News Release

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Janssen Inc. Announces Health Canada Approval of TREMFYA™ (guselkumab) for the Treatment of Adult Moderate to Severe Plaque Psoriasis

TREMFYA™ is the first approved biologic that selectively blocks interleukin-23

Toronto, ON (November 15, 2017) -- Janssen Inc. announced today that Health Canada has approved TREMFYA™ (guselkumab) for the treatment of adults living with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.[1] TREMFYA™ is the first approved biologic therapy that selectively blocks interleukin-23 (IL-23), a key inflammatory protein that plays an important role in plaque psoriasis.[1,2]

TREMFYA™ received this 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™.[3,4]

In clinical studies, patients who received TREMFYA™ experienced significant improvement in skin clearance and greater improvement in symptoms of plaque psoriasis including itch, pain, stinging, burning and skin tightness when compared with placebo at 16 weeks.[3,4] At least seven out of ten TREMFYA™ patients achieved at least 90 per cent clearer skin at 16 weeks.[3,4]

"In some patients, psoriasis can be extremely difficult to treat," said Dr. Richard Langley, dermatologist, professor of medicine and director of research in the Division of Clinical Dermatology and Cutaneous Science at Dalhousie University*. "TREMFYA™ represents an important milestone in the treatment of moderate to severe plaque psoriasis with skin clearance demonstrated in the majority of study patients receiving this IL-23–specific therapy at week 16 and up to week 48. The approval of TREMFYA™ represents the progress that has been made in understanding the science of psoriasis, and the important role IL-23 plays in this disease."

"A new and effective treatment option, like TREMFYA™, is always welcome news for the psoriasis patient community," said Kathryn Andrews-Clay, Executive Director, Canadian Association of Psoriasis Patients. "Psoriasis not only takes a tremendous toll on a patient's body as dry, flaky skin, which characterizes the disease can appear on the scalp, hands, feet and more, it can also impact a patient's confidence and mental health."

"We know from our membership and research that people with psoriasis are often debilitated by their disease. Therefore, new, innovative treatments can provide renewed hope to many patients looking for improved quality of life through clear skin," added Simmie Smith, President, Canadian Psoriasis Network.

For over 75 years, Janssen has been committed to helping improve the lives of patients with immunological diseases. This has led to advances in care for thousands of psoriasis patients worldwide, including Canada.

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. Psoriasis affects an estimated one million Canadians[5] and often causes as much disability as cancer, diabetes and other major medical diseases.[6]

About TREMFYA™ (guselkumab)[1]
TREMFYA™ is a human monoclonal antibody that selectively blocks the inflammatory protein interleukin-23 (IL-23) and is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who may benefit from taking systemic therapy or phototherapy. TREMFYA™ is administered as a 100 mg subcutaneous injection every eight weeks, following two starter doses at weeks 0 and 4. The most common side effects (>10%) experienced by TREMFYA™ patients were upper respiratory infections.[3,4]

Clinical trials evaluating TREMFYA™ in the treatment of active psoriatic arthritis are underway including a Phase 3 program evaluating the efficacy of TREMFYA™ compared with Cosentyx®* (secukinumab) in the treatment of adults with moderate to severe plaque psoriasis and a Phase 3 program is planned to study TREMFYA™ in the treatment of moderately to severely active Crohn's disease.

About the Janssen Pharmaceutical Companies
At the Janssen Pharmaceutical Companies, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com/canada. Follow us on Twitter @JanssenCanada.

*Dr. Langley was not compensated for any media work. He has been a paid consultant to Janssen Inc.

Cautions Concerning Forward-Looking Statements
This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding potential benefits and continued development of TREMFYA™ (guselkumab). 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 Inc. and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in product research and development, including the uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for

new products or new indications; 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 January 1, 2017, including under "Item 1A. Risk Factors," its most recently filed Quarterly Report on Form 10-Q, including in the section captioned "Cautionary Note Regarding Forward-Looking Statements," 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. Neither Janssen Inc. 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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References

[1] TREMFYA™ Product Monograph. Janssen Inc. November 10, 2017.
[2] Bachelez H. Interleukin 23 inhibitors for psoriasis: not just another number. *Lancet* 2017;390(10091):208-210.
[3] Blauvelt, A et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the continuous treatment of patients with moderate to severe psoriasis: Results from the phase III, double-blinded, placebo- and active comparator–controlled VOYAGE 1 trial. *Journal of the American Academy of Dermatology*. 2017;76:405-417.
[4] Reich, K et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the treatment of patients with moderate to severe psoriasis with randomized withdrawal and retreatment: Results from the phase III, double-blind, placebo- and active comparator–controlled VOYAGE 2 trial. *Journal of the American Academy of Dermatology*. 2017;76:418-431.
[5] Canadian Dermatology Association. https://dermatology.ca/public-patients/skin/psoriasis/ (Accessed October 26, 2017).
[6] Rapp, S.R. et al. Psoriasis causes as much disability as other major medical diseases. *Journal of the American Academy of Dermatology*. 1999;41:401-407.