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Astellas to treat men with metastatic castration-resistant prostate cancer in China

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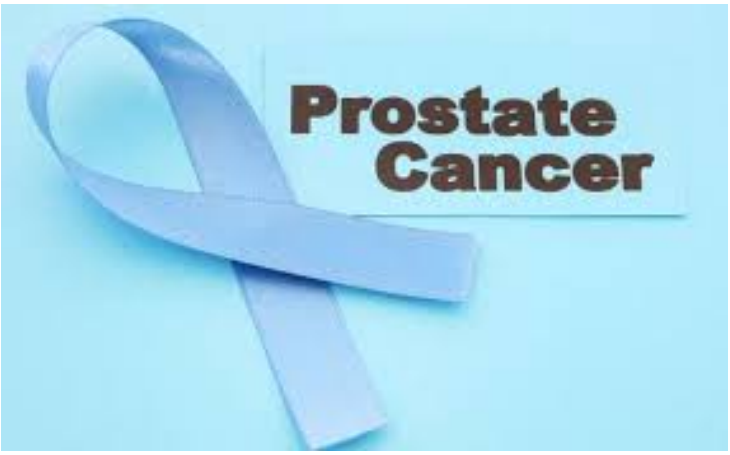
Astellas Announces the Approval of XTANDI® (enzalutamide) by the China National Medical Products Administration (NMPA).Approval is based on Asian PREVAIL study of men with metastatic castration-resistant prostate cancer



Astellas Pharma Inc., based in Tokyo, Japan has announced the China National Medical Products Administration (NMPA) approved a new drug application (NDA) for XTANDI® (enzalutamide) for the treatment of adult men with metastatic castration-resistant prostate cancer (CRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy (ADT) in whom chemotherapy is not yet clinically indicated.

The approval by the NMPA was based on the results of an Asian multinational Phase 3, randomized, double-blind, placebo controlled efficacy and safety study of enzalutamide in asymptomatic or mildly symptomatic patients with progressive metastatic prostate cancer who had disease progression despite ADT and a single-dose pharmacokinetic study in healthy Chinese volunteers (Protocol 9785-CL-0013).

The study, Asian PREVAIL (also known as 9785-CL-0232), evaluated oral enzalutamide (160 mg/day) versus placebo plus gonadotropin-releasing hormone (GnRH) therapy or after bilateral orchiectomy. The study, involving Asian patients including approximately 200 Chinese patients, showed consistent results with those in the global pivotal Phase 3 PREVAIL study in the same target population.

"Currently the treatment options are limited in China for men with metastatic castration-resistant prostate cancer," said Andrew Krivoshik, M.D., Ph.D., Senior Vice President and Global Therapeutic Area Head, Oncology Development, Astellas. "The approval of enzalutamide in China brings us one step closer to offering physicians a meaningful treatment option in an area where there is a high medical need."

In addition to the Asian PREVAIL data involving a Chinese sub-population, the approval was supported by results from the global Phase 3 PREVAIL trial, which were published in the *New England Journal of Medicine* in 2014. The Phase 3 PREVAIL trial was a randomized, double-blind, placebo-controlled, multi-national trial that enrolled more than 1,700 patients at sites in the United States, Canada, Europe, Australia, Russia, Israel and Asia including Japan.