

Press Release

Astellas Announces Launch of XTANDI® Tablets in Japan for the Treatment of Castration-Resistant Prostate Cancer

TOKYO, June 11, 2018 - Astellas Pharma Inc. (President and CEO: Kenji Yasukawa, Ph.D., “Astellas”) today announced that it launched 40 mg XTANDI® (generic name enzalutamide) Tablets and 80 mg XTANDI® Tablets in Japan for the treatment of castration-resistant prostate cancer, which add additional dosage forms to the previously available 40 mg XTANDI® Capsules. XTANDI® is an oral androgen receptor signaling inhibitor.

Both the 40 mg XTANDI® Tablets and 80 mg XTANDI® Tablets are smaller in size than the 40 mg XTANDI® Capsules; thus offering a more patient-friendly medication. With the 80 mg tablets, the number of doses taken each time will also be reduced.

As of May 2018, enzalutamide is available in more than 70 countries worldwide. In Japan, XTANDI® Capsules were launched in May 2014 for castration-resistant prostate cancer.

Astellas is pleased to deliver XTANDI® tablets to patients to further enhance its contributions to the treatment of castration-resistant prostate cancer.

Astellas reflected the impact from this launch in its financial forecasts of the current fiscal year ending March 31, 2019.

Product overview

Trade name	40 mg XTANDI® Tablets 80 mg XTANDI® Tablets
Generic name	Enzalutamide
Indication	Castration-Resistant Prostate Cancer
Dosage and administration	Normally to adult, 160 mg as enzalutamide once daily orally
Date of approval	February 23, 2018
Date of NHI inclusion	May 30, 2018
Date of release	June 11, 2018
NHI drug price	40 mg XTANDI® Tablets: 2,354.10 yen/tablet 80 mg XTANDI® Tablets: 4,563.70 yen/tablet

Product photo



About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information, please visit our website at <https://www.astellas.com/en>

About the Pfizer/Astellas Collaboration

In October 2009, Medivation, Inc., which is now part of Pfizer (NYSE:PFE), and Astellas (TSE: 4503) entered into a global agreement to jointly develop and commercialize enzalutamide. 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.

Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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Contacts for inquiries or additional information:

Astellas Pharma Inc.
Corporate Communications
TEL: +81-3-3244-3201 FAX: +81-3-5201-7473