

For Immediate Release

Astellas Introduces New Option for Men Living with Advanced Prostate Cancer

Health Canada Approves Xtandi™, a New Androgen Receptor Inhibitor

June 13, 2013 – Markham, ON – Xtandi™ (enzalutamide capsules) is now available in Canada. On May 30, 2013, Health Canada approved Xtandi for the treatment of patients with metastatic castration-resistant prostate cancer, or mCRPC, who have received prior docetaxel therapy (chemotherapy medication).ⁱ The announcement was made today by Astellas Pharma Canada, Inc., the Canadian subsidiary of Tokyo-based Astellas Pharma, Inc.

Prostate cancer is the most common cancer to affect Canadian men, generally 40 years of age and older, with one in seven developing the disease in their lifetime.ⁱⁱ Most often, initial presentation of the disease may be asymptomatic or show minimal symptoms.ⁱⁱⁱ However, approximately 10-20 per cent of cases will present with metastatic disease and another 33 per cent with early stage disease will go on to develop metastatic disease.^{iv}

Castration-resistant prostate cancer (CRPC) is an advanced form of prostate cancer where the cancer progresses despite an initial response to hormonal therapy that lowers testosterone known as androgen depletion therapy (ADT).^v Approximately 90 per cent of prostate cancer patients develop bone metastases causing significant morbidities, such as pain, pathologic fractures, spinal cord compression and bone marrow failure.⁵ Sadly, CRPC is eventually fatal.⁵

“Men living with advanced prostate cancer and their families experience a burden that many of us will never be able to fully understand,” says Jackie Manthorne, President and CEO, Canadian Cancer Survivors Network (CCSN). “The physical symptoms of the disease, such as pain, mean that not only are these men facing a terminal disease, but they may also be robbed of their quality of life and the ability to fully enjoy the time they have left with their loved ones.”

Docetaxel therapy in combination with prednisone is the current standard of care for men with mCRPC.⁵ Once a patient’s disease has progressed after docetaxel treatment, other treatment options include either chemotherapy, other new hormonal treatments or participation in a clinical trial.

Xtandi, a new hormonal therapy, is now available in Canada. It is an androgen receptor inhibitor that works by blocking the activity of androgens (like testosterone) at the level of the androgen receptor, slowing or stopping the growth of prostate cancer, which may result in tumour shrinkage.^{1,vi}

“In its early stages, patients can be successfully treated for prostate cancer and often cured. Yet for those patients whose disease continues to progress to the later stages, achieving optimal treatment outcomes is much more challenging therefore, ongoing research is crucial,” says Dr. Kim N. Chi, a medical oncologist and prostate cancer researcher at the BC Cancer Agency. “Patients with mCRPC often progress quickly. New therapies such as enzalutamide provide the medical community with an important option for treating metastatic disease.”

About Xtandi

The efficacy and safety of Xtandi were assessed in a randomized, placebo-controlled, multinational phase III clinical trial, called AFFIRM, that included eleven Canadian trial sites across the country in Kelowna, Vancouver, Victoria, Calgary, Edmonton, London, Hamilton, Toronto, Montreal, Quebec City, and Halifax. A total of 1,199 patients with mCRPC who had previously received docetaxel were randomized 2:1 to receive either Xtandi orally at a dose of 160 mg once daily (N = 800) or placebo (N = 399). Patients with a history of seizure, taking medications known to decrease the seizure threshold, or with other risk factors for seizure were excluded from the clinical trial. The primary endpoint of the trial was overall survival.⁶

“Astellas is committed to addressing the unmet medical needs of patients with advanced prostate cancer,” says Michael Tremblay, President, Astellas Pharma Canada, Inc. “Metastatic castration-resistant prostate cancer is a devastating illness that can present many treatment challenges. With the availability of Xtandi, Canadian physicians and their patients have an important new option.”

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.

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ⁱ Xtandi Canadian Product Monograph 2013.

ⁱⁱ Canadian Cancer Society. Canadian Cancer Statistics 2011. <http://cancer.ca/~media/CCS/Canada%20wide/Files%20List/English%20files%20heading/PDF%20-%20Policy%20-%20Canadian%20Cancer%20Statistics%20-%20English/Canadian%20Cancer%20Statistics%202011%20-%20English.ashx>. Accessed April 2013.

ⁱⁱⁱ Public Health Agency of Canada. Prostate Cancer. http://www.phac-aspc.gc.ca/cd-mc/cancer/prostate_cancer-cancer_prostate-eng.php. Accessed March 2013.

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

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

^{vi} Scher, H., et al. Increased Survival with Enzalutamide in Prostate Cancer after Chemotherapy. *N Engl J Med* 2012; 367:1187-1197.