News Release

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Janssen reports top-line Phase 3 results for TREMFYA® (guselkumab) in adults with active psoriatic arthritis

Data are part of the DISCOVER 1 and 2 program, the first Phase 3 studies to evaluate a selective IL-23 p19 inhibitor in the treatment of psoriatic arthritis

HORSHAM, PENNSYLVANIA, June 14, 2019 - The Janssen Pharmaceutical Companies of Johnson & Johnson today announced top-line results from the Phase 3 DISCOVER 1 and 2 studies, which evaluated the efficacy and safety of guselkumab compared to placebo in adult patients with active moderate to severe psoriatic arthritis (PsA). Both studies met their primary endpoints of American College of Rheumatology 20 percent improvement (ACR20), and the safety profiles observed for guselkumab in the DISCOVER program were consistent with previous studies of guselkumab and TREMFYA® current prescribing information.

The DISCOVER program comprises the first-ever Phase 3 studies evaluating an IL-23 p19 inhibitor for the treatment of psoriatic arthritis, and data will be presented at upcoming scientific medical meetings. Data from the two DISCOVER studies will serve as the basis of submissions to the U.S. Food and Drug Administration and European

Medicines Agency seeking approval of guselkumab as a treatment for psoriatic arthritis, which are anticipated for later this year.

The DISCOVER program consists of DISCOVER-1 and DISCOVER-2, two randomized, double-blind, multicenter Phase 3 studies designed to evaluate efficacy and safety of subcutaneous guselkumab in patients with active PsA compared to placebo. In addition to the primary endpoint of ACR20 response at week 24, multiple secondary endpoints were assessed that included ACR50/70, resolution of soft tissue inflammation (enthesitis and dactylitis), disease activity (DAS-28 CRP), improvement in physical function (HAQ-DI), skin clearance (IGA), and quality of life (SF-36 PCS and MCS). DISCOVER-2 also assessed effect on structural damage (vdH-S) as a key secondary endpoint.

DISCOVER-1 included 381 participants, including participants previously treated with anti-TNF biologics. The study continued through 52 weeks. DISCOVER-2 included 739 bio-naive participants and continued through 100 weeks.

About Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, immune-mediated inflammatory disease characterized by joint inflammation, enthesitis, dactylitis and the skin lesions associated with 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 and commonly appears between the ages of 30 and 50, but can develop at any time.[1] 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.[1]

About TREMFYA® (guselkumab)

TREMFYA® is a human monoclonal antibody developed by Janssen that selectively blocks the p19 subunit of 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, a Phase 2b program in Crohn's disease, and two Phase 2 programs – one for the treatment of 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. Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Learn more at www.janssen.com. Follow us at www.twitter.com/JanssenGlobal.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding new study data on 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 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. http://www.mayoclinic.org/diseases-conditions/psoriatic-arthritis/home/ovc-20233896. Accessed May 2019.
2. Mease PJ, et al. J Am Acad Dermatol. 2013;69(5):729-735