

Approval of STELARA™ in Canada Marks Advancement in Treatment of Moderate to Severe Plaque Psoriasis

~ In clinical studies, patients receiving STELARA showed sustained improvements in psoriasis and quality of life measures through 76 weeks ~

Toronto, ON – (December 15, 2008) – Canadians living with moderate to severe plaque psoriasis, a chronic and often debilitating inflammatory disease, now have a new treatment option with the approval of STELARA™ (ustekinumab). STELARA, which is self-injected every 12 weeks following two starter doses at weeks 0 and 4, has demonstrated significant efficacy in clinical studies involving more than 3,000 participants from around the world. In Canada, STELARA is marketed by Janssen-Ortho Inc.

The recommended dose of STELARA is 45 mg administered at Weeks 0 and 4, then every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight greater than 100 kg. Treatment is intended for use under the guidance and supervision of a physician. STELARA is indicated for adult patients who are candidates for phototherapy or systemic therapy.¹

“This is an exciting new advancement in the management of psoriasis with approximately two-thirds of adults receiving STELARA having achieved at least 75 per cent improvement in their psoriasis within the first 12-week course of dosing in clinical trials²,” said Dr. Richard Langley: Associate Professor of Medicine in Dermatology, Director of Dermatology Research at Dalhousie University, and study investigator. “Every twelve-week dosing makes STELARA a much-anticipated therapeutic option for patients living with moderate to severe psoriasis.”

A human monoclonal antibody, STELARA targets the activity of cytokines interleukin-12 (IL-12) and interleukin-23 (IL-23), naturally occurring proteins that are important in regulating the immune system and that are thought to be associated with some immune related inflammatory diseases including plaque psoriasis. The treatment regulates IL-12 and IL-23 interactions, reducing inflammation in the skin cells and helping to control the signs and symptoms of psoriasis.¹

Data Shows Improvements to Physical and Quality of Life Burdens

STELARA was studied in two pivotal phase III clinical trials.³ The trials demonstrated that the majority of patients with moderate to severe plaque psoriasis who received STELARA sustained, clinically significant improvement in their disease severity. At week 12, the primary endpoint of both studies, 66 percent to 76 percent of patients who received just two doses of STELARA, 45 mg or 90 mg, respectively, at weeks 0 and 4, achieved PASI 75 (75 per cent improvement on the Psoriasis Activity and Severity Index) compared with 3 to 4 per cent of patients receiving placebo (p<0.001). Long-term results from these studies through 76 weeks were published in *The Lancet* in May 2008.

Rates of serious adverse events, including serious infections, malignancies and cardiovascular event, were low and consistent with the expected background rates. The most common adverse events in Phase 3 clinical trials were arthralgia, cough, headache, injection site erythema, nasopharyngitis and upper respiratory tract infection.

An additional Phase 3 study evaluated the safety and efficacy of STELARA compared with etanercept* in 903 patients with chronic plaque psoriasis (etanercept=347, STELARA 45 mg=209, STELARA 90 mg=347)¹. Patients were randomized to receive STELARA 45 mg or 90 mg doses at weeks 0 and 4, while the etanercept group received twice-weekly doses of 50 mg over 12 weeks. The primary endpoint of the study was the proportion of patients who achieved a PASI 75 at week 12. Study results showed that 68 percent and 74 percent of patients receiving STELARA 45 mg or STELARA 90 mg, respectively, at weeks 0 and 4 achieved PASI 75 compared with 57 percent of patients receiving twice-weekly doses of etanercept 50 mg over 12 weeks (P=0.012 for STELARA 45 mg; P<0.001 for STELARA 90 mg, each compared with etanercept).

Through week 12, the comparator-controlled portion of the study, the percentages of study participants experiencing at least one adverse event (AE) were comparable between the STELARA 45 mg group (66 percent), the STELARA 90 mg group (68 percent) and the etanercept 50 mg group (69 percent). The most common AEs included nasopharyngitis, headache, upper respiratory tract infection, back pain, pruritus, fatigue, arthralgia, injection site erythema and injection site swelling.

In addition to improvements in physical symptoms, the phase III pivotal trials also demonstrated clinically meaningful improvements in quality of life measures, which were significant as early as Week 2 in patients treated with STELARA (p<0.001) in one of the Phase 3 studies and these improvements were maintained over time with continued dosing.⁴

“The approval of STELARA is an important milestone for psoriasis patients,” said Christine Jackson, Executive Director of the Canadian Skin Patient Alliance. “The impact of today’s news is significant for psoriasis patients. These individuals not only need new options to manage their disease, but it is critical that they have access to these treatments as well.”

About Psoriasis

Psoriasis is a chronic, recurring and often debilitating inflammatory disease that affects approximately one million Canadian adults.⁵ It is a common immune mediated skin disease in adults and one of the oldest skin conditions known to man.⁶ The symptoms of psoriasis usually appear between the ages of 15 and 35 with 75 per cent of people developing it before the age of 40.⁷

Plaque psoriasis is the most common form and affects approximately 80 per cent of those suffering from the condition.⁸ It usually results in painful, itchy, sore patches of thick, red



or inflamed skin covered with silvery scales known as plaques. Plaques can occur anywhere on the body – most commonly on the elbows, knees, lower back and the area around the bellybutton. Severity ranges from minor localized patches to complete body coverage.

About Janssen-Ortho Inc.

Janssen-Ortho Inc. is a brand-name pharmaceutical company headquartered in Toronto with a broad range of medications used in psychiatry, neurology, dementia, attention deficit hyperactivity disorder, pain management, women's health, gastroenterology, infectious disease and urology.

Centocor, Inc. developed STELARA and has exclusive marketing rights to the product in the United States.

* product of Amgen Canada, Inc., and Wyeth Canada

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References

¹ STELARA™ Product Monograph, December 12, 2008.

² Papp, K. et al. CNTO1275 (Ustekinumab) Treatment of Psoriasis: Phase 3 Trial Results. Presented at the 66th annual meeting of the American Academy of Dermatology. February 1 – 5, 2008, San Antonio, Texas.

³ Gordon, K. et al. Long-term Continuous Maintenance Therapy with CNTO 1275 (anti-IL-12/23p40) as Treatment for Psoriasis: Phase 3 Trial Results. Presented at the 66th annual meeting of the American Academy of Dermatology. February 1-5, 2008, San Antonio, Texas.

⁴ Langley, R. et al. CNTO 1275 (anti-IL12/23p40) significantly improves quality of life in patients with psoriasis: Results from Phase III study. Presented at 21st World Congress of Dermatology. September 30-October 5, 2007, Buenos Aires, Argentina.

⁵ Canadian Skin Patient Alliance web site: <http://www.skinpatientalliance.ca/en/skin-conditions-diseases/psoriasis>

⁶ Psoriasis Society of Canada. Available at <http://www.psoriasisociety.org/education.htm>

⁷ Skin Care Physicians. What is Psoriasis? Available at: www.skincarephysicians.com/psoriasisnet/whatis.html

⁸ National Psoriasis Foundation. About Psoriasis. Available at <http://www.psoriasis.org/about/psoriasis/plaque.php>