News Release

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STELARA®* (USTEKINUMAB) RECEIVES HEALTH CANADA APPROVAL FOR TREATMENT OF ACTIVE PSORIATIC ARTHRITIS

First and Only Anti-IL-12/23 Treatment Approved for Adult Patients Living with Psoriatic Arthritis

Toronto, ON, January 22, 2014 - Janssen Inc. announced today that Health Canada approved STELARA® (ustekinumab) for the treatment of adult patients with active psoriatic arthritis, alone or in combination with methotrexate. It is estimated that approximately 30 per cent of Canadians living with psoriasis may develop psoriatic arthritis,[i] a chronic autoimmune disease characterized by both joint inflammation and psoriasis skin lesions. The condition is associated with reduced quality of life and increased mortality.[ii]

"Already an established treatment for moderate to severe chronic plaque psoriasis, ustekinumab is the first and only anti-IL12/23 biologic option approved for psoriatic arthritis," said Dr. Wayne Gulliver**, Professor of Dermatology and Medicine, Faculty of Medicine, Memorial University of Newfoundland. "This is good news for patients because it offers an additional treatment option with a novel mode of action that addresses not only the signs and symptoms of psoriatic skin disease, but also the signs and symptoms of psoriatic arthritis along with improvement of physical function."

Psoriatic arthritis is a type of inflammatory arthritis that causes swelling, pain and inflammation.[iii] It affects both men and women in equal numbers and usually appears between the ages of 20 and 50.[iii] Although the exact cause of psoriatic arthritis is unknown, genes, the immune system and environmental factors are believed to play a role in the onset of the disease.[iii]

Health Canada's approval is supported by findings from two pivotal Phase 3 Multicenter, Randomised, Double-blind, Placebo-controlled trials of Ustekinumab, a Fully Human anti-IL-12/23p40 Monoclonal Antibody, Administered Subcutaneously, in Subjects with Active Psoriatic Arthritis (PSUMMIT I and PSUMMIT II), which evaluated the efficacy and safety of subcutaneously-administered STELARA® 45 mg or 90 mg at weeks 0, 4 and then every 12 weeks.[iv] The trials included 927 patients diagnosed with active psoriatic arthritis who had at least five tender and five swollen joints in spite of previous treatment with conventional

therapy.[ii,iv] PSUMMIT II also included 180 patients with previous exposure to one or more tumor necrosis factor (TNF) inhibitors.[iv]

Results from PSUMMIT I showed that at week 24, 42 per cent and 50 per cent of patients receiving STELARA® 45 mg and 90 mg, respectively, achieved at least 20 per cent improvement in signs and symptoms according to the American College of Rheumatology criteria (ACR 20), the primary endpoint for both studies.[ii] In PSUMMIT II, 44 per cent of patients receiving STELARA® 45 mg and 44 per cent of patients receiving STELARA® 90 mg achieved ACR 20 at week 24.[iv] Additionally, STELARA® improved soft tissue components of the disease, including dactylitis (inflammation of the finger or toe), enthesitis (inflammation of the entheses, the sites where tendons or ligaments attach to bone) and skin component as measured by Psoriasis Area and Severity Index score (PASI) 75.[iv]

Patients treated with STELARA® 45 mg and 90 mg also showed significant improvement in physical function as assessed using the Disability Index of the Health Assessment Questionnaire (HAQ-DI) at week 24 as compared to placebo in both PSUMMIT I and PSUMMIT II—a secondary endpoint in the studies.[iv]

The safety results of STELARA® observed in the PSUMMIT studies were consistent with the overall safety profile of STELARA® in the labelled chronic moderate to severe plaque psoriasis indication, which has five years of safety experience from clinical trials.

About STELARA® (Ustekinumab)

STELARA®, a human interleukin (IL)-12 and IL-23 antagonist, is approved for the treatment of adult patients (18 years or older) with chronic moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy, and alone or in combination with methotrexate for the treatment of adult patients with active psoriatic arthritis.[iv] IL-12 and IL-23 are naturally occurring proteins that are believed to play a role in inflammatory conditions such as psoriasis and psoriatic arthritis.[iv]

STELARA® is administered by subcutaneous injection. For the treatment of moderate to severe plaque psoriasis and active psoriatic arthritis, the recommended dose of STELARA® is 45 mg administered at weeks 0 and 4, then every 12 weeks thereafter.[iv] Alternatively, 90 mg may be used for patients with a body weight greater than 100 kg.[iv]

Common side effects of STELARA® include upper respiratory infections, headache, tiredness, joint pain and nausea. These are not all of the possible side effects with STELARA®. Tell your doctor about any side effect that you experience. Ask your doctor or pharmacist for more information.[iv]

Please refer to the STELARA® Product Monograph for additional safety information. Complete prescribing information is available at www.janssen.ca.

Janssen Biotech, Inc. discovered and developed STELARA®, and the Janssen Pharmaceutical Companies maintain exclusive worldwide marketing rights to STELARA®.

About Janssen Inc.

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, metabolic and chronic diseases and women's health. Driven by our commitment to patients, we bring innovative products, services and solutions to people throughout the world. Janssen Inc. is part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit www.janssen.ca for more information.

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

References:

[i] Psoriasis Community Canada. Psoriasis. Available at: http://www.canadianpsoriasis.ca/content/psoriasis. Accessed December 12, 2013.

[ii] McInnes et al. Efficacy and safety of ustekinumab in patients with active psoriatic arthritis: 1 year results of the phase 3, multicenter, double-blind, placebo-controlled PSUMMIT I trial. *Lancet* 2013; 382: 780-789. Summary | Full Text

[iii] The Arthritis Society. Psoriatic Arthritis. Available at: http://www.arthritis.ca/page.aspx?pid=1011. Accessed December 12, 2013.

[iv] STELARA® Product Monograph, Janssen Inc., 2014. Available at www.janssen.ca.