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**PREZCOBIX™ NOW AVAILABLE FOR CANADIANS LIVING WITH HIV**

*New Treatment Option Combining Protease Inhibitor and Boosting Agent Reduces the Number of Pills Required to Manage HIV*

Toronto, ON (September 17, 2014) – Janssen Inc. announced today that PREZCOBIX™ (darunavir/cobicistat), a once-daily, oral medication for the treatment of HIV infection in combination with other antiretroviral agents, is now available in Canada.<sup>1</sup> It is the first HIV treatment option available to patients that provides boosted darunavir in a single tablet.

“We have seen incredible advancements with HIV treatment in the last couple of decades, but managing treatment schedules remains a challenge for patients,” says Dr. Sharon Walmsley\*, Director of Clinical Research, Immunodeficiency Clinic, Toronto Hospital, UHN and Professor, University of Toronto, Department of Medicine. “PREZCOBIX™ is an important new option in HIV treatment as it helps physicians simplify medical regimes and reduces the burden often associated with taking multiple pills daily.”

Patients with conditions like HIV that require either taking medication more than once a day or taking multiple medications may find it difficult to adhere to their treatment schedules. Research has shown that reducing the number of pills given to patients living with HIV can significantly improve adherence.<sup>2</sup>

**PREZCOBIX™: A new option for the management of HIV**

PREZCOBIX™ is a fixed-dose combination tablet containing darunavir, a protease inhibitor currently marketed as PREZISTA®, with a boosting agent called cobicistat, marketed as TYBOST™\* by Gilead Sciences, Inc.<sup>3</sup> PREZCOBIX™ is approved in combination with other anti-retroviral agents for the treatment of HIV infection in treatment-naïve and treatment-experienced patients without darunavir resistance-associated mutations.<sup>4</sup>

“PREZCOBIX™ provides the same patient benefit that physicians have expected with boosted PREZISTA® for eight years, but is conveniently dosed in a single tablet taken once-daily,” says Dr. Walmsley.

PREZCOBIX™ received notice of compliance (NOC) from Health Canada on June 19, 2014.

## PREZCOBIX™ AVAILABILITY NEWS RELEASE /2

### About the Clinical Studies

The antiretroviral effect of PREZCOBIX™ is due to the darunavir component of the medication. The efficacy of PREZCOBIX™ is supported by two Phase 3 studies (ARTEMIS and ODIN) as well as a supportive study (GS-US-216-0130).

Data at 192 weeks of treatment in the ARTEMIS trial in treatment-naïve patients demonstrated sustained antiretroviral efficacy and immunological benefit of the darunavir/ritonavir arm. In the 192 weeks analysis, virologic response (HIV-1 RNA <50 copies/mL) in the intent-to-treat (ITT) population was 68.8% (N=343) and 57.2% (N=346) for the darunavir/ritonavir and lopinavir/ritonavir arms, respectively (p<0.001, difference = 11.6%, 95% CI = [-4.4; 18.8]). In the 48-week primary analysis in the ODIN trial of treatment-experienced patients with no darunavir resistance-associated mutations, the virologic response, defined as a confirmed plasma HIV-1 RNA viral load <50 copies/mL (ITT, TLOVR), was 72.1% (N=294) for the darunavir/ritonavir once-a-day arm and 70.9% (N=296) for the darunavir/ritonavir twice-a-day arm (p<0.001, difference = 1.2%, 95% CI = [-6.1; 8.5]).<sup>5</sup>

The overall safety profile of PREZCOBIX™ is based on all available clinical data from the Phase 3 single-arm trial (GS-US-216-0130) and on all available clinical trial and post-marketing data on darunavir/ritonavir and cobicistat in combination with other antiretroviral agents.<sup>6</sup>

The majority of the Adverse Drug Reactions (ADRs) reported during treatment with darunavir/cobicistat in GS-US-216-0130 were mild in severity. The most frequent (≥ 5%) ADRs to darunavir/cobicistat that were moderate to severe (Grade 2 to 4) were diarrhea and rash. The most frequent (≥ 1%) ADR that was severe (Grade 3 or 4) was drug hypersensitivity. All other Grade 3 or 4 ADRs were reported in less than 1% of the patients; 3.8% of the patients discontinued treatment due to ADRs.<sup>7</sup>

For additional information on adverse events please visit the Canadian Product Monograph at [www.janssen.ca](http://www.janssen.ca)

### About HIV

HIV is a virus that attacks the immune system, resulting in a chronic, progressive illness that leaves individuals vulnerable to infection. When the body can no longer fight infection, the disease has progressed into AIDS (Acquired Immune Deficiency Syndrome).<sup>8</sup> It is estimated that approximately 71,300 people in Canada were living with HIV at the end of 2011.<sup>9</sup> Approximately 2,250 to 4,100 people were newly infected with HIV in 2011 in Canada.<sup>10</sup> There is no cure for HIV, but with proper care and treatment those living with HIV can manage the virus effectively.<sup>11</sup>

## PREZCOBIX™ AVAILABILITY NEWS RELEASE /3

### About Janssen Inc.

Janssen Inc. is one of the Janssen Pharmaceutical Companies of Johnson & Johnson, 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.ca](http://www.janssen.ca) for more information.

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

*\*TYBOST™ is a registered trademark of Gilead Sciences, Inc.*

### References

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<sup>1</sup> PREZCOBIX™ Product Monograph. Janssen Inc. Last updated: April 14, 2014. Page 3.

<sup>2</sup> Nachega JB, Parienti JJ, Uthman OA et al. Lower pill burden and once-daily dosing antiretroviral treatment regimens for HIV infection: a meta-analysis of randomized controlled trials. Clin Infect Dis 2014; 58:1297-1307.

<sup>3</sup> PREZCOBIX™ Product Monograph. Janssen Inc. Last updated: April 14, 2014. Page 3.

<sup>4</sup> Ibid.

<sup>5</sup> Ibid.

<sup>6</sup> Ibid.

<sup>7</sup> Ibid.

<sup>8</sup> Government of Canada. HIV/AIDS. Available at: [http://www.healthycanadians.gc.ca/health-sante/disease-maladie/hiv-vih-eng.php?utm\\_source=aids\\_13&utm\\_medium=banner\\_link&utm\\_campaign=hpfeaturebox](http://www.healthycanadians.gc.ca/health-sante/disease-maladie/hiv-vih-eng.php?utm_source=aids_13&utm_medium=banner_link&utm_campaign=hpfeaturebox). Last modified: April 2, 2013.

<sup>9</sup> Ibid.

<sup>10</sup> Ibid.

<sup>11</sup> CATIE. HIV and AIDS Basics. Available at: <http://www.catie.ca/en/basics/hiv-and-aids#what>.