Scale, and the Work Limitations Questionnaire.[11] Efficacy was analysed using pre-specified treatment failure rules, non-responder imputation, and as observed methodology.[11]

About Plaque Psoriasis (Pso)

Plaque Pso is an immune-mediated disease resulting in an overproduction of skin cells, which causes inflamed, scaly plaques that may be itchy or painful.[12] It is estimated that more than 125 million people worldwide live with the

disease.[13] Nearly one-quarter of all people with plaque Pso have cases that are considered moderate to severe.[13] 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.[14]

About TREMFYA® (guselkumab)

Developed by Janssen, guselkumab is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor.[3,15] IL-23 is an important driver of the pathogenesis of inflammatory diseases such as moderate to severe plaque Pso and active psoriatic arthritis (PsA).[3] 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 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.[3] 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 are candidates for injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light), and for the treatment of adult patients with active PsA.[15,16,17] Guselkumab is being investigated in Phase 2/3 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).[18,19]

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).[3]

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) 1494567447.

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 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 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 or 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 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. 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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