



News Release

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New Phase 3 Data Showed First-in-Class TREMFYA® (guselkumab) Provided Durable Complete Skin Clearance Through Five Years in Moderate to Severe Plaque Psoriasis (PsO) and Robust Joint Symptom Improvement Through 52 Weeks in Active Psoriatic Arthritis (PsA)

Skin clearance rates were maintained at five years with 55.5 percent of patients achieving an Investigator's Global Assessment score of 0 and 53 percent achieving Psoriasis Area Severity Index 100 response in VOYAGE 2

TREMFYA, the first and only selective interleukin (IL)-23 inhibitor therapy approved for both PsO and PsA, improved overall PsA disease activity as evaluated by composite disease activity scores, and PsA axial symptoms as evaluated by the Bath Ankylosing Spondylitis Disease Activity Index in DISCOVER-1 and -2

SPRING HOUSE, PENNSYLVANIA, April 23, 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced new Phase 3 data which showed TREMFYA® (guselkumab) sustained durable, complete skin clearance rates in a majority of adults with moderate to severe plaque psoriasis (PsO) through five years (252 weeks),^a and improved disease activity and axial symptoms in adults with active psoriatic arthritis (PsA) through one year (52 weeks).^{1,2,3} These data are being presented at the American Academy of Dermatology Virtual Meeting Experience 2021, where Janssen will present a total of 22 abstracts. TREMFYA is the

first and only selective interleukin (IL)-23 inhibitor therapy approved in the U.S. to treat both adults with moderate to severe plaque PsO who are candidates for systemic therapy or phototherapy and adults with active PsA.⁴

“People living with psoriatic disease can face a lifetime of physical pain and discomfort, which places a significant burden on their lives,” said Kristian Reich,^b M.D., Ph.D., Professor of Translational Research in Inflammatory Skin Diseases, Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf, Germany, and lead author of the VOYAGE 2 study. “The signs and symptom improvements seen with TREMFYA are noteworthy for both patients who live with fear of disease recurrence and their physicians, as these data add to a growing body of evidence for this first-in-class IL-23 inhibitor treatment for moderate to severe plaque psoriasis and active psoriatic arthritis.”

Results show:

- **Durable and Complete Skin Clearance Rates:** In the PsO trial VOYAGE 2 (POSTER #27859), 55.5 percent of patients in the TREMFYA group^c achieved an Investigator’s Global Assessment (IGA)^d score of 0, indicating complete skin clearance, and 53 percent achieved a Psoriasis Area Severity Index (PASI)^e 100 skin clearance response (PASI 100) at week 252.¹ Additionally, in the same trial, 82 percent achieved a PASI 90 skin clearance response and 85 percent achieved an IGA score of 0/1 (clear/almost clear).¹ High efficacy rates were maintained through five years of TREMFYA treatment based on analyses using pre-specified treatment failure rules (patients discontinuing due to lack of efficacy, worsening of PsO, or use of a prohibited treatment were considered non-responders).¹
- **Robust Joint Symptom Improvement:** TREMFYA 100 mg every four weeks^f and every eight weeks improved PsA disease activity in joints and across multiple domains through week 52 in both PsA trials, DISCOVER-1 and -2, as measured by the Disease Activity Index for PsA, Minimal Disease Activity, Very Low Disease Activity and remission determined using Disease Activity Index for PsA (POSTER #27038).² Differences in response rates associated with composite indices between TREMFYA and placebo were seen as early as week eight and

increased over time through week 52.² In addition, data from a separate abstract show TREMFYA is the first IL-23 inhibitor to provide sustained improvements in PsA axial symptoms based on change from baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)⁹ score and percentage of patients achieving a BASDAI 50 response through week 52 (POSTER #27851).³

- **Established Safety Profile:** Across both PsO trials, VOYAGE 1 and 2, 78.4 percent of patients (n=1,349/1,721) with moderate to severe plaque PsO treated with TREMFYA continued treatment through week 252 (7,166 patient-years of follow-up).⁵ This comprehensive safety analysis of VOYAGE 1 and 2 showed a consistent safety profile for TREMFYA from year one through year five with low rates of adverse events (AEs) leading to discontinuation and serious AEs (POSTER #28095).⁵

“The durable response rates seen in the majority of patients enrolled in the VOYAGE and DISCOVER trials further demonstrate the important role that TREMFYA has in helping patients with their moderate to severe plaque psoriasis and their active psoriatic arthritis and add to the volume of scientific insights provided by the comprehensive TREMFYA research program,” said Lloyd S. Miller, M.D., Ph.D., Vice President, Immunodermatology Disease Area Leader, Janssen Research & Development, LLC.

Editor’s Note:

- a. VOYAGE 2 included a randomized withdrawal phase and some patients had treatment interrupted; all resumed treatment by week 76. Starting at 76 weeks and thereafter, patients and study investigators knew that all study participants were on TREMFYA.¹
- b. Dr. Reich is a paid consultant for Janssen. He was not compensated for any media work.
- c. The TREMFYA group included patients who were initially randomized to receive TREMFYA at week 0 and patients who were initially randomized to placebo then crossed over to TREMFYA at week 16.

- d. Investigator's Global Assessment (IGA Score) is a five-point scoring system used to characterize psoriasis severity. Scores range from 0 to 5 and represent cleared (0), almost clear (1), mild (2), moderate (3), severe (4) and very severe (5).⁶
- e. 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.⁷
- f. TREMFYA is FDA approved for administration as a 100 mg subcutaneous (SC) injection every eight weeks, following two starter doses at weeks 0 and 4.²
- g. BASDAI consists of a 0-10 scale (0 being no problem and 10 being the worst problem) which is used to answer 6 questions pertaining to the major symptoms of ankylosing spondylitis: fatigue, spinal pain, joint pain, enthesitis, morning stiffness and duration of morning stiffness.⁸

About Psoriasis

PsO is an immune-mediated disease resulting in an overproduction of skin cells, which causes raised, red, scaly plaques that may be itchy or painful.⁹ It is estimated that 8 million Americans and more than 125 million people worldwide live with the disease.¹⁰ Nearly one-quarter of all people with PsO have cases that are considered moderate to severe.¹⁰ Living with PsO can be a challenge and impact life beyond a person's physical health, including emotional health, relationships, and handling the stressors of life.¹¹

About Psoriatic Arthritis

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 PsO.^{12,13,14} In addition, in patients with PsA, comorbidities such as obesity, cardiovascular diseases, anxiety and depression are often present.¹⁵ Studies show up to 30 percent of people with PsO also develop PsA.¹⁶ 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.¹⁶ 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.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 VOYAGE 2 (NCT02207244)¹⁹

This Phase 3, randomized, double-blind, placebo and active comparator-controlled trial was designed to evaluate the efficacy and safety of TREMFYA compared with placebo and adalimumab in adults with moderate to severe plaque PsO. Patients (N=992) were randomized to receive SC 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. Weeks 28-72 incorporated a randomized withdrawal study design. During the open-label period (weeks 76-252), all patients received TREMFYA 100 mg q8w. Physician- and patient-reported outcomes were assessed. Efficacy was analyzed using pre-specified treatment failure rules (patients discontinuing due to lack of efficacy, worsening of PsO, or use of a prohibited treatment were considered non-responders). Data were combined for patients randomized to TREMFYA and for those originally randomized to placebo who later crossed over to TREMFYA at week 16. Patients were treated and followed for up to 264 weeks.

Co-primary endpoints of the study were proportions of patients receiving TREMFYA vs. patients receiving placebo achieving IGA 0/1 (clear/almost clear) [84 percent vs. 9 percent, respectively; $p < 0.001$ vs. placebo] and PASI 90 [70 percent vs. 2 percent, respectively; $p < 0.001$ vs. placebo] at week 16. Additional efficacy assessments included proportions of patients achieving PASI 75, and PASI 100 responses, as well as IGA scores of 0, a Dermatology Life Quality Index (DLQI) score of 0/1, a Psoriasis Signs and Symptoms Diary (PSSD) score of 0, the 36-Item Short-Form Health Survey (SF36), Hospital Anxiety and Depression scale (HADs) and the Work Limitations Questionnaire (WLQ). Efficacy was analyzed using pre-

specified treatment failure rules, non-responder imputation, and as observed methodology.

VOYAGE 2 is part of a comprehensive Phase 3 clinical development program for TREMFYA in moderate to severe plaque PsO that includes [VOYAGE 1](#), [NAVIGATE](#), and [ECLIPSE](#).^{20,21,22}

About DISCOVER-1 (NCT03162796)²³

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 tumor necrosis factor (TNF) inhibitors. DISCOVER-1 evaluated 381 participants who were treated and followed through approximately one year. The primary endpoint was response of American College of Rheumatology (ACR) 20 at week 24 and primary endpoint data was previously presented at scientific congresses. In addition to ACR20, multiple other clinical outcomes were assessed, including ACR50/70, resolution of soft tissue inflammation, enthesitis and dactylitis, improvement in physical function, skin clearance (IGA), and general health outcomes (36-Item Short-Form Health Survey [SF-36] Physical Component Summary [PCS] and Mental Component Summary [MCS]).

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)²⁴

DISCOVER-2 was a randomized, double-blind, multicenter Phase 3 study evaluating the efficacy and safety of TREMFYA administered by SC injection in bio-naïve patients with active PsA. DISCOVER-2 evaluated 739 participants who were treated and followed through approximately two years. The primary endpoint was response

of ACR 20 at week 24 and primary endpoint data was previously presented at scientific congresses. In addition to ACR20, multiple other clinical outcomes were assessed, including ACR50/70, resolution of soft tissue inflammation, enthesitis and dactylitis, improvement in physical function, skin clearance (IGA), and general health outcomes (SF-36 PCS and MCS). DISCOVER-2 also assessed changes in structural damage as a key secondary endpoint (van der Heijde-Sharp score).

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 TREMFYA® (guselkumab)⁴

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 PsO and PsA.²⁵

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.

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.

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 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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