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Singapore: The US Food and Drug Administration (FDA) has granted approval to Xtandi (enzalutamide) capsules for the treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel.

Xtandi is an oral, once-daily androgen receptor inhibitor. The FDA accepted the Xtandi new drug application (NDA) on July 23, 2012, and granted the filing Priority Review Designation with a Prescription Drug User Fee Act (PDUFA) action date of November 22, 2012. US firm Medivation and Astellas, the US subsidiary of the Japanese firm, said they expect to make Xtandi available to patients in the US in mid-September 2012. Medivation and Astellas are together developing Xtandi.

A marketing authorization application for Xtandi has also been accepted for review by the European Medicines Agency.

"Today's approval marks a significant accomplishment for Medivation. We are proud to be in a position to offer a new treatment, Xtandi, for this patient population for which there is a significant unmet medical need," said Dr David Hung, co-

founder, president and CEO, Medivation. "I would like to extend my thanks to the patients, physicians, and their study teams who participated in the clinical trials, and to our employees, and those of our partner Astellas, who have been instrumental in helping us reach this important milestone."

"Enzalutamide provides an exciting new option for physicians that can prolong the lives of patients with metastatic prostate cancer who have received chemotherapy," said Dr Howard I Scher, chief, Genitourinary Oncology Service, Sidney Kimmel Center for Prostate and Urologic Cancers, Memorial Sloan-Kettering Cancer Center, and the co-principal investigator of the AFFIRM pivotal study. "It is extremely gratifying to have led the clinical trial of enzalutamide, having followed the development of this drug from its early inception in the laboratory to the clinic."

"We believe Xtandi has the potential to play an important role in the treatment of advanced prostate cancer," said Dr Stephen Eck, vice president of medical oncology, Astellas Pharma Global Development. "We're eager to work with Medivation to make this much-needed new treatment available to medical professionals and patients in September."

As a post-marketing requirement, Medivation and Astellas have agreed with the FDA to conduct an open-label safety study of Xtandi (160 mg/day) in patients who are at high risk for seizure.

Medivation and Astellas have agreed to provide the data from this study in 2019.