

For Immediate Release**Health Canada Approves New Indication for the Use of Xtandi®
(enzalutamide) Capsules for Patients with Metastatic Castration-Resistant
Prostate Cancer**

Approval based on improved overall survival, delayed time to radiographic progression and an overall positive risk-benefit profile

Markham, ON April 16, 2015: Astellas Pharma Canada, Inc., the Canadian subsidiary of Tokyo-based Astellas Pharma, Inc. (Tokyo: 4503), announced today that Health Canada has approved a new indication for the use of Xtandi (enzalutamide) capsules to treat patients with metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy (ADT).¹

This new approved use follows a Priority Review of the Supplementary New Drug Submission (SNDS) by Health Canada that was based on results of the Phase III PREVAIL trial. The trial was a randomized, placebo-controlled, multinational clinical trial that enrolled 1,717 chemotherapy-naïve patients with progressive metastatic prostate cancer who had failed ADT. The PREVAIL trial included thirteen Canadian trial sites including Kelowna, Vancouver, Victoria, Calgary, Edmonton, Winnipeg, London, Hamilton, Toronto, Ottawa, Montreal, Quebec City, and Halifax.

In the Phase III PREVAIL trial, men receiving enzalutamide therapy exhibited a statistically significant improvement in both overall survival and delayed time to radiographic progression or death as compared to those on placebo.¹

Specifically, enzalutamide significantly reduced the risk of radiographic progression or death by 81 percent compared with placebo (HR=0.19; $p < 0.0001$). Enzalutamide also significantly reduced the risk of death by 29 per cent compared with placebo (HR=0.71; $p < 0.0001$) and significantly delayed the start of chemotherapy by a median of 17 months compared with placebo (HR=0.35, $p < 0.001$).

Health Canada initially approved enzalutamide, an oral, once-daily androgen receptor inhibitor for use in patients with mCRPC who previously received docetaxel (chemotherapy) in the setting of medical or surgical castration.¹ The new indication means enzalutamide can be used in the earlier stages of mCRPC, before patients may need chemotherapy.¹

“Treatment of patients with mCRPC continues to be a significant challenge regularly associated with pain and suffering. Extending life and maintaining quality of life are our key clinical priorities,” said Dr. Fred Saad, professor and chief of Urology, University of Montreal Hospital Centre. “As physicians, we welcome new data that supports the expanded use of drugs like enzalutamide, particularly when it means additional treatment options earlier in the process.”

About Enzalutamide

Enzalutamide is an androgen receptor inhibitor. Androgens are a group of hormones which include testosterone. When the androgen connects with the androgen receptor, it may cause the tumour cells to grow. Androgen receptor inhibitors interfere with the connection between androgens and androgen receptors. This can help slow cancer cell growth.ⁱⁱ

The most common adverse reactions seen with enzalutamide in two randomized clinical trials (AFFIRM and PREVAIL) were fatigue/asthenia (48.3%), hot flush (19.1%), headache (11.3%), and hypertension.

Enzalutamide has been shown to cause seizures in about 9 of every 1,000 people who had received prior cancer treatment with docetaxel, and in about 1 in every 1,000 people who had not received chemotherapy.

“We are very pleased that Health Canada has recognized the importance of Xtandi as a therapy for patients with metastatic castration-resistant prostate cancer in an earlier disease setting,” said Michael Tremblay, president, Astellas Pharma Canada. “Prostate cancer is the most common cancer to affect Canadian men. This is a wonderful milestone in our progress in treating prostate cancer and we hope that this new indication will further help those suffering from this disease.”

About Prostate Cancer

Prostate cancer is the most common cancer to affect Canadian men, representing 24 per cent of all new cancer cases to affect men in 2014.ⁱⁱⁱ The risk of prostate cancer increases with age and is diagnosed most frequently in men between the ages of 60 and 69.^{iv} Approximately 10-20 per cent of these cases account for the most advanced stage of the disease and another 33 per cent with early stage disease will go on to develop metastatic disease.^v

Castration-resistant prostate cancer (CRPC) is defined by disease progression despite castrate levels of testosterone and may be present as either a continuous rise in serum prostate-specific antigen (PSA) levels, the progression of pre-existing disease, and/or the appearance of new metastases.^{vi}

Metastatic castration-resistant prostate cancer, or mCRPC, indicates that the cancer has spread outside of the prostate to other parts of the body.^{vii} Approximately 90 per cent of CRPC patients develop bone metastases causing significant morbidities, such as pain, pathologic fractures, spinal cord compression and bone marrow failure.² Sadly, in most instances, CRPC is eventually fatal.²

About Astellas Pharma Canada, Inc.

Astellas Pharma Canada, Inc., headquartered in Markham, ON, is a Canadian affiliate of Tokyo-based Astellas Pharma Inc. Astellas is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The organization is committed to becoming a global category leader in focused areas by combining outstanding R&D and marketing capabilities. In Canada, Astellas has an intense commercial focus on five therapeutic areas – Urology, Immunology, Infectious Disease, Dermatology and Oncology.

For more information about Astellas Pharma Canada, Inc., please visit the corporate website: www.astellas.ca.

About the Medivation/Astellas Collaboration

In October 2009, Medivation (NASDAQ: MDVN) and Astellas (TSE: 4503) entered into a global agreement to jointly develop and commercialize enzalutamide. The companies are collaborating on a comprehensive development program that includes studies to develop enzalutamide across the full spectrum of advanced prostate cancer as well as advanced breast cancer. The companies jointly commercialize XTANDI in the United States and Astellas has responsibility for manufacturing and all additional regulatory filings globally, as well as commercializing XTANDI outside the United States.

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Reference

¹ Xtandi Canadian Product Monograph 2015.

² Saad, F., et al. Guidelines for the management of castrate-resistant prostate cancer. *Can Urol Assoc J* 2010;4(6):380-4.

³ Canadian Cancer Society. If prostate cancer spreads. <http://www.cancer.ca/en/cancer-information/cancer-type/prostate/if-cancer-spreads/?region=on>. Accessed March 2015.

⁴ Canadian Cancer Society. Canadian Cancer Statistics 2014. <http://www.cancer.ca/~media/cancer.ca/CW/cancer%20information/cancer%20101/Canadian%20cancer%20statistics/Canadian-Cancer-Statistics-2014--EN.pdf%20over%2050>. Accessed March 2015.

⁵ Bellmunt J, Carles J, Albanell J. Predictive modelling in hormone-refractory prostate cancer (HRPC). Clin Transl Oncol. 2009 Feb;11(2):82-5.

⁶ <https://www.xtandi.com/how-xtandi-works>

⁷ Canadian Cancer Society. If prostate cancer spreads. <http://www.cancer.ca/en/cancer-information/cancer-type/prostate/if-cancer-spreads/?region=on>. Accessed March 2015.