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27 June 2012 | Regulatory | By BioSpectrum Bureau

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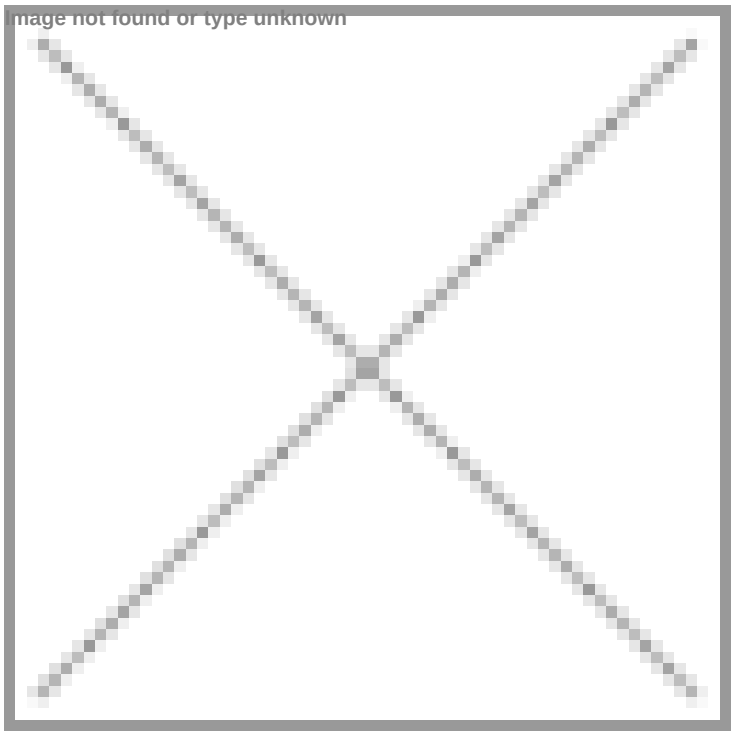

Singapore: Japan-based Astellas Pharma has submitted a European marketing authorization application to the European Medicines Agency (EMA) for enzalutamide for the treatment of men with metastatic castration-resistant prostate cancer who have been previously treated with docetaxel-based chemotherapy.

Enzalutamide is a novel, once-daily investigational oral androgen receptor signalling inhibitor and the submission follows positive results from the pivotal phase III AFFIRM study, which confirmed that enzalutamide demonstrated a statistically significant improvement p<0.0001) in overall survival with a median improvement over placebo of 4.8 months [hazard ratio (HR) = 0.631]1. The study also concluded that enzalutamide was generally well tolerated by patients and met all secondary endpoints1. A New Drug Application (NDA) has been submitted in the United States, where priority review of the compound has been requested2.

"Data from clinical studies, including the phase III AFFIRM study, have demonstrated that enzalutamide significantly improves overall survival whilst providing a favourable tolerability profile for patients," said Professor Johann de Bono, M.D., MSc, Ph.D., FRCP, Honorary Consultant in Medical Oncology, Professor in Experimental Cancer Medicine, The Institute of Cancer Research,

The Royal Marsden Hospital and co-principal investigator of the AFFIRM study. "This is vital for patients at this late stage of their disease and the submission of enzalutamide represents an important step towards making this promising treatment

available to men with advanced prostate cancer across Europe."