News Release

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TREMFYA® (guselkumab) Provides Sustained Improvements Across All Minimal Disease Activity Domains for Adults Living with Active Psoriatic Arthritis in Phase 3b Trial

Additional post-hoc clinical data will be presented from Phase 3 DISCOVER trials providing clinical insights on the importance of shared decision making to address patient-reported symptoms

SPRING HOUSE, PENNSYLVANIA, May 31, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new data from the Phase 3b COSMOS clinical trial showing that treatment with TREMFYA® (guselkumab) provided sustainable improvements in all minimal disease activity (MDA)[a] domains through week 48 in adults living with active psoriatic arthritis (PsA) who previously had an inadequate response to one to two tumor necrosis factor inhibitors (TNFi-IR).[1] In a separate post-hoc analysis of the Phase 3 DISCOVER-1 and DISCOVER-2[b] clinical trial findings, TREMFYA was shown to be associated with prompt and sustained improvements in all identified determinants.[2] This analysis also identified factors that influenced disagreement between patient and physician global assessments (GA), such as patient-reported pain, physical aspects of health-related

quality of life and fatigue.[2] TREMFYA is the first and only fully human selective interleukin (IL)-23 inhibitor therapy approved for the treatment of adult patients living with active PsA.[3] These study results are among 41 company-sponsored abstracts being presented by Janssen at the 2023 Annual European Congress of Rheumatology (EULAR) meeting taking place in Milan, Italy, May 31 - June 3, 2023.

A previous study has shown that sustained MDA is typically only achieved by a minority of patients receiving biologic therapy for active PsA.[1] However, in a post-hoc analysis of the Phase 3b COSMOS clinical trial, TREMFYA provided sustained improvement in all MDA domains from baseline through week 48 in adult patients living with active PsA and who were inadequate responders to one to two TNFis (n=189).[1]

- Overall response rates at week 24 and week 48 were Psoriasis Area and Severity Index (PASI)[c] (66.8/81.5 percent), Leeds Enthesitis Index (LEI)[d] (74.5/79.8 percent), swollen joint count (SJC)[e] (46.2/63.0 percent), patient GA (24.5/39.9 percent), Health Assessment Questionnaire – Disability Index (HAQ-DI)[f] (26.1/37.0 percent), patient pain (14.7/30.6 percent) and tender joint count (TJC)[e] (14.7/28.3 percent), respectively.[1]
- Physician-reported domains (LEI, PASI and SJC) were achieved faster than patient-driven domains (patient GA, HAQ-DI, patient pain and TJC).[1]

"Assessing patient-reported symptoms is a vital part of our research that helps us to address unmet needs and provide treatments that can improve outcomes," said Laura Coates, M.D., Ph.D., Senior Clinical Research Fellow at the University of Oxford.[g] "These results advance our understanding of the psoriatic arthritis patient experience and will help healthcare professionals develop individualized treatment plans that can target debilitating symptoms and, ultimately, aim to improve quality of life for people living with psoriatic arthritis."

The importance of a personalized approach to PsA treatment that prioritizes shared decision-making and open dialogue is reinforced in a separate post-hoc analysis of the Phase 3 DISCOVER-1 and DISCOVER-2 studies, which identified differences

between patient GA and physician GA.[2] The results showed that while scores were aligned across most factors, patients weighed pain, fatigue and physical health higher than physicians.[2] TREMFYA was associated with prompt and sustained improvements in all identified determinants, including those driving higher patient versus physician scores, such as patient-reported pain, physical aspects of health-related quality of life, and fatigue.[2]

- At baseline, patient GA and physician GA scores were similar in most instances (61.2 percent) with 23.2 percent of cases characterized by a patient GA score higher than a physician GA score.[2] Higher patient scores meant the patient considered this aspect of their disease to be worse than the physician.[2] 15.7 percent of cases had a physician GA score higher than patient GA.[2]
- The proportion of patients with higher patient GA score than physician GA score increased to 39.1 percent at week 24, while the proportion with higher physician GA scores decreased to 11.2 percent.[2]
- The main determinant of higher patient scores was patient pain, with additional factors including worse physical health-related quality of life at baseline and worse fatigue at week 24.[2] Conversely, physicians emphasized objective disease measures, including SJCs, TJCs and elevated C-reactive protein when assessing patient disease status.[2]

"Our continued research underscores Janssen's commitment to not only provide therapeutic options for psoriatic disease, but also to better understand and support the pressing needs of the patients we serve," said Terence Rooney, M.D., Ph.D., Vice President, Rheumatology and Maternal-Fetal Immunology Disease Area Leader, Janssen Research & Development, LLC. "Active psoriatic arthritis is a challenging, chronic disease, so these findings have important implications for patients and their providers as they work together to address the full spectrum of disease symptoms, including patient-reported outcomes, with the goal of achieving long-term relief."

At the 2023 annual EULAR meeting, Janssen is also presenting data that demonstrate its commitment to clinical advancements in the treatment of

autoantibody diseases including rheumatoid arthritis, idiopathic inflammatory myopathies, Sjögren's disease and systemic lupus erythematosus.

Editor's Notes:

a. MDA was defined as fulfillment of five or more out of seven domains: tender entheses (LEI) $\leq$1, HAQ-DI $\leq$0.5, patient pain $\leq$15, PASI $\leq$1, patient GA $\leq$20, SJC $\leq$1 and TJC $\leq$1.[1]
b. This analysis assessed agreement between patient GA and physician GA to potentially provide valuable insight into the differential importance of specific PsA manifestations to patients and physicians.[2]
c. The PASI score grades the amount of surface area on each body region that is covered by psoriasis (PsO) plaques and the severity of plaques for their redness, thickness, and scaliness.[4]
d. The LEI index evaluates the absence or presence of entheseal tenderness at six anatomical sites: bilateral lateral epicondyles, medial femoral condyles, and Achilles tendon insertion sites.[5]
e. The TJC and SJC are core outcome measures used to assess arthritis disease activity in the context of clinical trials and observational studies.[6]
f. The HAQ-DI was designed to represent a model of patient-oriented outcome.[7] Patients complete the 20-item HAQ-DI to assess their level of functional ability; the HAQ-DI includes questions of fine movements of the upper extremity, locomotor activities of the lower extremity, and activities that involve both upper and lower extremities.[7]
g. Dr. Laura Coates is a paid consultant for Janssen. She has not been compensated for any media work.
h. ACR20 response is defined as both at least 20 percent improvement from baseline in the number of tender and number of swollen joints, and a 20 percent improvement from baseline in three of the following five criteria: patient GA, physician GA, functional ability measure (HAQ-DI), patient-reported pain using a visual analog scale, and erythrocyte sedimentation rate or C-reactive protein.[8]

About COSMOS (NCT03796858)

COSMOS was a Phase 3b, multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of TREMFYA, administered by subcutaneous injection, in 285 adult patients with active PsA and inadequate response to TNFi therapy.[8] The primary endpoint was ACR20[h] response at week 24.[8] The primary endpoints results were announced in June 2021.[9] Participants were randomized (2:1) to receive TREMFYA 100 mg at weeks 0, 4 and every eight weeks thereafter, or placebo.[8] The study included two periods: a 24-week double-blind, placebo-controlled period for the primary analysis of the efficacy and safety of TREMFYA compared with placebo and a 32-week active-treatment and safety follow-up period for additional analysis of the efficacy and safety of TREMFYA.[8] Through week 48, non-responder imputation rules were used for missing data (after the application of treatment failure rules).[1] Safety was monitored throughout the study to week 56.[8] In patients with active PsA and prior inadequate response to ≤2 TNFi, TREMFYA demonstrated an adverse event (AE) profile consistent with placebo through week 24, with no increase in AEs through one year of treatment.[10] As such, the COSMOS safety results were consistent with the known safety profile of TREMFYA in biologic-naïve patients with PsA.[11,12,13,14,15]

About DISCOVER-1 (NCT03162796)

DISCOVER-1 was a Phase 3, multicenter, randomized, double-blind study evaluating the efficacy and safety of TREMFYA administered by subcutaneous injection in participants with active PsA, including those previously treated with one to two TNFis.[16] DISCOVER-1 evaluated 383 participants who were treated and followed through approximately one year.[16] The study consisted of a screening phase of up to six weeks, a blinded treatment 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.[16] In a mixed population of patients with active PsA (69 percent bio-naïve; 31 percent TNFi-experienced), TREMFYA demonstrated an AE profile consistent with placebo through week 24, with no increase in time-adjusted rates of AEs through one year of treatment, regardless of prior TNFi exposure.[11,12,13] 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).[16] Efficacy, safety, pharmacokinetic, immunogenicity and biomarker evaluations were performed in the study on a defined schedule.[16] The primary endpoint was response of ACR20 at week 24.[16]

About DISCOVER-2 (NCT03158285)

DISCOVER-2 was a Phase 3, multicenter, randomized, double-blind study evaluating the efficacy and safety of TREMFYA administered by subcutaneous injection in biologic-naïve patients with active PsA.[17] DISCOVER-2 evaluated 741 participants who were treated and followed through approximately two years.[17] 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.[17] 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).[17] In a large cohort of biologic-naïve patients with active PsA, TREMFYA demonstrated an AE profile consistent with placebo through week 24, with no increase in time-adjusted AE rates through two years of TREMFYA treatment.[14,15] Clinical efficacy, radiographic efficacy, health economics, safety, pharmacokinetics, immunogenicity, biomarker, and pharmacogenomics evaluations were performed in the study on a defined schedule.[17] The primary endpoint was response of ACR20 at week 24.[17]

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.[18,19,20] 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.[21] 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.[22] In patients with PsA, comorbidities such as obesity,

cardiovascular disease, anxiety and depression are often present.[23] Studies show up to 30 percent of people with plaque PsO also develop PsA.[21] 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.[24]

About TREMFYA® (guselkumab)

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.[3,25] IL-23 is an important driver of the pathogenesis of inflammatory diseases such as moderate to severe plaque PsO and active PsA.[3] 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.[3,26,27] 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 conventional synthetic disease modifying antirheumatic drug therapy.[3]

In vitro studies have demonstrated that TREMFYA also binds to CD64 which is expressed on the surface of IL-23 producing cells in an inflammatory monocyte model.[28,29,30] The clinical significance of this finding is not known.[31]

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). 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, Janssen Biotech, Inc., Janssen Scientific Affairs, 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 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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