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Astellas receives approval for prostate cancer drug

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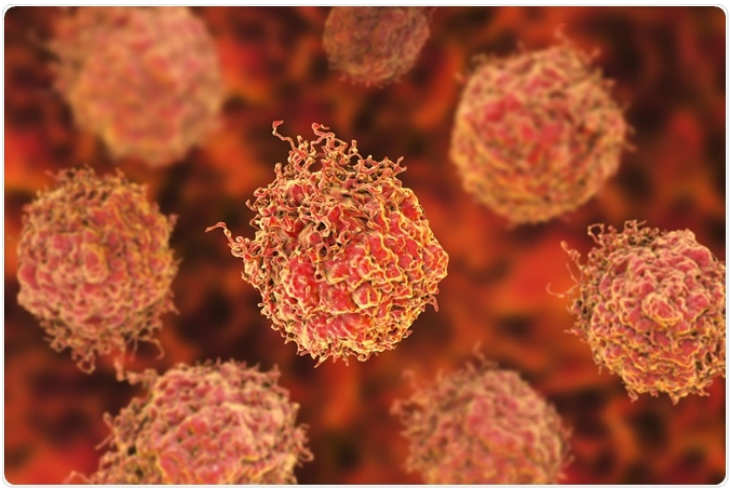
XTANDI is now MHLW-approved for both metastatic hormone-sensitive prostate cancer and castration-resistant prostate cancer in Japan



Japanese firm Astellas Pharma Inc. has announced that the Japan Ministry of Health, Labour and Welfare (MHLW) has approved XTANDI® (enzalutamide), an oral androgen receptor signaling inhibitor, for the treatment of prostate cancer patients with distant metastasis.

With this approval, XTANDI is now indicated for the treatment of metastatic hormone-sensitive prostate cancer (mHSPC), a form of prostate cancer that has spread to other parts of the body and still responds to a medical or surgical treatment that lowers testosterone. This is in addition to an existing indication for castration-resistant prostate cancer (CRPC).

The approval for mHSPC is based on results from the ARCHES trial, a randomized multi-national Phase 3 study which evaluated enzalutamide plus androgen deprivation therapy (ADT) versus placebo plus ADT in 1,150 men with mHSPC and met its primary endpoint of radiographic progression-free survival (rPFS).

It is also supported by data from the ENZAMET trial, an overseas Phase 3 study evaluating enzalutamide plus ADT versus ADT plus a standard nonsteroidal antiandrogen therapy (bicalutamide, nilutamide or flutamide) in men with mHSPC.