ENZALUTAMIDE (XTANDI) NOW APPROVED IN EUROPE FOR THE TREATMENT OF MEN WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER WHO ARE CHEMOTHERAPY-NAÏVE

Tokyo, December 2, 2014 –Astellas Pharma Inc. (TSE: 4503, "Astellas") today announced that the European Commission (EC) has granted a variation to amend the Marketing Authorisation for enzalutamide (trade name XTANDI). Enzalutamide is now approved for the treatment of adult men with metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen-deprivation therapy in whom chemotherapy is not yet clinically indicated.

The approval of the variation is based on results from the pivotal phase III PREVAIL study which demonstrate that enzalutamide improves outcomes for men with advanced prostate cancer who have not received chemotherapy.

Compared with placebo, enzalutamide reduced the risk of death by 29% (HR=0.71; $p<0.001$) and the risk of radiographic progression or death by 81% (HR=0.19; $p<0.001$). Men treated with enzalutamide experienced a 17-month delay in the time to initiation of chemotherapy compared to placebo (28.0 months versus 10.8 months, respectively; HR=0.35; $p<0.001$).

Astellas expects to launch enzalutamide in the pre-chemotherapy setting in the first European countries, including the UK, from December 2014.

The approval of this new indication for enzaltamide triggers $45 million in milestone payments to Medivation (NASDAQ: MDVN) under its collaboration agreement with Astellas. The impact has been accounted in Astellas' financial forecasts for fiscal year ending March 2015.

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