Media Contact:
Laura Espinoza
Office: (416) 382-5156

Investor Contact:
Lesley Fishman
Office: (732) 524-3922

Health Canada Approves New Indication for STELARA®* (ustekinumab) for the Treatment of Adults with Moderately to Severely Active Ulcerative Colitis

In the Phase 3 pivotal trial, nearly 44 per cent of patients receiving STELARA® subcutaneous (SC) injections every 8 weeks were in clinical remission at one year

TORONTO, ON (January 27, 2020) — The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that Health Canada has approved STELARA® (ustekinumab) for the treatment of adult patients with moderately to severely active ulcerative colitis (UC). The approval for this new indication is based on the pivotal Phase 3 UNIFI clinical trial which achieved its primary endpoint of clinical remission. Results from UNIFI demonstrate that treatment with STELARA® both induced and maintained clinical remission in a significantly greater proportion of adult patients with moderately to severely active UC compared to placebo.[1]

Ulcerative colitis is a chronic and progressive inflammatory disease of the digestive tract.[2] It is one of the main forms of inflammatory bowel disease (IBD),[3] a disease that affects 270,000 Canadians,[4] one of the highest rates of IBD worldwide.[5] While symptoms vary, the disease can be characterized by bloody diarrhea, abdominal pain and cramps, but can also include mild fever, anemia, fatigue, loss of appetite

and weight loss.[6]

"There still remains significant unmet need in UC as the disease affects each patient differently, and it can be more difficult to achieve remission than in other immune disease states," says Dr. Hillary Steinhart, gastroenterologist, Mount Sinai Hospital Inflammatory Bowel Disease Centre.** "This new indication for STELARA® offers patients with moderately to severely active UC the possibility of durable remission and relief from the often painful and debilitating symptoms of the disease."

In patients with UC, two proteins (or cytokines) in the body called interleukin (IL)-12 and IL-23 that are involved in the immune system are dysregulated, which triggers an inflammatory response. STELARA® is the first and only biologic therapy for UC that blocks IL-12 and IL-23 cytokines. The IL-12 and IL-23 pathway has been shown to play a key role in controlling mucosal inflammation and immune responses.[7] Since receiving Health Canada approval in December 2008 for the treatment of adults living with moderate to severe plaque psoriasis, STELARA® has received approval for four additional indications: adolescent patients with moderate to severe plaque psoriasis, adults with active psoriatic arthritis, adults with moderately to severely active Crohn's disease (CD), and now adults with moderately to severely active ulcerative colitis.

About the UNIFI Trial

The UNIFI trial included an initial Induction study (UNIFI-I) where patients received a single dose of STELARA® 6 mg/kg intravenous (IV) infusion, followed 8 weeks later by a Maintenance study (UNIFI-M) where patients received STELARA® 90 mg subcutaneous (SC) injections every 8 or 12 weeks for 44 weeks. Both studies demonstrated the safety and efficacy of STELARA® as a treatment option for patients with moderately to severely active UC, and the design and complete results were recently published in the New England Journal of Medicine.[8]

In the Induction study, 16 per cent of patients receiving STELARA® achieved clinical remission in just 8 weeks.[9] In addition, STELARA® provided patients with rapid relief of their symptoms as 62 per cent of patients receiving STELARA® experienced a clinical response at week 8. In the Maintenance study, 44 per cent of patients receiving STELARA® every 8 weeks were in clinical remission at one year. STELARA® also helped patients achieve clinical remission without the use of corticosteroids. At one year, 42 per cent of patients treated with STELARA® were in corticosteroid-free clinical remission.[10]

The overall safety profile of STELARA® in UC was consistent with what has been observed across all approved indications of STELARA®.

About Ulcerative Colitis

IBD is believed to involve a genetic predisposition and a trigger in the environment that are combined to set off inflammation in the gut.[11] In UC, inflammation invades the inner lining of the bowel tissue, and typically affects the colon (large intestine).[12] Rates are similar for men and women, and the peak onset is usually between 15-45 years of age.[13]

About STELARA® (ustekinumab)

STELARA® is indicated in Canada for the treatment of adults living with Crohn's disease, ulcerative colitis, psoriasis, and active psoriatic arthritis, as well as for adolescent patients with psoriasis.[14]

STELARA® blocks the action of two proteins in the body called interleukin (IL)-12 and IL-23. In people with psoriasis, psoriatic arthritis, Crohn's disease or UC, their immune system may attack parts of their body, and that attack uses IL-12 and IL–23. STELARA® can block the IL-12 and IL-23 from causing the immune system to attack the skin, nails, joints or the digestive tract.[15]

Common side effects reported with STELARA® include, upper respiratory infections (such as the common cold), infections of the nose and throat, sore throat, dizziness, headache, diarrhea, nausea and vomiting, itching, back pain, muscle aches, joint pain, tiredness, redness and pain at the injection site, sinus infections.[16]

For full Product Monograph and more information about STELARA®/ STELARA® IV, please visit www.janssen.com/canada.

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.

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***Dr. Steinhart was not compensated for any media work. He has been compensated as a consultant.*

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding STELARA®. 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., 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.

References

[1] Sands, B.E. et al. Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis. *New England Journal of Medicine.* 2019; 381:1201-1214.
[2] Crohn's and Colitis Canada. What are Crohn's and Colitis? Available at: https://crohnsandcolitis.ca/About-Crohn-s-Colitis/What-are-Crohns-and-Colitis. Accessed November 19, 2019.
[3] Crohn's and Colitis Canada. What are Crohn's and Colitis? Available at: https://crohnsandcolitis.ca/About-Crohn-s-Colitis/What-are-Crohns-and-Colitis. Accessed November 19, 2019.

[4] Crohn's and Colitis Canada. 2018 Impact of Inflammatory Bowel Disease in Canada. Available at: https://crohnsandcolitis.ca/Crohns_and_Colitis/documents/reports/2018-Impact-Report-LR.pdf. Accessed November 19, 2019.
[5] Rocchi A, Benchimol EI, Bernstein CN, et al. Inflammatory bowel disease: a Canadian burden of illness review. *Can J Gastroenterol*. 2012;26(11):811-7.
[6] Crohn's and Colitis Canada. What are Crohn's and Colitis? Available at: https://crohnsandcolitis.ca/About-Crohn-s-Colitis/What-are-Crohns-and-Colitis. Accessed November 19, 2019.
[7] STELARA® Product Monograph. Janssen Inc. Updated January 23, 2020.
[8] Sands, B.E. et al. Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis. *New England Journal of Medicine.* 2019; 381:1201-1214.
[9] Sands, B.E. et al. Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis. *New England Journal of Medicine.* 2019; 381:1201-1214.
[10] Sands, B.E. et al. Ustekinumab as Induction and Maintenance Therapy for Ulcerative Colitis. *New England Journal of Medicine.* 2019; 381:1201-1214.
[11] Crohn's and Colitis Canada. Are you at Risk? Available at: https://crohnsandcolitis.ca/About-Crohn-s-Colitis/Are-you-at-risk. Accessed November 19, 2019.
[12] Crohn's and Colitis Canada. What are Crohn's and Colitis? Available at: https://crohnsandcolitis.ca/About-Crohn-s-Colitis/What-are-Crohns-and-Colitis. Accessed November 19, 2019.
[13] Crohn's and Colitis Canada. What are Crohn's and Colitis? Available at: https://crohnsandcolitis.ca/About-Crohn-s-Colitis/What-are-Crohns-and-Colitis. Accessed November 19, 2019.
[14] STELARA® Product Monograph. Janssen Inc. Updated January 23, 2020.
[15] STELARA® Product Monograph. Janssen Inc. Updated January 23, 2020.
[16] STELARA® Product Monograph. Janssen Inc. Updated January 23, 2020.