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Astella's Xtandi variation receives EU nod

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Singapore: The European Commission has amended the marketing authorization for Xtandi, manufactured by the Japanese drug major Astellas pharma. The amendment was made to include first-line treatment for men with metastatic castration-resistant prostate cancer (mCRPC) after failure of androgen deprivation therapy.

The drug, Enzalutamide (trade name Xtandi) 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 drug is found to reduce the risk of death by 81 percent. The approval of the variation is based on results from the pivotal Phase III PREVAIL study which demonstrated that enzalutamide is effective in men with advanced prostate cancer who have not received chemotherapy.

The approval of this new variation is expected to add $45 million revenue to Medivation following its collaboration agreement with Astellas. The financial impact had been captured in Astellas' financial forecasts for fiscal year ending March 2015.