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USFDA grants priority to XTANDI's sNDA

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Pfizer and Astellas Pharma announced that a supplemental New Drug Application (sNDA) for XTANDI (enzalutamide) has been accepted for filing and granted Priority Review designation by the U.S. Food and Drug Administration (FDA).

When approved, the sNDA would expand the indication of XTANDI to include men with non-metastatic Castration-Resistant Prostate Cancer (CRPC), based on data from the Phase 3 PROSPER trial. XTANDI is currently indicated for the treatment of patients with metastatic CRPC.

The PROSPER trial evaluated XTANDI plus androgen deprivation therapy (ADT) versus ADT alone in 1,401 patients with non-metastatic CRPC. The study met its primary endpoint, demonstrating that the use of XTANDI plus ADT significantly reduced the risk of developing metastasis or death compared to ADT alone.

“Once cancer spreads and metastasizes, men with castration-resistant prostate cancer face a daunting prognosis and challenging odds,” said Steven Benner, M.D., senior vice president and global therapeutic area head, Oncology Development, Astellas. “We’re pleased to see the FDA’s Priority Review designation as we work to potentially bring XTANDI to men living with non-metastatic CRPC.”

“Treatment options have been limited for men with non-metastatic CRPC, in whom the only evidence of progressive disease is a rapidly rising PSA,” said Mace Rothenberg, M.D., chief development officer, Oncology, Pfizer Global Product Development. “XTANDI is already established as a standard of care for men with metastatic CRPC. This milestone marks an important step toward our ability to bring XTANDI to CRPC patients in an earlier setting.”

Under Priority Review, the FDA aims to take action on an application within six months of receipt, as compared to ten months under standard review. Pfizer said in its press release that the European Medicines Agency (EMA) has validated the Type II Variation submitted for XTANDI seeking to expand the current indication to the same patient population and started the review process on March 5.

Prostate cancer is the second most common cancer in men worldwide.[2] More than 164,000 men in the United States are estimated to be newly diagnosed with prostate cancer in 2018.[3] In the European Union, the estimated number of new prostate cancer cases in 2015 was 365,000