News Release

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TREMFYA® (guselkumab) Real-World Data Analyses Show 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 TREMFYA showed improvements in scalp psoriasis and quality-of-life measures at week 48

SPRING HOUSE, PENNSYLVANIA, March 17, 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] Additionally, in a post-hoc analysis of Phase 3 VOYAGE 2 clinical trial results, TREMFYA demonstrated durable clinical efficacy, itch relief and quality-of-life improvements in patients living with scalp PsO.[3] TREMFYA is the first and only fully human selective interleukin (IL)-23 inhibitor therapy approved in the U.S. for adults with moderate to severe plaque PsO.[4] These study results are among 14 company-sponsored abstracts being

presented by Janssen at the 2023 American Academy of Dermatology (AAD) Annual Meeting in New Orleans, LA.

Analysis of real-world data from the IBM MarketScan Research Databases from July 13, 2017, to May 1, 2021, showed TREMFYA 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 TREMFYA 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 TREMFYA versus secukinumab cohorts, and 2,241 and 2,007 patients for pairwise analysis of the TREMFYA versus ixekizumab cohorts, respectively.[1]

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

- The TREMFYA 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 TREMFYA and secukinumab cohorts, and 1,564 and 2,667 patients for pairwise analysis of the TREMFYA and ixekizumab cohorts, respectively.[2]

"These persistency real-world results potentially indicate that TREMFYA 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 TREMFYA with placebo and with adalimumab in patients with moderate to severe plaque PsO, TREMFYA 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:[3]

- Among TREMFYA responders (patients achieving at least 90 percent improvement from baseline in Psoriasis Area and Severity Index [PASI 90] score)[3,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.[3]
- Changes in mean PSSD itch scores and Dermatology Life Quality Index scores paralleled changes in mean ss-IGA scores for all cohorts.[3]

"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 TREMFYA 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 TREMFYA or >60 days for secukinumab/ixekizumab.[1,2]
b. Adults with moderate to severe plaque PsO initiated (index date) on TREMFYA, secukinumab, or ixekizumab between July 13, 2017, and May 1,

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 TREMFYA, 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 (TREMFYA versus secukinumab, TREMFYA versus ixekizumab).[1,2] Results may not be generalized 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 TREMFYA treatment and withdrawal in patients with scalp involvement (as indicated at screening) who were randomized to TREMFYA 100 mg at week 0 and week 4, then every 8 weeks. At week 28, PASI 90 responders were re-randomized to continue (n=159) or discontinue (n=164) TREMFYA; non-responders continued TREMFYA (n=84).[3]
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.[3]
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, randomized, double-blind, placebo- and active comparator-controlled

clinical trial was designed to evaluate the efficacy and safety of TREMFYA compared with placebo and adalimumab in adults with moderate to severe plaque PsO.[9] Patients (N=992) were randomized to receive subcutaneous injections of TREMFYA 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 TREMFYA 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 randomized withdrawal study design.[11] During the open-label period (weeks 76-252), all patients received TREMFYA 100 mg q8w.[9] Physician- and patient-reported outcomes were assessed.[11] Efficacy was analyzed using prespecified 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 randomized to TREMFYA and for those originally randomized to placebo who later crossed over to TREMFYA 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 TREMFYA 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 analyzed 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 eight million Americans and 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