Astellas Contacts:
Mindy Dooa
Communications Director
+44 (0) 7826 912339

Katy Pogson
Red Door Communications
+44 (0) 7941 418962

Medivation Contacts:
Anne Bowdidge
Senior Director, Investor Relations
(650) 218-6900

ASTELLAS ANNOUNCES MARKETING AUTHORISATION APPLICATION FOR XTANDI™ (ENZALUTAMIDE) FOR CHEMOTHERAPY-NAÏVE METASTATIC PROSTATE CANCER

TOKYO, JAPAN – April 03, 2014 – Astellas Pharma Inc. (TSE:4503) today announces the submission of a variation to amend the Marketing Authorisation Application for XTANDI™ (enzalutamide) capsules for the treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy and in whom chemotherapy is not yet clinically indicated. Enzalutamide is currently approved in Europe for the treatment of adult men with mCRPC whose disease has progressed on or after docetaxel chemotherapy.[i]

This announcement follows presentation of the Phase III data for the PREVAIL trial at the American Society of Clinical Oncology (ASCO) 2014 Genitourinary (GU) Cancers Symposium in San Francisco on Thursday, January 30, 2014.[ii]

In the Phase III PREVAIL trial, treatment with enzalutamide showed a statistically significant overall survival benefit compared with placebo, with enzalutamide reducing the risk of death by 29% (HR=0.71; p<0.0001), compared with placebo.[ii] Treatment with enzalutamide also significantly reduced the risk of radiographic progression or death by 81% compared with placebo treatment (HR=0.19; p<0.0001).[ii] Men taking enzalutamide experienced a 17-month delay in the time to initiation of chemotherapy compared with men taking placebo (28.0 months versus 10.8 months; HR=0.35; p<0.0001).[ii] The study also concluded that enzalutamide was generally well tolerated by patients and met all secondary endpoints.[ii]

Prostate cancer is the most common cancer in men in Europe, accounting for over 20% of all cancer diagnoses (excluding non-melanoma skin cancer) and is the third most common cause of cancer death in Europe.[iii] Up to 40% of men with prostate cancer develop metastatic disease and a high number of these men eventually fail androgen deprivation treatment, which is called castration-resistant prostate cancer (CRPC).[iv]

“Oncology is a growing area of focus for Astellas, and we are committed to developing and bringing to market medicines which meet current unmet medical needs” said Dr Ayad Abdulahad, Senior Vice President, Medical Affairs & Health Economics, Astellas Pharma Europe Ltd. We will continue to work with our partner, Medivation, to seek the necessary

European regulatory approval for Xtandi, that will allow for its use amongst patients who have not received chemotherapy for their advanced prostate cancer."

Upon the acceptance of the application, Astellas will provide Medivation with a $15 million milestone payment.

About the PREVAIL Trial

The Phase 3 PREVAIL trial is a randomized, double-blind, placebo-controlled, multi-national trial that enrolled more than 1,700 patients at sites in the United States, Canada, Europe, Australia, Russia, Israel and Asian countries including Japan. The trial enrolled patients with chemotherapy-naïve metastatic prostate cancer whose disease progressed on a luteinizing hormone-releasing hormone analogue or after bilateral orchiectomy. The co-primary endpoints of the trial were overall survival and radiographic progression-free survival. The trial was designed to evaluate enzalutamide at a dose of 160 mg taken orally once daily versus placebo.

About XTANDI™

Xtandi is a novel, oral, once-daily androgen receptor signalling inhibitor. Xtandi directly targets the androgen receptors (AR) and exerts its effects on all three steps of AR signalling pathway:

- Blocks androgen binding[v]
    - Androgen binding induces a conformational change that triggers activation of the receptor[vi]
- Prevents nuclear translocation[v]
    - Transit of the AR to the nucleus is an essential step in AR-mediated gene regulation[vi]
- Impairs DNA binding[v]
    - Binding of the AR to the DNA is essential for modulation of gene expression[vi]

Xtandi was approved by the FDA on August 31, 2012 and is indicated for the treatment of adult men with mCRPC who have previously received docetaxel[vii]

Xtandi is currently licensed in Europe for the treatment of adult men with mCRPC whose disease has progressed on or after docetaxel therapy.[i] Marketing authorisation was granted by the European Commission on June 21, 2013.

In March 2014, Astellas and Medivation submitted a supplemental new drug application for Xtandi for chemotherapy-naïve advanced prostate cancer to the US Food and Drug Administration.

Important Safety Information for XTANDI™

For important Safety Information for Xtandi please see the full Summary of Product Characteristics at:

http://www.medicines.org.uk/emc/medicine/27912/SPC/Xtandi+40mg+soft+capsules/

About Astellas Pharma Inc.

Astellas Pharma Inc. is a pharmaceutical company dedicated to improving the health of people around the world through provision of innovative and reliable pharmaceuticals. The organisation

is committed to being a global category leader in Oncology and Urology, and has several oncology compounds in development in addition to enzalutamide. For more information on Astellas Pharma Inc., please visit our website at www.astellas.com/en.

About the Astellas /Medivation Collaboration

In October 2009, Medivation and Astellas 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 will have responsibility for manufacturing and all additional regulatory filings globally, as well as commercializing Xtandi outside the United States.

---

[i] European Medicines Agency, XTANDI, (enzalutamide) Summary of Product Characteristics, 2013

[ii] Beer T, et al. Enzalutamide Decreases Risk of Death and Delays Progression in Phase 3 Trial of Men with Metastatic Prostate Cancer. Presentation ASCO GU 2014

[iii] Ferlay J, Shin HR, Bray F et al. Globocan 2008 v2.0, cancer incidence and mortality worldwide. IARC CancerBase No. 10 [Internet]. Lyon, France: International Agency for Research on Cancer 2010. Available from: http://globocan.iarc.fr. Last accessed March 2014

[iv] Beltran H, Beer TM, Carducci MA et al. New therapies for castration-resistant prostate cancer: Efficacy and safety. Eur Urol 2011; 60 (2): 279–290

[v] Tran C, et al. Development of a second-generation antiandrogen for treatment of advanced prostate cancer. Science 2009;324:787-790

[vi] Hu R, Denmeade SR and Luo J. Molecular processes leading to aberrant androgen receptor signaling and castration resistance in prostate cancer. Expert Rev Endocrinol Metab 2010; 5 (5): 753–764

[vii] U.S. Food and Drug Administration. Enzalutamide (XTANDI Capsules). Available from: http://www.fda.gov/drugs/informationondrugs/approveddrugs/ucm317997.htm. Last accessed March 2014