News Release

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Latest Phase 3 Data for First-in-Class TREMFYA® (guselkumab) Demonstrates Significant and Durable Improvement in Signs and Symptoms of Active Psoriatic Arthritis while Maintaining its Safety Profile in Patients with Inadequate Response to Tumor Necrosis Factor Inhibition (TNFi-IR)

The COSMOS study met its primary endpoint, with a significantly higher proportion of TREMFYA-treated patients (44.4 percent) versus placebo-treated patients (19.8 percent) achieving ACR20 response at week 24; the TREMFYA treatment effect in these TNFi-IR patients was seen by week four

Response rates continued to improve at one year (week 48) with 57.7 percent of TREMFYA patients achieving ACR20 with a similar safety profile (week 56)

TREMFYA is the first and only selective interleukin (IL)-23 inhibitor therapy approved in the U.S. for moderate to severe plaque psoriasis and active psoriatic arthritis irrespective of prior TNFi exposure

SPRING HOUSE, PENNSYLVANIA, December 3, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new TREMFYA® (guselkumab) efficacy and safety data from the Phase 3b COSMOS trial published in *Annals of the Rheumatic Diseases (ARD)*, evaluating this selective interleukin (IL)-23

inhibitor in adults with active psoriatic arthritis (PsA) who demonstrated inadequate efficacy or intolerance to tumor necrosis factor inhibition (TNFi).[1] Results showed significantly higher proportions of patients treated with TREMFYA had improvement in joint signs and symptoms and complete skin clearance versus placebo at week 24 in this documented TNFi-IR[a] patient population, which is often more difficult to treat.[1] Furthermore, improvements in signs and symptoms of PsA were maintained or numerically increased through one year (week 48) among TREMFYA-randomized patients.[1]

"Active psoriatic arthritis is a heterogenous disease and a significant number of patients do not respond adequately to TNF inhibition," said lead author Laura Coates, M.D., Ph.D., Associate Professor, University of Oxford, UK.[b] "The COSMOS data demonstrate that TREMFYA significantly improved signs and symptoms of active psoriatic arthritis across multiple clinical disease domains, including patient reported outcomes, with treatment effects observed by week four. These findings reinforce the utility of this alternative mechanism of action as a therapeutic option for adults with active psoriatic arthritis who have not responded to one or more therapies."

Results show:

Joint Symptom Improvement:

- 44.4 percent (84/189) of patients who received TREMFYA versus 19.8 percent (19/96) of patients who received placebo achieved at least 20 percent improvement in the American College of Rheumatology criteria (ACR20) at week 24, the study's primary endpoint.[1,c] Results of the Early Escape (EE)-correction sensitivity analysis[d] indicated an ACR20 response rate of 48.1 percent (91/189) in the TREMFYA group.[1] 54.9 percent of placebo patients who crossed over to TREMFYA at week 24 achieved ACR20 at week 48.[1]
- ACR20 response rates continued to improve across different analysis sets during the first year – 57.7 percent of TREMFYA patients at week 48 utilizing non-responder imputation [NRI] and >80 percent of week 24 responders maintained a response at week 48.[1]

- TREMFYA-treated patients had higher ACR20 and ACR50 response rates versus placebo as early as weeks four and eight, respectively.[1]
- At week 24, TREMFYA-treated patients had a greater least square (LS) mean change in Disease Activity in Psoriatic Arthritis (DAPSA)[e] score (-14.5 vs -5.7) and a higher DAPSA low disease activity (LDA) response rate (29.6 percent vs 13.5 percent) versus placebo, which increased over time to 44.4 percent at week 48.[1] At week 24, the proportion of patients achieving DAPSA remission was numerically higher in the TREMFYA group versus placebo (5.3 percent vs 2.1 percent).[1]
- Among patients affected at baseline, numerically higher proportions of TREMFYA-treated patients than placebo patients had resolved enthesitis[f] (39.7 percent vs 18.8 percent) or dactylitis[g] (44.8 percent vs 25 percent) at week 24.[1]

Improvements in Physical Function, Health-Related Quality of Life (HRQoL) and Fatigue:

- At week 24, higher proportions of TREMFYA-treated patients versus placebo (37.5 percent vs 16.1 percent) achieved clinically meaningful improvements in physical function (Health Assessment Questionnaire Disability Index [HAQ-DI]),[h] which increased to 53.4 percent at week 48.[1]
- TREMFYA-treated patients also reported better physical aspects of HRQoL (Short Form [SF]-36 Physical Component Summary [PCS] scores) versus placebo.[1,i]
- At week 24, higher proportions of TREMFYA-treated patients achieved a ≥4-point increase in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) versus placebo (42.9 percent vs 20.8 percent), reflecting a clinical meaningful improvement in fatigue.[1,j] This response was maintained and increased over time to 55.6 percent at week 48.[1,2]

Complete Skin Clearance:

- At week 24, the proportion of patients with ≥3 percent body surface area psoriatic involvement and an Investigator's Global Assessment (IGA)[k] score of ≥2 at baseline achieving complete skin clearance (100 percent improvement in Psoriasis Area Severity Index [PASI])[l] was significantly higher among those receiving TREMFYA than those receiving placebo (30.8 percent vs 3.8 percent).[1]

- At week 48, more than half of patients (53.4 percent) receiving TREMFYA (utilizing NRI) achieved complete skin clearance (PASI 100).[1]

Consistent Safety Profile:

- The TREMFYA treatment group demonstrated low rates of adverse events (AEs) leading to discontinuation and serious AEs (SAEs), which were comparable to that of the placebo group.[1]
- Through week 56, time-adjusted incidences of SAEs and AEs leading to treatment discontinuation, and serious infections were 6.3, 2.7, and 0.8 per 100 patient years, respectively.[1] In the TREMFYA treatment group, one patient experienced a major adverse cardiovascular event at week 44; one malignancy occurred (prostatic adenocarcinoma); and two patients reported psychiatric disorders as SAEs.[1] One case of suspected, but unconfirmed, inflammatory bowel disease was reported around one month after the patient discontinued TREMFYA due to an influenza-like illness.[1]
- Two TREMFYA-treated patients had a serious infection: one TREMFYA-randomized patient was hospitalized with community-acquired pneumonia diagnosed at week 12 (history of chronic obstructive pulmonary disease and heart disease) and the patient recovered with antibiotic treatment and resumed study agent. The second patient was hospitalized with acute pneumonia (week 48), who recovered following antibiotic therapy and continued TREMFYA.[1] No opportunistic infections, cases of active TB, or deaths occurred.[1]
- These safety findings in TNFi-IR PsA patients through week 56 of COSMOS expand upon, and are consistent with, the accumulated TREMFYA safety profile established in psoriasis (PsO) patients receiving TREMFYA through five years (VOYAGE 1 and 2) and those seen in bio-naïve and TNFi-experienced PsA patients evaluated in DISCOVER-1 (one year) and DISCOVER-2 (two years).[1]

"Results from this study provide further evidence that TREMFYA is effective in treating patients with various manifestations of active psoriatic arthritis even when TNF inhibitor treatment has failed," said Soumya D. Chakravarty, M.D., Ph.D., Senior Director, Strategic Lead, Rheumatology Therapeutic Area, Janssen Scientific Affairs, LLC. "Active psoriatic arthritis is a chronic and often debilitating disease, so

patients need treatment options with durable efficacy and an established safety profile. It is our goal to advance therapeutic options for people living with active psoriatic arthritis to enhance their chances to live life with reduced symptoms of active PsA."

Editor's Note:

a. TNFi-IR was defined by the presence of active PsA despite being on treatment with either one or two nonconcurrent anti-TNF alpha agents or an intolerance to anti-TNF alpha therapy. This was documented in the participant history by the treating physician, after at least 12 weeks of etanercept, adalimumab, golimumab, or certolizumab pegol therapy (or biosimilars) and/or at least a 14-week dosage regimen (i.e., at least four doses) of infliximab (or biosimilars).[2]
b. Professor Coates is a paid consultant for Janssen. She was not compensated for any media work.
c. ACR20/50/70 response is defined as both at least 20/50/70 percent improvement from baseline in the number of tender and swollen joints, and at least 20/50/70 percent improvement from baseline in three of the following five criteria: patient global assessment, physician global assessment, patient-reported functional ability (HAQ-DI), patient-reported pain using a visual analogue scale, and a laboratory marker of systemic inflammation (erythrocyte sedimentation rate or C-reactive protein level).[3]
d. A pre-planned sensitivity analysis, termed the 'Early Escape-correction analysis' was conducted to address 20 patients (12 TREMFYA and 8 placebo) who were incorrectly routed to early escape and considered non-responders in the primary analysis.[1]
e. The DAPSA derives from the summation of visual analogue scales (0-10 cm) of patient's global and pain assessments, 66 swollen joint count (66SJC), 68 tender joint count (68TJC) and C-reactive protein (CRP, mg/dL).[4] A DAPSA score of ≤14 represents a state of low disease activity (DAPSA-LDA), and a score of ≤4 represents remission (DAPSA-REM).[4]
f. Enthesitis in PsA is inflammation where the bone, tendon and ligament meet.[5]
g. Dactylitis in PsA is severe inflammation of the digits of the fingers and toes.[5]

h. HAQ-DI is a patient questionnaire that assesses physical function and disability across rheumatic diseases.[6] Normalized physical function is defined as a HAQ-DI score of ≤0.5.[6] The results seen in this study were among patients with HAQ-DI ≥0.35 at baseline.[1]
i. SF-36 is a set of quality-of-life measures used for patient self-reporting. The SF-36 includes one multi-item scale that assesses eight health concepts: limitations in physical activities because of health problems; limitations in social activities because of physical or emotional problems; limitations in usual role activities because of physical health problems; bodily pain; general mental health (psychological distress and well-being); limitations in usual role activities because of emotional problems; vitality (energy and fatigue); and general health perceptions.[7]
j. The FACIT-Fatigue scale is a 40-item measure that assesses self-reported fatigue and its impact upon daily activities and function.[8]
k. IGA is a five-point scoring system used to characterize PsO severity. Scores range from 0 to 4 and represent cleared (0), almost clear (1), mild (2), moderate (3), or severe (4) skin PsO.[9]
l. PASI 75/90/100 responses are defined as at least 75/90/100 percent improvement in the PASI score from baseline. The PASI score grades the amount of surface area covered by PsO plaques in each body region, and the degree of plaque redness, thickness, and scaliness.[10]

About Active Psoriatic Arthritis (PsA)

Active PsA is a chronic, immune-mediated inflammatory disease characterized by peripheral joint inflammation, enthesitis (pain where the bone, tendon and ligament meet), dactylitis (severe inflammation of the fingers and toes), axial disease, and the skin lesions associated with plaque PsO.[11-13] In addition, in patients with active PsA, comorbidities, such as obesity, cardiovascular diseases, anxiety and depression are often present.[14] Studies show up to 30 percent of people with plaque PsO also develop active PsA.[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 time.[15] Nearly half of patients with active PsA experience moderate fatigue and about 30

percent suffer from severe fatigue as measured by the modified fatigue severity scale.[16] Although the exact cause of active PsA is unknown, genes, the immune system and environmental factors are all believed to play a role in disease onset.[17]

About COSMOS (NCT03796858)[2,18]

COSMOS was a Phase 3b, multicenter, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of TREMFYA in 285 patients with active PsA and IR to TNFi therapy. The primary endpoint was ACR20 response at week 24. Participants were randomized (2:1) to receive TREMFYA 100 mg at weeks 0, 4, and every 8 weeks thereafter, or placebo. 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. Through week 48, NRI rules were used for missing data (after the application of treatment failure rules [TFR]). Safety was monitored throughout the study to week 56.

About TREMFYA® (guselkumab)[18]

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.[19] 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 disease-modifying antirheumatic drug 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, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal.

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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 3, 2021, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent 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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