Janssen Announces Health Canada Approval of TREMFYA ONE-PRESS™ (guselkumab) – A Patient-Controlled Injector for Adults with Moderate-to-Severe Plaque Psoriasis

Toronto, ON – May 29, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that Health Canada has approved TREMFYA ONE-PRESS™, a single-dose, patient-controlled injector for adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.[1] In 2017, TREMFYA™ (guselkumab) was the first biologic therapy approved by Health Canada that selectively blocks interleukin-23 (IL-23), an inflammatory protein which is present at increased levels in people with plaque psoriasis.[2] TREMFYA ONE-PRESS™, the only anti-IL-23 with a novel patient-controlled self-injection device, is now available in Canada.

Psoriasis affects an estimated one million Canadians. The most common type is plaque psoriasis, affecting 90 per cent of those with the disease.[3] Similar to other chronic conditions, treatment of plaque psoriasis requires significant self-management and can include self-injection of medication. According to recent studies, many patients can struggle when self-administering treatment due to factors including anxiety and fear of injection.[4, 5]

The ergonomic design of TREMFYA ONE-PRESS™ fits comfortably in the hand, features a hidden needle, allows patients to control the rate of their injection, and indicates when administration is complete with a soft click.[6] In the Phase 3, multicentre, double-blind, randomized and placebo-controlled ORION study, nearly 99 per cent of patients had a successful first injection with TREMFYA ONE-PRESS™.[7]

“With no cure, plaque psoriasis requires lifelong management, thus the need for treatment options that are effective, and easy to use, is essential,” said Dr. Ron Vender, Dermatologist and Associate Clinical Professor at McMaster University in the Department of Medicine in Hamilton, ON. “The latest clinical data show positive patient experience with TREMFYA ONE-PRESS™. It’s good news that I can now offer appropriate patients a simple treatment that’s convenient and can help them achieve clear skin.”

The efficacy and safety of TREMFYA™ administered using a novel patient-controlled injector (One-Press) in patients with moderate-to-severe plaque psoriasis was also evaluated in the ORION study.[8] The week 16 co-primary endpoints were the proportions of patients achieving Investigator Global Assessment (IGA) cleared/minimal (IGA 0/1) and Psoriasis Area and Severity Index 90 per cent improvement (PASI 90) responses.[9] A greater proportion of patients in the TREMFYA™ group achieved an IGA of 0 or 1 or a PASI 90 at week 16 (81 per cent and 76 per cent, respectively) than in the placebo group (0 per cent for both endpoints).[10] The proportion of patients who achieved an IGA of 0 or a PASI 100 (indicating 100 per cent clear skin) at week 16 was higher in the TREMFYA™ group (56 per cent and 50 per cent) compared to the placebo group (0 per cent for both endpoints).[11] The majority of injection-site reaction symptoms with One-Press were mild and transient in nature.[12]

About Psoriasis

Psoriasis is a chronic, inflammatory skin condition in which a person's skin cells shed at 10 times the normal rate. It is characterized by raised, red patches called "plaques" which are often covered with silvery-white flakes called scales.[13] Psoriasis often causes as much disability as cancer, diabetes and other major medical diseases.[14]

About TREMFYA™/TREMFYA ONE-PRESS™ [15]

TREMFYA™/ TREMFYA ONE-PRESS™ (guselkumab injection) 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).

TREMFYA ONE-PRESS™ is administered as a 100 mg subcutaneous injection once every 8 weeks, after starter doses at weeks 0 and 4. TREMFYA ONE-PRESS™ is intended for use under the guidance and supervision of a physician, and patients may self-inject after proper training.

TREMFYA™ received Health Canada approval based on results from two 48 week pivotal phase 3 studies, VOYAGE 1 and VOYAGE 2, which demonstrated significant efficacy in adult patients with moderate to severe plaque psoriasis treated with TREMFYA™.[16, 17]

In the VOYAGE 1 and VOYAGE 2 studies, at week 16 at least seven out of ten TREMFYA™-treated patients achieved at least 90 percent clearer skin, and more than 80 percent demonstrated cleared or almost cleared skin. In VOYAGE 1 at week 16, 37% of patients receiving TREMFYA™ achieved PASI 100 compared to 17% of adalimumab treated patients, and 1% of placebo treated patients. In VOYAGE 2, at Week 16, 34% of patients receiving TREMFYA™ achieved PASI 100 compared to 21% of adalimumab treated patients, and 1% of placebo-treated patients.

For information on TREMFYA™/TREMFYA ONE-PRESS™, please refer to the Canadian product monograph, which can be found here.

About ORION[18]

ORION is a Phase 3 study that evaluated the efficacy, safety and pharmacokinetics of guselkumab administered using a novel patient-controlled injector (TREMFYA ONE-PRESS™). 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.

A greater proportion of patients in the guselkumab group achieved an IGA score of 0 or 1 or a PASI 90 response at Week 16 (81% and 76%, respectively) than in the placebo group (0% for both endpoints). The proportion of patients who achieved an IGA score of 0 at Week 16 was higher in the guselkumab group compared to the placebo group (56.5% vs. 0%). The proportion of patients who achieved a PASI 100 response at Week 16 was higher in the guselkumab group compared to the placebo group (50.0% vs. 0%).

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/canada. Follow us on Twitter at @JanssenCanada.

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 ONE-PRESS™. 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 behaviour 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. Vender was not compensated for any media work. He has been compensated as a consultant.*

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For further information: Media Contact: Janssen Inc., Gina DeBenedetti, Office: 416-382-5138

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