FDA Approves Enzalutamide for Castration-Resistant Prostate Cancer

Androgen receptor inhibitor now approved for both metastatic and nonmetastatic disease.

July 16, 2018 By Food and Drug Administration (FDA)

On July 13, 2018, the Food and Drug Administration approved enzalutamide (Xtandi, Astellas Pharma US, Inc.), for patients with castration-resistant prostate cancer (CRPC).

This approval broadens the indicated patient population to include patients with both non-metastatic CRPC (NM-CRPC) and metastatic CRPC. Enzalutamide was previously approved for the treatment of patients with metastatic CRPC.

Approval in patients with NM-CRPC was based on a randomized, multicenter clinical trial (PROSPER, NCT020032924), that randomized 1,401 patients 2:1 to either enzalutamide 160 mg orally once daily or placebo orally once daily. Patients continued on gonadotropin-releasing hormone (GnRH) therapy or had prior bilateral orchiectomy.

The major efficacy outcome was metastasis-free survival (MFS), defined as the time from randomization to loco-regional and/or distant radiographic progression (blinded independent central review), or death up to 112 days after treatment discontinuation without radiographic progression. The trial demonstrated a statistically significant improvement in MFS for patients receiving enzalutamide compared to those receiving placebo, with median MFS of 36.6 and 14.7 months, respectively (HR 0.29; 95% CI: 0.24, 0.35; $p<0.0001$).

The most common adverse reactions (≥10%) that occurred more frequently (≥2% over placebo) in the enzalutamide-treated patients in PROSPER were asthenia/fatigue, hot flush, hypertension, dizziness, nausea, and falls.

The recommended enzalutamide dose is 160 mg (four 40 mg capsules) administered orally once daily.

View full prescribing information for Xtandi

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System or by calling 1-800-FDA-1088.

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