**News Release**

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# Janssen Submits Application to U.S. FDA Seeking First-in-Class Approval of TREMFYA® (guselkumab) for Treatment of Adults with Active Psoriatic Arthritis

**HORSHAM, PENNSYLVANIA, September 16, 2019** - The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the submission of a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) seeking first-in-class approval of TREMFYA® (guselkumab) for the treatment of adult patients with active psoriatic arthritis (PsA). Developed by Janssen, TREMFYA is a human monoclonal antibody against the p19 subunit of interleukin (IL)-23. TREMFYA is the first approved selective IL-23 inhibitor. It was approved in the U.S. in July 2017 for the treatment of adult patients with moderate to severe plaque psoriasis and has also been approved in Canada, the European Union, Japan and several other countries worldwide.

The TREMFYA sBLA is based on results from the Phase 3 DISCOVER-1 and DISCOVER-2 studies, which met their primary endpoints of patients achieving an American College of Rheumatology 20 percent improvement (ACR20) response after 24 weeks of treatment. The safety profile observed for TREMFYA in the DISCOVER studies was generally consistent with previous studies as well as the current TREMFYA prescribing information. The DISCOVER program comprises the first-ever Phase 3 studies evaluating a human monoclonal antibody against the p19 subunit of IL-23 for active PsA, and the results have been submitted for presentation at an upcoming medical meeting.

"We're excited about the DISCOVER data and the potential of TREMFYA as a treatment option given the unmet needs of patients living with psoriatic arthritis, a chronic lifelong disease," said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. "DISCOVER-1 and 2 are the ninth and tenth Phase 3 studies Janssen has completed in PsA, across our portfolio of medicines."

In addition to the primary endpoint of ACR20 response at week 24, multiple secondary endpoints were assessed, including ACR50/70, resolution of soft tissue inflammation (enthesitis and dactylitis), disease activity (DAS-28 CRP), improvement in physical function (HAQ-DI), skin clearance (IGA), improvement in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and quality of life (SF-36 PCS and MCS). DISCOVER-2 also assessed effect on structural damage using the van der Heide-Sharp score (vdH-S) as a key secondary endpoint.

"With this submission to the FDA, we hope to offer the first IL-23 p19 inhibitor to clinicians and their patients for active psoriatic arthritis," said Andrew Greenspan, M.D., Vice President, Immunology Medical Affairs, Janssen Scientific Affairs, LLC. "Psoriatic arthritis is a complex disease involving both the skin and the joints with a heterogeneous range of clinical manifestations, and it requires treatment options with different mechanisms of action."

Both DISCOVER trials were randomized, double-blind, multicenter Phase 3 studies designed to evaluate the efficacy and safety of TREMFYA administered by

subcutaneous injection in patients with active PsA compared to placebo. DISCOVER-1 evaluated 381 participants, including those previously treated with anti-TNF therapy, and continued through 52 weeks. DISCOVER-2 included 739 biologic-naïve participants and is planned to continue through 100 weeks.

Janssen also expects to submit a marketing application to the European Medicines Agency seeking approval of TREMFYA as a treatment for PsA before the end of the year.

**About Psoriatic Arthritis**

Psoriatic arthritis (PsA) is a chronic, immune-mediated inflammatory disease characterized by joint inflammation, enthesitis, dactylitis and the skin manifestations of psoriasis.[1] It is estimated that at least one million Americans are living with PsA, and up to 30 percent of patients living with psoriasis can develop PsA.[2] 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.[2] 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.[2]

**About TREMFYA® (guselkumab)**

Developed by Janssen, TREMFYA® is a human monoclonal antibody against the p19 subunit of interleukin (IL)-23, and 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). IL-23 is an important driver of the pathogenesis of inflammatory diseases such as psoriasis and psoriatic arthritis. The TREMFYA development program includes: two Phase 3 programs evaluating TREMFYA in the treatment of active psoriatic arthritis, a Phase 2b/3 program in Crohn's disease, a Phase 2b/3 program in Ulcerative Colitis, and two Phase 2 programs – one exploring biologic combination therapy in Ulcerative Colitis and the other for the treatment of Hidradenitis Suppurativa.

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® may cause serious side effects, including infections.** TREMFYA® is a prescription medicine that 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®?"**

**Serious Allergic Reactions**
Stop using TREMFYA® and get emergency medical help right away if you have any of the following symptoms of a serious allergic reaction: feel faint, swelling of your face, eyelids, lips, mouth, tongue or throat, trouble breathing or throat tightness, chest tightness, or skin rash, hives.

**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 and herpes simplex infections.

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 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 the sBLA submission of TREMFYA to the U.S. Food and Drug Administration. 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 30, 2018, 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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[1] Mayo Clinic. Psoriatic Arthritis. https://www.mayoclinic.org/diseases-conditions/psoriatic-arthritis/symptoms-causes/syc-20354076. Accessed May 2019.
[2] Mease PJ, et al. Prevalence of rheumatologist-diagnosed psoriatic arthritis in patients with psoriasis in European/North American dermatology clinics. J Am Acad Dermatol. 2013;69(5):729-735.