



News Release

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TREMFYA® (guselkumab) Approved by U.S. Food and Drug Administration as the First Selective Interleukin (IL)-23 Inhibitor for Active Psoriatic Arthritis

In two Phase 3 clinical trials, TREMFYA significantly improved signs and symptoms in joints, skin and soft tissue in adults with active psoriatic arthritis

TREMFYA is the first and only biologic approved for the treatment of active psoriatic arthritis to have improvement in fatigue as measured by FACIT-F in the product label

More than 45,000 patients in the U.S. with moderate to severe plaque psoriasis have been treated with TREMFYA since its original approval in 2017

HORSHAM, PA, July 14, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the U.S. Food and Drug Administration (FDA) has approved TREMFYA® (guselkumab) for adult patients with active psoriatic arthritis (PsA), a chronic progressive disease characterized by painful joints and skin inflammation.^{1,2} TREMFYA is the first treatment approved for active PsA that selectively inhibits interleukin (IL)-23, a naturally occurring cytokine that is involved in normal inflammatory and immune responses associated with the symptoms of PsA.

The safety and efficacy of TREMFYA in PsA have been demonstrated in two pivotal Phase 3 clinical trials. TREMFYA is administered as a 100 mg subcutaneous injection every eight weeks, following two starter doses at weeks 0 and 4. TREMFYA can be used alone or in combination with a conventional Disease Modifying Anti-Rheumatic Drug or DMARD (e.g., methotrexate).

The Unmet Needs in PsA

Psoriatic arthritis affects about 1.5 million Americans.³ Studies show that up to 30 percent of the more than eight million Americans living with psoriasis will also develop PsA.⁴ There is currently no cure for the disease and, despite available treatments, many people living with PsA are still searching for more options that can help alleviate their symptoms and provide some relief.

Psoriatic arthritis is a chronic, progressive, immune-mediated disease characterized by joint inflammation, enthesitis (inflammation where the bone, tendon and ligament meet), dactylitis (severe inflammation of the digits of the hands and feet), axial disease (pain in the axial skeleton, primarily in the spine, hips and shoulders) and the skin lesions associated with psoriasis.¹ The disease commonly appears between the ages of 30 and 50 but can develop at any time.⁵ 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. Without early recognition, diagnosis and treatment, the disease can continue to progress.⁵

“Psoriatic arthritis is a complex multi-faceted disease and, for many patients, additional biologic options are very much needed,” said Philip J. Mease¹, M.D., DISCOVER-2 Lead Study Investigator, Director of Rheumatology Research at the Swedish Medical Center/Providence St. Joseph Health and Clinical Professor at the University of Washington School of Medicine in Seattle, WA. “The two Phase 3 pivotal trials evaluating the safety and efficacy of TREMFYA, an IL-23 inhibitor, for the treatment of adults with active psoriatic arthritis provided insight into how it can improve joint symptoms. Today’s approval is exciting for both patients and their physicians, as there is now a new approach available to help manage the symptoms

of active psoriatic arthritis that patients face day to day.”

Pivotal Data Supporting the TREMFYA Approval

The approval of TREMFYA 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 subcutaneous injection in adults with active PsA compared to placebo. The results, recently published in [The Lancet](#), showed that a significant percentage of patients treated with TREMFYA reached the studies’ primary endpoint of ACR20^a at 24 weeks, with 52 and 64 percent of patients achieving an ACR20 response compared to 22 and 33 percent in patients treated with placebo in DISCOVER-1 and DISCOVER-2, respectively.

In addition, treatment with TREMFYA improved patients’ symptoms, which included skin manifestations of psoriasis, physical functioning as measured by the HAQ-DI (Health Assessment Questionnaire Disease Index)^b and SF-36 Physical Component Summary^c score, and soft tissue (enthesitis and dactylitis). TREMFYA also resulted in improvement in fatigue as measured by the Functional Assessment of Chronic Illness Therapy - Fatigue (FACIT-F).^d

“At Janssen, we strive to reimagine what is possible in how immune-mediated diseases like active psoriatic arthritis are understood and treated,” said David M. Lee, M.D., Ph.D., Therapeutic Area Head, Immunology, Janssen Research & Development, LLC. “TRMFYA is the first and only selective IL-23 inhibitor approved for both active psoriatic arthritis and moderate to severe plaque psoriasis, as well as the only biologic approved for the treatment of psoriatic arthritis to have improvement in fatigue as measured by FACIT-F included in the U.S. Prescribing Information. Today’s approval marks an exciting milestone as we follow the science and search for solutions for patients with these complicated diseases.”

[Click to Tweet](#): #BREAKING: The @US_FDA approves TREMFYA® (guselkumab) for new indication. Read more: <https://bit.ly/3gWQ46c>

The overall safety profile observed in patients with PsA treated with TREMFYA is

generally consistent with the safety profile in patients with plaque psoriasis with the addition of bronchitis and neutrophil count decreased.

About the DISCOVER Development Program

DISCOVER-1 and DISCOVER-2 were Phase 3 randomized, double-blind, placebo-controlled studies that evaluated the safety and efficacy of TREMFYA in 1,120 adult patients with active PsA who had inadequate response to standard therapies. In DISCOVER-1, approximately 31 percent of patients had been previously treated with up to two anti-tumor necrosis factor alpha (anti-TNF α) agents whereas in DISCOVER-2 all patients were naïve to biologic therapy. Approximately 58 percent of patients from both studies had concomitant methotrexate (MTX) use.

The DISCOVER-1 study showed that in patients who received TREMFYA 100 mg every 8 weeks after two starter doses, 52 percent achieved an ACR20 response versus 22 percent treated with placebo ($p < 0.0001$), with a comparable response irrespective of prior TNF exposure. In DISCOVER-2, 64 percent of patients who received TREMFYA every 8 weeks achieved an ACR20 response, versus 33 percent treated with placebo ($p < 0.0001$).

TREMFYA was also shown to relieve patients' pain in their soft tissue and inflammation in their fingers and toes. In a pooled analysis of DISCOVER-1 and -2 at week 24, treatment with TREMFYA every 8 weeks resolved enthesitis in 50 percent of patients, versus 29 percent in patients receiving placebo ($p = 0.0301$). In another pooled analysis at week 24, treatment with TREMFYA every 8 weeks also resolved dactylitis in 59 percent of patients, versus 42 percent receiving placebo ($p = 0.0301$).

Beyond its impact on improving symptoms of PsA in joints, among patients with psoriatic skin involvement, TREMFYA also resulted in an improvement in the skin manifestations of psoriasis in patients with PsA.

"Finding the right psoriatic arthritis treatment can be hard. Individuals living with this complex disease are often left searching for answers, so it's important for patients to understand their options and to work closely with their doctor on a treatment plan,"

said Stacie Bell, Ph.D., Chief Scientific and Medical Officer, National Psoriasis Foundation. "Approval of new treatments for psoriatic arthritis is welcome news for this community and offers physicians and patients more options in their fight to manage this chronic disease."

Administration and Access for TREMFYA

Patients may self-inject with the TREMFYA One-Press injector after physician approval and proper training. The TREMFYA One-Press is a single-dose, patient-controlled injector that has received the Arthritis Foundation's Ease of Use Commendation after being tested in patients with PsA.

Janssen will work closely with payers, providers and pharmacy benefit managers in an effort to help ensure TREMFYA is broadly accessible and affordable for patients living with PsA.

Janssen [CarePath](#) offers a comprehensive support program that helps patients get started on TREMFYA and stay on track. Janssen CarePath provides information on insurance coverage, potential out-of-pocket costs and treatment support, and identifies options that may help make treatment more affordable, including the Janssen CarePath Savings Program for commercially insured patients who are eligible. TREMFYA [BiocoordiNATION](#) offers resources to bio-coordinators within rheumatology and dermatology practices who help patients navigate the healthcare system so that they can start and stay on their prescribed therapy.

About TREMFYA® (guselkumab)

Developed by Janssen, TREMFYA® is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of interleukin (IL)-23 and inhibits its interaction with the IL-23 receptor. It is approved 1) in the U.S., Canada, 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 or UV light) and 2) in the U.S., Japan and Brazil for the treatment of adult patients with active psoriatic arthritis. IL-23 is an important driver of the pathogenesis of

inflammatory diseases such as psoriasis and psoriatic arthritis.¹

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

WHAT IS TREMFYA® (guselkumab)?

TREMFYA® is a prescription medicine used to treat adults with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light).

TREMFYA® is a prescription medicine used to treat adults with active psoriatic arthritis.

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 or www.twitter.com/JanssenUS. Janssen Research & Development, LLC is one 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. 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.

Dr. Philip J. Mease is a paid consultant for Janssen. He has not been compensated for any media work.

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- a. 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).
- b. Health Assessment Questionnaire Disease Index (HAQ-DI): includes 8 categories, reviewing a total of 20 specific functions to evaluate patient difficulty with activities of daily living over the past week. Categories include dressing and grooming, arising, eating, walking, hygiene, reaching, gripping, and errands and chores.
- c. SF-36 Physical Component Summary: 8 multi-item scales assessing physical function, role limitations due to physical health problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems and emotional well-being.
- d. 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).

¹ Belasco J, Wei N. Psoriatic Arthritis: What is Happening at the Joint? *Rheumatol Ther* 2019;6:305-315.

² McLaughlin M, Ostor A. Early Treatment of Psoriatic Arthritis Improves Prognosis. *Practitioner* 2014;258:4-21.

³ Johns Hopkins. Psoriatic Arthritis. Available at: <https://www.hopkinsarthritis.org/arthritis-info/psoriatic-arthritis/#:~:text=What%20is%20Psoriatic%20Arthritis%3F,may%20also%20affect%20the%20spine>. Accessed July 2020.

⁴ National Psoriasis Foundation. Statistics. Available at: <https://www.psoriasis.org/content/statistics>. Accessed July 2020.

⁵ National Psoriasis Foundation. About Psoriatic Arthritis. Available at: <https://www.psoriasis.org/about-psoriatic-arthritis/#:~:text=PsA%20can%20start%20at%20any,psoriatic%20arthritis%20without%20having%20psoriasis>. Accessed July 2020.