News Release

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TREMFYA® (guselkumab) Reduced Fatigue over 52 Weeks in Adult Patients with Psoriatic Arthritis in Two Phase 3 Clinical Trials

Studies confirm improvement achieved and maintained through one year of active treatment with similar scores for patients switching from placebo to TREMFYA

TREMFYA is the first and only U.S. FDA-approved selective anti-IL-23 therapy for active psoriatic arthritis and the only therapy for psoriatic arthritis to have improvement in fatigue as measured by FACIT-F in the product label

SPRING HOUSE, PENNSYLVANIA, November 6, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced data from two Phase 3 clinical trials, DISCOVER-1 and DISCOVER-2, which showed TREMFYA® (guselkumab) improved fatigue in adult patients with active psoriatic arthritis (PsA) and maintained response through 52 weeks of active treatment, as measured by the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) Scale.[1,a] TREMFYA improved fatigue during the placebo-controlled periods of both studies at week 24, and through one year of active treatment. In both studies, TREMFYA had positive effect on fatigue, in addition to other clinical outcomes, including ACR20 response.[b,1] TREMFYA is FDA-approved for administration as a 100 mg subcutaneous (SC) injection every eight weeks (q8w), following two starter doses at weeks 0 and 4.[2]

Data assessing fatigue outcomes of the studies will be presented as a poster presentation (Abstract #0347) on Friday, November 6 from 9:00 - 11:00 a.m. EST during ACR Convergence 2020, the American College of Rheumatology (ACR) virtual annual meeting.[1]

Fatigue is considered one of the three most important symptoms by patients with active PsA, and moderate to severe fatigue occurs in up to 50 percent of these patients.[3-6] Fatigue is defined as an overwhelming, sustained sense of exhaustion and decreased capacity for physical and mental work.[7] It includes a range of experiences, from tiredness to exhaustion, which can interfere with normal daily function and reduce health-related quality of life. Fatigue is ranked high by patients regarding impact on life and priority for improvement.[6]

"Fatigue associated with psoriatic arthritis can have a serious impact on patients' health-related quality of life and can lead to social isolation and loss of employment,"[8] said Proton Rahman,[i] M.D., Professor of Medicine, Rheumatology, Memorial University in Newfoundland, Canada and presenting author of the study. "These findings from the DISCOVER-1 and DISCOVER-2 studies showing an improvement in fatigue a full year into treatment with TREMFYA add to the previously presented 52-week data demonstrating an improvement in joint and skin symptoms. Considered together, the data are encouraging for active psoriatic arthritis patients who struggle with multiple symptoms."

In both DISCOVER-1 and DISCOVER-2 clinical trials:[1]

- The FACIT-Fatigue Scale, a validated patient-reported outcomes instrument, was used to assess fatigue and its impact on daily activities and function over the prior 7 days. Scale scores range from 0 to 52, with the higher score denoting less fatigue. A change of ≥4 points is considered clinically meaningful.[9]
- At baseline in both studies, the mean FACIT-Fatigue scores were 30.4 (10.4) and 29.7 (9.7), respectively, indicating that patients with active PsA experienced fatigue worse than the general population [43.6 (9.4)].

- At week 24 in both studies, treatment with TREMFYA led to greater improvements in FACIT-Fatigue scores compared with placebo, as early as week 16 in DISCOVER-1 and week 8 in DISCOVER-2, with 54%-63% of TREMFYA patients achieving clinically meaningful improvement (≥4 points) in FACIT-Fatigue compared with 35%-46% of placebo patients (unadjusted p≤0.003).[9]
    - FACIT-Fatigue least squares (LS) mean changes from baseline were 5.6 and 5.8 for q8w and every four weeks (q4w), respectively, compared with 2.2 for placebo in DISCOVER-1, and 7.6 and 7.1 for q8w and q4w, respectively, compared with 3.6 for placebo in DISCOVER-2.
- After crossing over to TREMFYA q4w at week 24, patients who had previously been on placebo achieved FACIT-Fatigue scores comparable to those of TREMFYA patients through week 52 (mean change from baseline of 6.6 vs. 6.9, respectively, in DISCOVER-1, and 7.5 vs. 7.7, respectively, in DISCOVER-2).
- At 52 weeks, 61%-70% of both TREMFYA patients and those who crossed over from placebo to TREMFYA after 24 weeks achieved a clinically meaningful improvement in FACIT-Fatigue score.

In both studies, TREMFYA was well-tolerated through study completion, and adverse events (AEs) were generally consistent with previous studies of TREMFYA and current prescribing information.[2] Serious AEs and serious infections occurred in 4 percent and 1 percent of TREMFYA-treated patients, respectively, in both DISCOVER-1 and DISCOVER-2.[10,11]

"Data from the DISCOVER-1 and DISCOVER-2 studies demonstrating TREMFYA reduced fatigue through 52 weeks provide evidence of an additional treatment benefit for patients with active PsA," said Alyssa Johnsen, M.D., Ph.D., Vice President, Rheumatology Disease Area Leader, Janssen Research & Development, LLC. "The positive outcomes in fatigue assessment add to the body of data for TREMFYA, which has shown improvements in multiple clinical outcomes including joint symptoms, skin symptoms, soft tissue inflammation, and physical function."

TREMFYA was approved in July 2020 by the U.S. FDA for adult patients with active PsA, a chronic progressive disease characterized by painful joints and skin

inflammation,[2,12] and is the first and only therapy approved for active PsA to have improvement in fatigue as measured by FACIT-F in the product label. The approval was based on results from two pivotal Phase 3 clinical trials, DISCOVER-1 and DISCOVER-2, which evaluated the efficacy and safety of TREMFYA administered by SC injection in adults with active PsA compared to placebo, and showed that a significant percentage of patients treated with TREMFYA reached the studies' primary endpoint of ACR20 at 24 weeks.[13,14] Recently announced data showed that TREMFYA demonstrated improvements in multiple clinical outcomes including joint symptoms, skin symptoms, soft tissue inflammation, physical function, axial-related disease,[15,16] and reduction in radiographic progression at week 52.[10,11]

Editor's Note:

a. Functional Assessment of Chronic Illness Therapy - Fatigue (FACIT-F) Scale: measured on a 4-point Likert scale (4 = not at all fatigued to 0 = very much fatigued).[17]

b. ACR20 Response: defined as both improvement of 20 percent in the number of tender and number of swollen joints, and a 20 percent improvement in three of the following five criteria: patient global assessment, physician global assessment, functional ability measure, visual analog pain scale, and erythrocyte sedimentation rate or C-reactive protein (CRP).[18]

About DISCOVER-1 (NCT03162796)[19]

DISCOVER-1 is a randomized, double-blind, multicenter Phase 3 study evaluating the efficacy and safety of TREMFYA administered by SC injection in participants with active psoriatic arthritis including those previously treated with biologic anti-TNF alpha agent(s). DISCOVER-1 evaluated 381 participants and continued through approximately one year.

The study consisted of a screening phase of up to six weeks, a blinded treatment phase of 52 weeks that includes a placebo-controlled period from week 0 to week 24 and an active treatment period from week 24 to week 52. It also includes a safety follow-up phase of eight weeks after week 52 (week 52 to 60; 12 weeks from the last administration of study agent [at week 48] through to the final visit in the safety

follow-up phase). Efficacy, safety, pharmacokinetic, immunogenicity and biomarker evaluations were performed in the study on a defined schedule.

About DISCOVER-2 (NCT03158285)[20]

DISCOVER-2 is a randomized, double-blind, multicenter Phase 3 study evaluating the efficacy and safety of TREMFYA administered by SC injection in subjects with active psoriatic arthritis. DISCOVER-2 is evaluating 739 participants and continuing through approximately two years.

The study consists of a screening phase of up to six weeks, a blinded treatment phase (approximately 100 weeks) that includes a placebo-controlled period from week 0 to week 24, and an active treatment period from week 24 to week 100. It also includes a safety follow-up phase of 12 weeks after the last administration of study agent. Efficacy, health economics, safety, pharmacokinetics, immunogenicity, biomarker, and pharmacogenomics evaluations are being performed in the study on a defined schedule.

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, immune-mediated inflammatory disease characterized by peripheral joint inflammation, enthesitis, dactylitis, axial disease, and the skin lesions associated with psoriasis.[21] Studies show that up to 30 percent of people with psoriasis also develop PsA.[22] 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.[22] Nearly half of patients with PsA experience moderate fatigue and about 30 percent suffer from severe fatigue.[4] Though the exact cause of PsA is unknown, genes, the immune system and environmental factors are all believed to play a role in the onset of the disease.[12]

About TREMFYA® (guselkumab)[2]

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. TREMFYA is approved in the U.S., Canada, the European Union, Japan, and a number of other countries worldwide for the treatment of adult patients with moderate to severe plaque psoriasis who may benefit from taking

injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet [UV] light). It is approved in the U.S., Japan, Brazil, and Ecuador for the treatment of adult patients with active psoriatic arthritis, and the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending its expanded use for the treatment of adult patients with active PsA in the European Union (EU).[23] A final decision from the European Commission (EC) regarding PsA indication expansion is expected later this year. IL-23 is an important driver of the pathogenesis of inflammatory diseases such as psoriasis and PsA.[24]

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.

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 Janssen 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.
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Janssen Research & Development, LLC is a 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 ongoing and planned development efforts involving TREMFYA® (guselkumab) as a treatment for adult patients with active psoriatic arthritis. 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 December 29, 2019, 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.

[i] *Dr. Proton Rahman is a paid consultant for Janssen. He has not been compensated for any media work.*

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