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Health Canada Approves TREMFYA®* (guselkumab injection), a First-In-Class Selective Interleukin (IL)-23 Inhibitor for Active Psoriatic Arthritis

Data show TREMFYA® significantly improved signs and symptoms in joints, skin, and soft tissue of adults with active psoriatic arthritis

Toronto, ON, September 10, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that Health Canada has approved TREMFYA® (guselkumab injection) for adult patients with active psoriatic arthritis (PsA), a chronic progressive disease characterized by painful joints and skin inflammation. TREMFYA® can be used alone or in combination with a conventional disease-modifying antirheumatic drug (cDMARD), such as methotrexate. TREMFYA® is also approved for the treatment of adult patients with moderate-to-severe plaque psoriasis.[1]

TREMFYA® is the first and only biologic approved for the treatment of both active PsA and moderate to severe plaque psoriasis that selectively inhibits interleukin (IL)-23, a naturally occurring cytokine involved in normal inflammatory and immune responses. Interleukin (IL)-23 is present at increased levels in people with plaque psoriasis.[2]

Psoriatic arthritis is an inflammatory form of arthritis affecting approximately 94,000 Canadians.[3] Studies show up to 30 percent of the one million Canadians living with psoriasis will develop PsA during their lifetime.[4] Psoriatic arthritis causes swelling and pain in the joints, often leading to mobility issues. Without treatment, persistent inflammation from PsA can lead to irreversible joint damage.[5]

"This new approval represents an important advancement for patients and physicians navigating treatment options for psoriatic arthritis," said Dr. Ron Vender**, Associate Clinical Professor of Medicine at McMaster University, and Director of Dermatrials Research Inc. "TREMFYA® is already a well-established and proven treatment for patients with psoriasis of the skin, and the data show it

can now benefit patients with psoriatic arthritis, providing evidence of significant improvement in joint symptoms."

This approval for TREMFYA® is based on results from two pivotal Phase 3 clinical trials; DISCOVER-1 and DISCOVER-2, which evaluated the efficacy and safety of TREMFYA®, administered by subcutaneous injection in adults with active PsA compared to a placebo. The results, recently published in *The Lancet*, demonstrated that patients treated with TREMFYA® reached the primary endpoint of ACR20 response at 24 weeks in both studies (an improvement of at least 20 percent in the number of tender and swollen joints, and at least 20 percent improvement in three of the following five criteria: patient global assessment, physician global assessment, functional ability measure, visual analog pain scale, and C-reactive protein).[6,7] In DISCOVER-1 and DISCOVER-2 respectively, 52 and 64 percent of patients achieved an ACR20 response, compared to 22 and 33 percent of patients treated with the placebo.[8]

"We are excited to have the opportunity to bring guselkumab to patients living with psoriatic arthritis, as well as to the doctors who treat them," said Alyssa Johnsen, M.D., Ph.D., Vice President, Rheumatology Disease Area Leader, Janssen Research & Development, LLC. "Guselkumab reinforces our broad commitment to developing first-in-class treatments for patients living with psoriatic arthritis and other immune-mediated diseases."

The DISCOVER clinical program also demonstrated that treatment with TREMFYA® improved other patient symptoms including skin lesions associated with psoriasis, physical functioning, and soft tissue inflammation (enthesitis and dactylitis). TREMYFA® also resulted in improvement in fatigue.[9]

"Although there is no cure for psoriatic arthritis, starting the right treatment can help patients manage pain and improve physical function and quality of life," said Dr. Proton Rahman***, Rheumatologist at Eastern Health, and Professor of Medicine at Memorial University, St John's, NL. "The safety and efficacy data supporting this approval are an essential step forward for the psoriatic arthritis community, providing physicians with a new option when determining the most appropriate therapy for their patients, and ensuring continuity throughout the treatment journey."

About Psoriatic Arthritis

Psoriatic arthritis is a chronic, progressive, immune-mediated disease characterized by joint inflammation, enthesitis (inflammation where the bone, tendon and ligament meet), dactylitis (severe inflammation of the digits of the hands and feet), axial disease (pain in the axial skeleton, primarily in the spine, hips and shoulders) and the skin lesions associated with psoriasis.[10] The disease commonly appears between the ages of 30 and 50 but can develop at any time. 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. Without early recognition, diagnosis and treatment, the disease can continue to progress.[11]

About the DISCOVER Development Program

DISCOVER-1 and DISCOVER-2 were Phase 3 randomized, double-blind, placebo-controlled studies that evaluated the safety and efficacy of TREMFYA® in 1,120 adult patients with active PsA who had inadequate response to standard therapies. In DISCOVER-1, approximately 30 percent of patients had been previously treated with up to two anti-tumor necrosis factor alpha (anti-TNFα) agents, whereas in DISCOVER-2 all patients were naïve to biologic therapy. Approximately 58 percent of patients from both studies had concomitant methotrexate (MTX) use.[12]

The DISCOVER-1 study showed that in patients who received TREMFYA® 100 mg every 8 weeks after two starter doses, 52 percent achieved an ACR20 response versus 22 percent treated with placebo ($p < 0.001$) at week 24, with a comparable response irrespective of prior TNF exposure. In DISCOVER-2, 64 percent of patients who received TREMFYA® every 8 weeks after two starter doses achieved an ACR20 response, versus 33 percent treated with placebo ($p < 0.001$) at week 24.[13]

In addition, treatment with TREMFYA® resulted in improvement in dactylitis and enthesitis in patients with pre-existing dactylitis or enthesitis.[14]

Beyond its impact on improving symptoms of PsA in joints, among patients with psoriatic skin involvement, TREMFYA® also resulted in an improvement in the skin manifestations of psoriasis in patients with PsA.[15]

About TREMFYA® / TREMFYA ONE-PRESS™ (guselkumab injection)

TREMFYA® / TREMFYA ONE-PRESS™ is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of interleukin (IL)-23 and inhibits its interaction with the IL-23 receptor. It 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). It is also approved in Canada, the U.S., Japan and Brazil for the treatment of adult patients with active psoriatic arthritis. IL-23 is an important driver of the pathogenesis of inflammatory diseases such as psoriasis and psoriatic arthritis.[16]

TREMFYA ONE-PRESS™ is administered as a 100 mg subcutaneous injection once every 8 weeks for plaque psoriasis and every 8 weeks for psoriatic arthritis, 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.[17]

The overall safety profile observed in patients is similar across indications. The most frequently reported adverse drug reaction (>1%) through the placebo-controlled period of the Phase 3 plaque psoriasis and psoriatic arthritis clinical trials in TREMFYA®-treated patients were respiratory tract infections, injection site reactions, diarrhea, headache, joint pain (arthralgia), and increased level of liver enzymes in the blood.[18]

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

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

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 at @JanssenCanada. Janssen Inc. and Janssen Research & Development, LLC are members 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 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 29, 2019, 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.

*All trademark rights used under license.
**Dr. Ron Vender was not compensated for any media work. He has been compensated as a consultant.
***Dr. Proton Rahman was not compensated for any media work. He has been compensated as a consultant.

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