News Release

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New TREMFYA® (guselkumab) Post-Hoc Analysis Reveals Early Efficacy Predicted Longer-Term Efficacy And Sustained Achievement Among A Diverse Active Psoriatic Arthritis Patient Population

Early skin and enthesitis responses in active psoriatic arthritis patients treated with TREMFYA predicted long-term clinical response, measured at two years, including disease remission

Bio-naïve, TREMFYA-treated patients maintained several disease control endpoints through two years, regardless of baseline characteristics or dosing regimen

SPRING HOUSE, PENNSYLVANIA, November 11, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced a new post-hoc analysis of the Phase 3 DISCOVER program (DISCOVER-1 and DISCOVER-2) evaluating TREMFYA® (guselkumab) in adult patients with active psoriatic arthritis (PsA), which showed that early skin and enthesitis responses[a,b] predicted longer-term clinical response,[c] including disease remission, at week 52.[1] TREMFYA is the first fully human selective interleukin (IL)-23 inhibitor therapy approved in the U.S. for adults with moderate to severe plaque psoriasis (PsO) and adults with active PsA.[2]

In another post-hoc analysis of DISCOVER-2, a diverse population of bio-naïve, TREMFYA-treated patients sustained several PsA disease control endpoints through two years, regardless of their baseline characteristics[d] or dosing regimen,[e] including minimal disease activity (MDA) response,[f] skin clearance (IGA 0)[g] and resolution of dactylitis.[3,h]

"Active psoriatic arthritis is a chronic, lifelong condition that can be progressive for many patients, leading to extensive and permanent joint damage," said Philip J. Mease, M.D.,[i] Swedish Medical Center/Providence St. Joseph Health and University of Washington in Seattle, Washington. "The data derived from TREMFYA-treated patients in the DISCOVER program give us more tools to evaluate treatment plan options that may help facilitate long-term relief as we work toward the ultimate goal of disease remission."

Presented at the 2022 American College of Rheumatology (ACR) Convergence meeting, taking place in Philadelphia, PA and virtually, November 10-14, 2022, these new analyses of DISCOVER-1 and DISCOVER-2 data[j] show:

Early Skin and Entheseal Responses in TREMFYA-Treated Active PsA Patients May Predict Future Achievement of Rigorous Measures of Disease Control:[1]

- At week 24, early skin response[a] was associated with greater odds of achieving MDA, Disease Activity in Psoriatic Arthritis (DAPSA) Low Disease Activity (LDA), DAPSA remission, and DAPSA50[k] in PsA.
- Early entheseal response was associated with greater odds of achieving MDA, DAPSA LDA, DAPSA50, and resolution of enthesitis or dactylitis.
- DAPSA remission was achieved by a greater proportion of early entheseal responders, though the association was significant only at week 52.
- Among patients with baseline PsO and enthesitis, a dual effect was observed: those who responded early in both domains were more likely to achieve clinical response (MDA, DAPSA LDA, DAPSA50, DAPSA remission) than patients with individual responses to these domains.
- These results highlight the importance of early entheseal and skin responses on the trajectory of future patient outcomes.

Treatment with TREMFYA Sustained Stringent PsA Disease Control Endpoints Through Two Years Among a Diverse Population of Adults with Active PsA in Post-hoc Analysis of DISCOVER-2[3]:

- Sustained achievement of stringent endpoints spanning key GRAPPA-recommended domains, including ACR50 and ACR70, IGA 0, dactylitis[h] and enthesitis resolution, and MDA responses was seen across a variety of diverse, baseline demographics[d] (sex, body mass index [BMI]) and disease characteristics (swollen joint count [SJC], tender joint count [TJC], PsA duration, C-reactive protein [CRP], Body Surface Area [BSA], Psoriasis Area and Severity Index [PASI]).
- At week 100, sustained achievement of stringent endpoints was observed across all domains (MDA response, IGA 0 and resolution of dactylitis),

irrespective of use of concomitant therapies (nbDMARDs and methotrexate [MTX])
- No consistent differences were observed in the proportion of responders across patient subgroups[d] of adequate sample size or between TREMFYA dosing regimens.
- Results of this post-hoc analysis further support the long-term efficacy (week 100) of TREMFYA across the full spectrum of active PsA disease domains and diverse PsA populations.

"These analyses from the DISCOVER program give us greater insight into the potential for TREMFYA to provide long-term efficacy across multiple stringent disease control endpoints in diverse patient groups with active psoriatic arthritis," said Terence Rooney, M.D., Vice President, Rheumatology and Maternal-Fetal Immunology Disease Area Leader, Janssen Research & Development, LLC. "The data underscore Janssen's ongoing commitment to extensive research in active psoriatic arthritis, so that we may provide effective therapeutic options for patients living with the disease."

Editor's Notes:

a. Early skin response was defined as skin visual analogue scale (VAS) <=15mm at week 8 or PASI score ≤1 at week 16.
b. Enthesitis is defined as inflammation where tendons and ligaments meet bone. It is associated with certain kinds of arthritis, including active PsA.[4] Early entheseal response was defined as Leeds Enthesitis Index (LEI) score ≤1 at week 8.[1]
c. Longer-term clinical responses were defined by achievement of MDA,[f] DAPSA (LDA or remission), DAPSA50[k] and enthesitis/dactylitis resolution at week 24 or week 52.
d. Baseline characteristics of interest were patient's sex, BMI, swollen joint count (0-66, SJC), tender joint count (0-68, TJC), PsA duration, CRP, percent of BSA with PsO, PASI score, and use of conventional synthetic (cs) DMARDs and MTX.
e. In DISCOVER-2, 739 patients were randomized (1:1:1) and treated with TREMFYA 100 mg q4w (n=245); TREMFYA 100 mg at week 0, week 4, then q8w (n=248); or placebo (n=246) with crossover to TREMFYA 100 mg q4w at week 24.[3]
f. MDA is defined by fulfillment of 5/7 criteria: TJC ≤1, SJC ≤1, PASI score ≤1, patient pain score ≤15, patient global disease (arthritis and skin) activity score ≤20, Health Assessment Questionnaire–Disability Index (HAQ-DI) score ≤0.5, and ≤1 tender entheses.[4]
g. Skin clearance was evaluated using an Investigator's Global Assessment score of 0 [clear skin] (IGA 0). The IGA score is a 5-point clinical scale evaluating PsO severity.[5]
h. Dactylitis involves the swelling of fingers or toes and is associated with active PsA.[6]
i. Dr. Mease is a paid consultant for Janssen. He has not been compensated for any media work.

j. Please see the 'About DISCOVER-1' and 'About DISCOVER-2' sections for further details regarding study design.
k. DAPSA50 response represents at least 50 percent improvement in the DAPSA score from baseline. The DAPSA score is derived via summation of the following five variables: TJC, SJC, patient global assessment of arthritis (0-10 VAS), and patient assessment of joint pain (0-10 VAS, and CRP level.[7]
l. Disease activity control was measured by the following endpoints: MDA, ACR50 and ACR70,[m] IGA 0, PASDAS LDA, resolution of enthesitis and dactylitis, FACIT-F response (≥4-point improvement), and HAQ-DI response (≥0.35-point improvement).
m. ACR50 and ACR70 response criteria require ≥50 percent or ≥70 percent improvement in both the TJC and SJC, as well as in three of the following: patient global assessment of disease (arthritis) activity (VAS), physician global assessment (VAS), patient assessment of pain (VAS), HAQ-DI score, and either erythrocyte sedimentation rate or CRP.[8,9]

About DISCOVER-1 (NCT03162796)[10]
DISCOVER-1 was a randomized, double-blind, multicenter Phase 3 study evaluating the efficacy and safety of TREMFYA administered by SC injection in participants with active PsA, including those previously treated with one or two TNF inhibitors. DISCOVER-1 evaluated 381 participants who were treated and followed through approximately one year. The study consisted of a screening phase of up to six weeks, a blinded treatment phase of 52 weeks that included a placebo-controlled period from week 0 to week 24 and a blinded active treatment period from week 24 to week 52. It also included a safety follow-up phase through week 60 (i.e., approximately 12 weeks from the last administration of study agent at week 48). Efficacy, safety, pharmacokinetic, immunogenicity and biomarker evaluations were performed in the study on a defined schedule.

About DISCOVER-2 (NCT03158285)[12]
DISCOVER-2 is a randomized, double-blind, multicenter Phase 3 study evaluating the efficacy and safety of TREMFYA 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. 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.

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.[4,6,14] 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.[15] In patients with PsA, comorbidities such as obesity, cardiovascular diseases, anxiety and depression are often present.[16] Studies show up to 30 percent of people with plaque PsO also develop PsA.[17] 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)[3]
Developed by Janssen, TREMFYA 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. IL-23 is an important driver of the pathogenesis of inflammatory diseases such as moderate to severe plaque PsO and active PsA. TREMFYA is 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. It is also approved in the EU for the treatment of moderate to severe plaque PsO in adults who are candidates for systemic therapy and for the treatment of active PsA in adult patients who have had an inadequate response or who have been intolerant to a prior csDMARD therapy.

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to TREMFYA®.

IMPORTANT SAFETY INFORMATION
What is the most important information I should know about TREMFYA®?
TREMFYA® is a prescription medicine that may cause serious side effects, including:

- **Serious Allergic Reactions.** Stop using TREMFYA® and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:
    - fainting, dizziness, feeling lightheaded (low blood pressure)
    - swelling of your face, eyelids, lips, mouth, tongue or throat
    - trouble breathing or throat tightness
    - chest tightness
    - skin rash, hives
    - itching

- **Infections.** TREMFYA® may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with TREMFYA® and may treat you for TB before you begin treatment with TREMFYA® if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with TREMFYA®.

Tell your healthcare provider right away if you have an infection or have symptoms of an infection, including:

- fever, sweats, or chills
- muscle aches
- weight loss
- cough
- warm, red, or painful skin or sores on your body different from your psoriasis
- diarrhea or stomach pain
- shortness of breath
- blood in your phlegm (mucus)
- burning when you urinate or urinating more often than normal

Do not take TREMFYA® if you have had a serious allergic reaction to guselkumab or any of the ingredients in TREMFYA®.

Before using TREMFYA®, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section **"What is the most important information I should know about TREMFYA®?"**
- have an infection that does not go away or that keeps coming back.
- have TB or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with TREMFYA®.
- are pregnant or plan to become pregnant. It is not known if TREMFYA® can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TREMFYA® passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of TREMFYA®?
TREMFYA® may cause serious side effects. See "What is the most important information I should know about TREMFYA®?"

The most common side effects of TREMFYA® include: upper respiratory infections, headache, injection site reactions, joint pain (arthralgia), diarrhea, stomach flu (gastroenteritis), fungal skin infections, herpes simplex infections, and bronchitis.

These are not all the possible side effects of TREMFYA®. Call your doctor for medical advice about side effects.

Use TREMFYA® exactly as your healthcare provider tells you to use it.

Please read the full Prescribing Information, including Medication Guide for TREMFYA®, and discuss any questions that you have with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.
cp-82626v3

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. Follow us at www.twitter.com/JanssenGlobal and www.twitter.com/JanssenUS.

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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