News Release

Media contacts:
Megan Farina
Mobile: (610) 724-1079

Linda Davis
Mobile: (215) 272-8787

Investor contacts:
Chris DelOrefice
Office: (732) 524-2955

Lesley Fishman
Office: (732) 524-3922

Janssen Announces U.S. FDA Approval of Novel TREMFYA® (guselkumab) One-Press Patient-controlled Injector for Adults with Moderate-to-Severe Plaque Psoriasis

Nearly 99 percent of patients using One-Press for the first time completed a successful injection[1]

Following three injections of TREMFYA, half of the patients experienced 100 percent clear skin[1]

HORSHAM, PENNSYLVANIA, February 27, 2019 - The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the U.S. Food and Drug Administration (FDA) has approved TREMFYA® One-Press, a single-dose, patient-controlled injector for adults with moderate-to-severe plaque psoriasis. TREMFYA® (guselkumab) is the first FDA-approved medication of its kind to offer the One-Press patient-controlled injector. One-Press was designed with patients in mind: it fits

comfortably in the hand and offers a controlled injection that hides the needle throughout the process. TREMFYA is administered as a 100 mg subcutaneous injection once every 8 weeks, after starter doses at weeks 0 and 4. TREMFYA is intended for use under the guidance and supervision of a physician, and patients may self-inject with TREMFYA One-Press after physician approval and proper training. TREMFYA One-Press is now available in the U.S.

At times, patients living with plaque psoriasis may struggle with self-administering treatments due to a number of factors, including needle phobia. In the Phase 3, multicenter and randomized ORION study, patient experience with One-Press was assessed through a validated Self-Injection Assessment Questionnaire (SIAQ), which evaluated patient experience at weeks 0, 4 and 12 on a scale of 0 (worst) to 10 (best) across six domains (feelings about injections, self-image, self-confidence, pain and skin reactions during or after the injection, ease of use of the self-injection device and satisfaction with self-injection). The mean score for "Satisfaction with Self Injection" was 9.18 (with 10 indicating "Very Satisfied") and the mean score for "Ease of Use" was 9.24 (with 10 indicating "Very Easy").

The efficacy and safety of TREMFYA administered with One-Press in patients with moderate-to-severe plaque psoriasis was also evaluated in the double-blind, placebo-controlled ORION study. In the study, a greater proportion of patients in the TREMFYA group achieved an IGA score of 0 or 1 or a PASI 90 response at week 16 (81 percent and 76 percent, respectively) than in the placebo group (0 percent for both endpoints). The proportion of patients who achieved an IGA score of 0 at week 16 was higher in the TREMFYA group compared to the placebo group (56 percent vs. 0 percent). The proportion of patients who achieved a PASI 100 response at week 16 was higher in the TREMFYA group compared to the placebo group (50 percent vs. 0 percent). The majority of injection-site reaction symptoms with One-Press were mild and transient in nature.[1]

"The results of the ORION study showed the administration of TREMFYA with One-Press was safe and effective, providing patients with a new, more convenient way to inject their treatment," said Laura Ferris, M.D., Ph.D., Associate Professor, Department of Dermatology, University of Pittsburgh Medical Center*. "These findings

are also exciting as they demonstrated that treatment with TREMFYA helped half the patients achieve complete clearance with a PASI 100 response at week 16."

The design of One-Press allows patients to control the rate and pressure of their injection. A soft click indicates when administration is complete resulting in nearly 99 percent of patients reporting a successful first injection;[1] One-Press also includes a safety system that protects the needle after use. After three injections, patients still reported favorable outcomes with the usability of the One-Press device.[1]

"Patients living with plaque psoriasis often struggle with a conventional syringe when administering treatment," said Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. "With the approval of One-Press, patients now have the option to self-administer TREMFYA with a novel device that is both simple and intuitive to use."

About ORION

ORION is a Phase 3 study that evaluated the pharmacokinetics, efficacy and safety of TREMFYA® (guselkumab) administered with the One-Press injector. In this study, 78 patients were randomized to receive either TREMFYA (100 mg at weeks 0 and 4 and every 8 weeks thereafter) [n=62], or placebo [n=16]. Baseline characteristics for patients were comparable to those observed in VOYAGE 1 and VOYAGE 2. The co-primary endpoints were the proportion of patients who achieved an IGA score of 0/1 and the proportion of patients who achieved a PASI 90 response at Week 16, the same as VOYAGE 1 and VOYAGE 2. Secondary endpoints included the proportion of patients who achieved an IGA score of 0 at week 16 and the proportion of patients who achieved a PASI 100 response at week 16.

About Psoriasis

Psoriasis is a chronic, autoimmune inflammatory disorder that results in the overproduction of skin cells, characterized by raised, inflamed, red lesions, or plaques, which can cause physical pain and itching.[2] It is estimated that more than 7.5 million Americans live with the disease.[3] Approximately 80 percent of those affected with psoriasis have mild to moderate disease, while 20 percent have moderate-to-severe plaque psoriasis.[2]

About TREMFYA® (guselkumab)

TREMFYA® is a human monoclonal antibody developed by Janssen that selectively blocks the protein interleukin (IL)-23 and is approved 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). Ongoing trials include: Two Phase 3 programs evaluating TREMFYA in the treatment of active psoriatic arthritis and a Phase 3 program in Crohn's disease.

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

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

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 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 is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

**Dr. Ferris is a paid consultant for Janssen. She was not compensated for any media work.*

# # #

1. Janssen Global Services, LLC. Data on file. 2018
2. American Academy of Dermatology. What is Psoriasis? https://www.aad.org/public/diseases/scaly-skin/psoriasis/what-is-psoriasis. Accessed January 11, 2019.
3. National Psoriasis Foundation. https://www.psoriasis.org/content/statistics. Accessed January 11, 2019.