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Pfizer, Astellas' Xtandi Gets FDA nod

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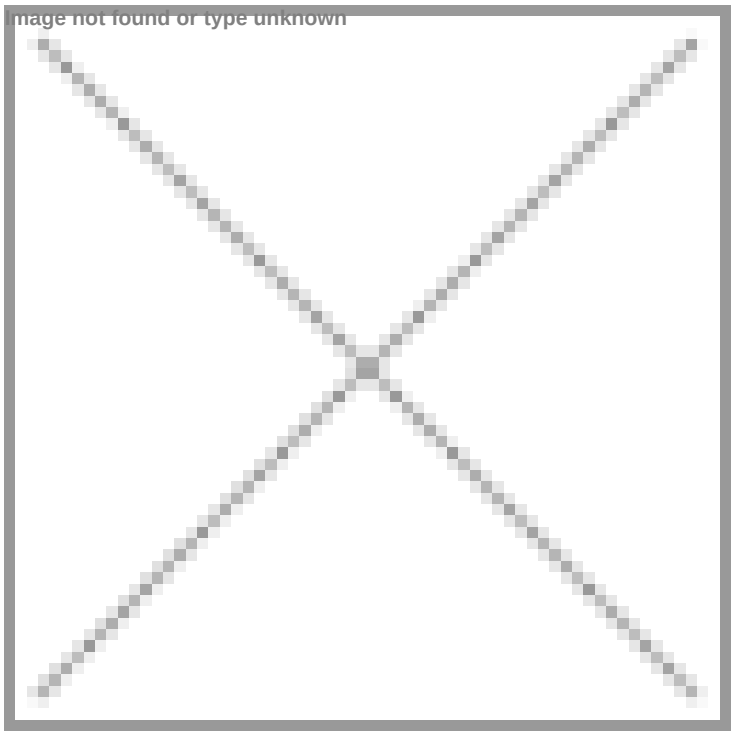
For the treatment of patients with metastatic castration-sensitive prostate cancer



Pfizer and Japan based Astellas Pharma have announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental New Drug Application (sNDA) for XTANDI® (enzalutamide) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC). In 2019, it is estimated that just over 40,000 men in the United States are living with mCSPC, 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.

With this approval, XTANDI is now the first and only oral treatment approved by the FDA in three distinct types of advanced prostate cancer – non-metastatic and metastatic castration-resistant prostate cancer (CRPC) and mCSPC. The approval is based on results from ARCHES, a randomized Phase 3 study which evaluated 1,150 men with mCSPC and met its primary endpoint of radiographic progression-free survival (rPFS).

“Men with metastatic castration-sensitive prostate cancer face complex treatment decisions and it is critical for physicians and patients to have as much information as possible when deciding on all of the options available,” said Andrew Armstrong, M.D., Professor of Medicine, Surgery, Pharmacology and Cancer Biology, Director of Research in the Duke Cancer Institute’s Center for Prostate and Urologic Cancers and lead investigator of ARCHES. “The research supporting the FDA approval and updated treatment guidelines provide physicians and patients with compelling evidence to consider enzalutamide as a treatment option for men with this disease.”

Data from the ARCHES trial demonstrated that the use of XTANDI plus androgen deprivation therapy (ADT) significantly reduced the risk of radiographic progression or death by 61 percent compared to placebo plus ADT (n=1,150; hazard ratio

[HR]: 0.39 [95% confidence interval (CI): 0.30-0.50]; p<0.0001). Overall survival data were not mature at the time of final rPFS analysis.

The safety analysis of the ARCHES trial is generally consistent with the safety profile of XTANDI in previous clinical trials in CRPC. In ARCHES, common adverse reactions (Grade 1 to 4 ARs; occurring in at least 5% of patients) that were reported more frequently in patients treated with XTANDI plus ADT vs placebo plus ADT included hot flush (27% vs 22%), asthenic conditions (24% vs 20%), hypertension (8.0% vs 5.6%), fractures (6.5% vs 4.2%), and musculoskeletal pain (6.3% vs 4.0%).

“XTANDI has been established as a standard of care for men with castration-resistant prostate cancer and has been prescribed to more than 420,000 patients worldwide since it was first approved in 2012,” said Andrew Krivoshik, M.D., Ph.D., Senior Vice President and Oncology Therapeutic Area Head at Astellas. “This approval in metastatic castration-sensitive prostate cancer means physicians can now offer XTANDI to men earlier in their advanced prostate cancer treatment journey.”

“Today’s approval adds to over a decade of global clinical research aimed at better understanding the potential benefit of XTANDI for men with advanced prostate cancer,” said Andy Schmeltz, Global President, Pfizer Oncology. “The FDA approval marks continued progress to help meet the needs of patients, including men living with metastatic castration-sensitive prostate cancer.”