

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 ($\geq 10\%$) that occurred more frequently ($\geq 2\%$ 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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