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Astellas Announces Launch of XTANDI® (enzalutamide) Capsules in Japan for Prostate Cancer Treatment

Tokyo, Japan– May 23, 2014 – Astellas Pharma Inc. (TSE: 4503) announced that oral androgen receptor signaling inhibitor, XTANDI® Capsules 40mg (generic name: enzalutamide) becomes available for the treatment of patients with castration-resistant prostate cancer in Japan today.

XTANDI is an oral, once-daily, androgen receptor signaling inhibitor. It inhibits multiple steps in the androgen receptor signaling pathway, which has been shown to decrease cancer cell growth and can induce cancer cell death (apoptosis).

XTANDI (product name: XTANDI®), which is being jointly developed and commercialized with US-based company, Medivation Inc. (NASDAQ MDVN), obtained approval in August 2012 in the U.S. and in June 2013 in Europe for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in patients who have previously received docetaxel (chemotherapy). As of the end of April 2014, it has been launched as XTANDI in 23 countries including the U.S., Canada, the U.K., Germany, France, and South Korea.

Astellas reflected the impact from the launch of XTANDI in Japan in its current fiscal year (from April 1, 2014 to March 31, 2015) financial forecast.

Product outline of "XTANDI® Capsules 40mg" is as follows.

Brand name:	XTANDI® Capsules 40mg
Generic name:	Enzalutamide
Indication:	Castration-resistant prostate cancer

Precautions regarding indication:

1. The efficacy and safety of the drug have not been established in patients with prostate cancer who have not received chemotherapy.
2. Appropriate patients shall be selected by physicians who are well aware of the details of the "clinical results" and who have sufficient understanding of the efficacy and safety of the drug.

Dosage regimen: Normally, 160mg of enzalutamide is administered orally, once daily.

Precautions regarding dosage regimen:

Efficacy and safety without surgery or medical castration have not been established.

Packaging:	XTANDI® Capsules 40mg: 56 capsules (14 capsules x 4 sheets)
Price:	XTANDI® Capsules 40mg (one 40mg capsule): 3,138.80 yen
Drug Price Listing:	May 23, 2014
Launch Date:	May 23, 2014



With the objective of preventing medical accidents, Astellas has adopted user-friendly artwork to the products, an easily-identifiable letter size, color, and so on. For example, Astellas has printed the product name and dosage “XTANDI 40”on each medicine. That makes it easy to identify even when each medicine is taken out of the blisters.

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.

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.