



**Astellas Contact:**  
Corporate Communications  
+81-3-3244-3201

## **Astellas Announces Revision of Package Insert in Japan for XTANDI<sup>®</sup> (enzalutamide) Capsules, a Prostate Cancer Treatment**

**Tokyo, Japan**– October 22, 2014 – Astellas Pharma Inc. (TSE: 4503) (“Astellas”) announced the revision of the package insert for the oral androgen receptor signaling inhibitor XTANDI<sup>®</sup> Capsules 40mg (generic name: enzalutamide, “XTANDI”).

Based on the results of the Phase 3 AFFIRM trial for the treatment of advanced castration-resistant prostate cancer (“CRPC”) in patients who have previously received docetaxel (chemotherapy), XTANDI, which is being jointly developed and commercialized with US-based company Medivation Inc. (NASDAQ MDVN), obtained the marketing approval in Japan for use in CRPC treatment in March 2014 and went on sale in May 2014.

The Phase 3 PREVAIL trial evaluating XTANDI as compared to placebo in chemotherapy-naïve metastatic CRPC patients recognized the clinical benefits and favorable tolerability of XTANDI for metastatic CRPC patients who have not received chemotherapy. The item “Indication” of the package insert has been revised based on the results of the PREVAIL trial, which means the sentence, “The efficacy and safety of the drug have not been established in patients with prostate cancer who have not received chemotherapy”, has been deleted from the “Precautions regarding indication” item. Also, the items “Side effects” and “Clinical results” of the package insert have been revised.

In addition to the revisions, “thrombocytopenia” has been added to the “Significant side effects” in the “Side effects” item in accordance with Authorities’ instruction.

The revision of the “Precautions regarding indication” item of the package insert triggers a \$45 million milestone payment to Medivation under its collaboration agreement with Astellas.

### **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 organization 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](http://www.astellas.com/en).

### **About the Astellas/Medivation Collaboration**

In October 2009, Astellas and Medivation 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.