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## **HEALTH CANADA APPROVES STELARA® AS FIRST BIOLOGIC IN NORTH AMERICA FOR THE TREATMENT OF MODERATE-TO-SEVERE PSORIASIS IN ADOLESCENTS**

*STELARA®\* offers a beneficial, convenient treatment option<sup>1</sup> for adults and now adolescents*

TORONTO, ON (January 13, 2016) — Janssen Inc. announced today that Health Canada has approved STELARA® (ustekinumab) for the treatment of chronic moderate-to-severe plaque psoriasis in adolescent patients (12 to 17 years) who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.<sup>2</sup> Psoriasis is a chronic, inflammatory autoimmune disease, in which skin cells multiply faster than normal.<sup>3</sup> This can result in raised, red, scaly patches that appear on the skin.<sup>4</sup> While psoriasis can present at any age, approximately one-third of people living with the disease develop it before 20 years of age.<sup>5</sup>

“The long-term efficacy and safety of STELARA® is well-documented in adults,” says Dr. Ian Landells\*\*, MD, FRCPC, Clinical Associate Professor Department of Pediatrics and Medicine, Memorial University of Newfoundland and Clinical Chief of Dermatology, Eastern Health in St. John’s, Newfoundland and Labrador. “It’s encouraging that adolescents now have this effective treatment option to help manage their psoriasis, and one that has demonstrated good tolerability according to the CADMUS clinical study results.”

The Health Canada approval of STELARA® for adolescents with psoriasis is based on data from the Phase 3 CADMUS study, designed to evaluate the efficacy and safety of STELARA® in patients aged 12 to 17 years with moderate-to-severe plaque psoriasis. The primary endpoint of the study was the proportion of patients achieving a Physician’s Global Assessment of cleared/minimal (PGA 0/1) at week 12. This psoriasis assessment tool demonstrated that 69.4 per cent of patients who received standard dosing of STELARA® achieved PGA 0/1 at week 12.<sup>6</sup>

“The emotional and social impact of psoriasis can affect many aspects of day-to-day life,” says Andrew Gosse, President, Canadian Psoriasis Network, who lives with psoriasis. “For adolescents living with the disease, this can be particularly devastating as they are in a pivotal time of life, when self-esteem and confidence can be fragile.”

STELARA® blocks the action of two naturally occurring proteins called interleukin 12 (IL-12) and interleukin 23 (IL-23) that are believed to play a role in inflammatory conditions such as psoriasis and psoriatic arthritis.<sup>7</sup> STELARA® received approval in Canada in 2008 for the treatment of adults living with psoriasis.<sup>8</sup>

For more information visit [www.janssen.com/canada](http://www.janssen.com/canada) or the [STELARA® Product Monograph](#).

### **About Psoriasis**

Psoriasis affects 125 million people worldwide and nearly one million Canadians.<sup>9</sup> It is a chronic, inflammatory autoimmune disease that manifests in the skin and joints.<sup>10</sup> The condition can have a dramatic impact on day-to-day life and carries a significant emotional and social burden.<sup>11</sup>



Plaque psoriasis is the most common form of the disease and appears as raised, red patches covered with a silvery white buildup of dead skin cells.<sup>12</sup> These plaques can be itchy and painful and most often show up on the scalp, knees, elbows and lower back.<sup>13</sup>

### **About STELARA® (Ustekinumab)**

STELARA®, a fully human interleukin (IL)-12 and IL-23 antagonist, is indicated for the treatment of chronic moderate-to-severe plaque psoriasis in adult patients who are candidates for phototherapy or systemic therapy and also for adolescent patients from 12 to 17 years of age, who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.<sup>14</sup>

STELARA® is also indicated for the treatment of adult patients with active psoriatic arthritis. It can be used alone or in combination with methotrexate.<sup>15</sup>

STELARA® is administered by subcutaneous injection. For the treatment of moderate-to-severe plaque psoriasis and active psoriatic arthritis in adults, the recommended dose of STELARA® is 45 mg administered at weeks 0 and 4, then every 12 weeks thereafter.<sup>16</sup> Alternatively, 90 mg may be used for patients with a body weight greater than 100 kg.<sup>17</sup> For the treatment of moderate-to-severe plaque psoriasis in adolescents, the recommended dose of STELARA® is based on body weight as follows: (1) weight based dose of 0.75 mg/kg\* (patients weighing less than 60 kg), (2) fixed 45-mg dose (patients weighing at least 60 to less than or equal to 100 kg), and (3) fixed 90-mg dose (patients weighing greater than 100 kg).<sup>18</sup>

The most common side effects of STELARA® include upper respiratory tract infections, such as the common cold and headache.<sup>19</sup>

### **About Janssen Inc.**

Janssen Inc. is one of the Janssen Pharmaceutical Companies, which are dedicated to addressing and solving some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we bring innovative products, services and solutions to people throughout the world. Please visit [www.janssen.com/canada](http://www.janssen.com/canada) for more information.

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

## References

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- <sup>1</sup>Landells et al. Ustekinumab in adolescent patients age 12 to 17 years with moderate-to-severe plaque psoriasis: Results of the randomized phase 3 CADMUS study. *J Am Acad Dermatol.* 2015;73: 594 – 603.
- <sup>2</sup>STELARA® Product Monograph. Janssen Inc. December 10, 2015.
- <sup>3</sup>Living Well With Psoriasis. Available at: <http://www.livingwellwithpsoriasis.com/about-psoriasis>. Accessed November 18, 2015.
- <sup>4</sup>Canadian Psoriasis Network. Available at: <http://www.cpn-rcp.com/what-is-psoriasis/>. Accessed December 23, 2015.
- <sup>5</sup>World Health Organization. Available at [http://apps.who.int/gb/ebwha/pdf\\_files/EB133/B133\\_5-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/EB133/B133_5-en.pdf). Accessed November 18, 2015.
- <sup>6</sup>Landells et al. Ustekinumab in adolescent patients age 12 to 17 years with moderate-to-severe plaque psoriasis: Results of the randomized phase 3 CADMUS study. *J Am Acad Dermatol.* 2015;73: 594 – 603.
- <sup>7</sup>STELARA® Product Monograph. Janssen Inc. December 10, 2015.
- <sup>8</sup>Ibid.
- <sup>9</sup>Canadian Dermatology Association. Available at: <http://www.dermatology.ca/skin-hair-nails/skin/psoriasis/living-with-psoriasis/>. Accessed December 15, 2015.
- <sup>10</sup>Canadian Psoriasis Network. Available at: <http://www.cpn-rcp.com/what-is-psoriasis>. Accessed November 18, 2015.
- <sup>11</sup>Living Well With Psoriasis. Available at: <http://www.livingwellwithpsoriasis.com/about-psoriasis/emotional-social-impact>. Accessed November 18, 2015.
- <sup>12</sup>National Psoriasis Foundation. Available at <https://www.psoriasis.org/about-psoriasis#type>. Accessed November 19, 2015.
- <sup>13</sup>Ibid.
- <sup>14</sup>STELARA® Product Monograph. Janssen Inc. December 10, 2015.
- <sup>15</sup>Ibid.
- <sup>16</sup>Ibid.
- <sup>17</sup>Ibid.
- <sup>18</sup>Ibid.
- <sup>19</sup>Ibid.