News Release

Media contacts:
Kellie McLaughlin
Mobile: (609) 468-8356

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

Lesley Fishman
Office: (732) 524-3922

TREMFYA® (guselkumab), a First-in-Class IL-23 p19 Subunit Inhibitor, Meets Primary Endpoints of Superior ACR20 Responses versus Placebo at Week 24 in Phase 3 Psoriatic Arthritis Studies

Findings from the DISCOVER-1 and DISCOVER-2 studies are presented, for the first time, at the 2019 American College of Rheumatology and Association of Rheumatology Professionals Annual Meeting

These are the first Phase 3 results evaluating p19-specific IL-23 inhibition in active psoriatic arthritis

SPRING HOUSE, PENNSYLVANIA, November 11, 2019 - The Janssen Pharmaceutical Companies of Johnson & Johnson today announced 24-week Phase 3 data showing a significantly greater proportion of patients with active psoriatic arthritis (PsA) treated with TREMFYA® (guselkumab) achieved at least a 20 percent improvement in disease signs and symptoms (American College of Rheumatology ACR20 response) compared to placebo. These findings represent the primary endpoints of the DISCOVER-1 and DISCOVER-2 Phase 3 studies, which were designed

to evaluate the efficacy and safety of investigational use of TREMFYA for the treatment of adult patients with active PsA. These data were presented as part of an oral plenary session (abstract 0807) and a late-breaking poster session (abstract L13), respectively, at the American College of Rheumatology and Association of Rheumatology Professionals (ACR/ARP) 2019 Annual Meeting taking place November 8-13 in Atlanta. Janssen presented more than 30 abstracts at the meeting.

"People living with psoriatic arthritis cope with symptoms like pain, joint swelling and irreversible joint damage that may interfere with their daily activities," said Atul Deodhar, MD, MRCP, FACP, FACR, Professor of Medicine, Oregon Health & Science University and study steering committee member.* "These data show TREMFYA as a potential treatment option to help patients living with this serious disease."

The data presented at ACR are the first Phase 3 study results in active PsA evaluating a human monoclonal antibody against the p19 subunit of IL-23. DISCOVER-1 evaluated 381 participants with active PsA who had an inadequate response to standard therapies, including participants previously treated with anti-tumor necrosis factor (TNF) alpha biologics. DISCOVER-2 evaluated 739 participants with active PsA who were biologic-naive and had an inadequate response to standard therapies.

Results from DISCOVER-1 show that at week 24, 59 percent of adult patients with active PsA receiving TREMFYA every four weeks (q4w) and 52 percent of patients receiving TREMFYA at weeks 0, 4 and every eight weeks thereafter (q8w) achieved an ACR20 response compared to 22 percent of patients receiving placebo (both $p<0.001$). Among patients who had a ≥3 percent body surface area (BSA) affected with psoriasis, and an Investigator Global Assessment (IGA) score of ≥2 at baseline, 75 percent of patients receiving TREMFYA q4w and 57 percent of patients receiving TREMFYA q8w achieved an IGA score of 0 (cleared) or 1 (minimal) and a $\geq$2 grade reduction, compared to 15 percent of patients receiving placebo (both $p<0.001$).

Results from DISCOVER-2 show that at week 24, 64 percent of adult, biologic-naive patients with active PsA receiving TREMFYA q4w or q8w respectively, achieved an ACR20 response, compared to 33 percent of patients receiving placebo (both $p<0.001$). Among patients who had a ≥3 percent BSA affected with psoriasis, and an

IGA score of ≥2 at baseline, 69 percent receiving TREMFYA q4w and 71 percent receiving TREMFYA q8w achieved an IGA score of 0 or 1, and a ≧2 grade reduction from baseline, compared to 19 percent of patients receiving placebo (both $p<0.001$). Patients with active PsA receiving TREMFYA q4w showed significantly reduced radiographic damage progression vs. placebo at week 24.

In DISCOVER-1 and DISCOVER-2, observed adverse events (AEs) were generally consistent with previous studies of TREMFYA and current prescribing information.

Data from the DISCOVER program formed the basis of the September 13, 2019 supplemental Biologics License Application submission to the U.S. Food and Drug Administration (FDA) for approval of TREMFYA and the validated filing on October 11, 2019 to the European Medicines Agency (EMA) for approval of TREMFYA in the European Union for adult patients with active psoriatic arthritis.

"We are passionate about the development of therapies, such as TREMFYA, since patients are still struggling with active psoriatic arthritis and need new treatment options," said Alyssa Johnsen, MD, PhD, Vice President, Rheumatology Disease Area Leader, Janssen Research & Development, LLC. "These results from the DISCOVER program represent a major step in the development of TREMFYA as a treatment for psoriatic arthritis."

The DISCOVER studies also evaluated multiple secondary endpoints, including ACR50/70 response, resolution of soft tissue inflammation (enthesitis and dactylitis), disease activity (DAS-28 CRP), improvement in physical function (HAQ-DI), and general health outcomes (SF-36 PCS and MCS).

About DISCOVER-1 (NCT03162796)

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

The study consists 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, and 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 are being performed in the study on a defined schedule.

About DISCOVER-2 (NCT03158285)

DISCOVER-2 is a randomized, double-blind, multicenter Phase 3 study evaluating the efficacy and safety of TREMFYA administered by subcutaneous 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, and 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.[1] Studies show that up to 30 percent of people with psoriasis also develop psoriatic arthritis.[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.[3] 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.[3]

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 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 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 the Phase 3 TREMFYA DISCOVER-1 and DISCOVER-2 studies. 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.

** Dr. Atul Deodhar is a paid consultant for Janssen. He has not been compensated for any media work.*

# # #

[1] Belasco J. Rheumatol Ther. 2019 Sep; 6(3): 305–315.
[2] Mease PJ, et al. J Am Acad Dermatol. 2013;69(5):729-735
[3] National Psoriasis Foundation. About Psoriatic Arthritis. https://www.psoriasis.org/about-psoriatic-arthritis. Accessed October 2019.