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Health Canada Approves New Indication for ZYTIGA®* (abiraterone acetate), Broadening its Use for Treatment of Newly Diagnosed Metastatic Prostate Cancer

ZYTIGA®, used in combination with prednisone and androgen deprivation therapy, was shown to reduce the risk of death by 38 per cent¹

TORONTO, ON (February 15, 2018) – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced Health Canada’s approval of ZYTIGA® (abiraterone acetate) in combination with prednisone and androgen deprivation therapy (ADT) for the treatment of patients with newly diagnosed, high-risk metastatic hormone-sensitive prostate cancer (mHSPC) who may have received up to three months of prior ADT.²

This latest approval is based on Phase 3 data from the pivotal LATITUDE clinical trial, a multinational, multicenter, randomized, double-blind, placebo-controlled trial (N=1,199) that examined the use of ZYTIGA® 1,000 mg once daily in combination with prednisone 5 mg once daily and ADT, compared to placebos plus ADT in patients with newly diagnosed mHSPC.³ The study showed ZYTIGA®, in combination with prednisone and ADT reduced the risk of death by 38 per cent compared to placebo plus ADT (median OS not reached vs. 34.7 months, respectively; HR=0.62; 95% confidence interval [CI], 0.51 to 0.76; P<0.001) in patients with mHSPC.⁴

“Previously men with newly diagnosed metastatic prostate cancer have had limited options for first-line treatments,” Dr. Fred Saad, Chief of Urology, Centre Hospitalier de l’Université de Montréal, Université de Montreal and LATITUDE clinical investigator.** “This latest approval for ZYTIGA® is an exciting milestone for men, their caregivers and treating clinicians as it provides a new first-line treatment option for high-risk metastatic hormone-sensitive prostate cancer that improves overall survival and quality of life.”

About the LATITUDE Study

The LATITUDE study, published in the *New England Journal of Medicine*,⁵ enrolled 1,199 newly diagnosed patients with high-risk mHSPC and was conducted at 235 sites in 34 countries, including sites in 10 Canadian cities and with 33 Canadian patients.^{6,7} A total of 597 patients were randomized within three months of diagnosis to receive ADT plus ZYTIGA® and prednisone, while 602 patients were randomized to receive ADT and placebo.⁸ Patients were high-risk mHSPC as defined as having at least two of the three following factors associated with poor prognosis: Gleason score ≥ 8 , ≥ 3 bone lesions and/or presence of measurable visceral metastases.⁹

Overall, the safety profile of ZYTIGA® in combination with prednisone and ADT was similar to prior studies in patients with metastatic castration-resistant prostate cancer (mCRPC).¹⁰ In the LATITUDE study, patients received a lower dose of prednisone at 5 mg/day with the usual dose of ZYTIGA® at 1,000 mg/day plus ADT. The most common all grade adverse reactions ($\geq 10\%$) observed with ZYTIGA® compared to placebo were hypertension (36.7% versus 22.1%), hypokalemia (20.4% versus 3.7%) and hot flushes (15.4% versus 12.5%).

About Prostate Cancer in Canada

Prostate cancer is a disease where prostate cells lose control of growth and division, and are no longer able to function as healthy cells.^{11,12} It can be slow-growing and go undetected for years.¹³

Prostate cancer is the most common cancer among Canadian men, with approximately 21,300 men diagnosed each year.¹⁴ Roughly 10 to 20 per cent of those living with prostate

cancer will present with metastatic disease,¹⁵ in which the tumour has spread beyond the prostate to other parts of the body. There is no cure for metastatic prostate cancer.¹⁶

Metastatic hormone-sensitive prostate cancer refers to prostate cancer that still responds to testosterone suppression therapy.¹⁷ Patients with newly diagnosed metastatic disease and high-risk disease characteristics tend to have a poorer prognosis.¹⁸

About ZYTIGA®

ZYTIGA® blocks CYP17-mediated androgen production at three sources: in the testes, adrenals and the prostate tumour tissue.¹⁹ Androgen production left unchecked fuels the growth of prostate cancer.²⁰

Health Canada first approved ZYTIGA® in 2011 to be used in combination with prednisone for the treatment of mCRPC in patients who have received prior chemotherapy containing docetaxel after failure of ADT. In 2013, it was approved for mCRPC in patients who are asymptomatic or mildly symptomatic after failure of ADT.²¹

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com/canada. Follow us on Twitter [@JanssenCanada](https://twitter.com/JanssenCanada).

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

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References

- ¹ Fizazi K., et al. Abiraterone plus Prednisone in Metastatic, Castration-Sensitive Prostate Cancer. *New England Journal of Medicine*. June 2017. Accessed January 10, 2018.
- ² ZYTIGA® Canadian Product Monograph. February 12, 2018.
- ³ Fizazi K., et al. Abiraterone plus Prednisone in Metastatic, Castration-Sensitive Prostate Cancer. *New England Journal of Medicine*. June 2017. Accessed January 10, 2018.
- ⁴ Ibid.
- ⁵ Ibid.
- ⁶ Ibid.
- ⁷ Ibid.
- ⁸ Ibid.
- ⁹ Ibid.
- ¹⁰ Ibid.
- ¹¹ Canadian Cancer Society. Prostate Cancer Statistics. Available at: <http://www.cancer.ca/en/cancer-information/cancer-type/prostate/statistics/?region=on>. Accessed January 10, 2018.
- ¹² Prostate Cancer Canada. Prostate Cancer. Available at: <http://www.prostatecancer.ca/Prostate-Cancer/About-Prostate-Cancer/Prostate-Cancer>. Accessed January 10, 2018.
- ¹³ Ibid.
- ¹⁴ Canadian Cancer Society. Prostate Cancer Statistics at a glance. Available at: <http://www.cancer.ca/en/cancer-information/cancer-type/prostate/statistics/?region=sk>. Last accessed January 4, 2018.
- ¹⁵ Bellmunt J, Charles J, Albanell J. Predictive modelling in hormone-refractory prostate cancer (HRPC). *Clin Transl Oncol*. 2009 Feb;11(2):82-5.
- ¹⁶ Ibid.
- ¹⁷ American Society of Clinical Oncology. Prostate Cancer: Treatment Options. <http://www.cancer.net/cancer-types/prostate-cancer/treatment-options>. Accessed January 11, 2018
- ¹⁸ Fizazi K., et al. Abiraterone plus Prednisone in Metastatic, Castration-Sensitive Prostate Cancer. *New England Journal of Medicine*. June 2017. Accessed January 10, 2018.
- ¹⁹ ZYTIGA® Canadian Product Monograph. February 12, 2018.
- ²⁰ Ibid.
- ²¹ Ibid.