



Brief summaries of recent drug approvals, interactions, and adverse events

Enzalutamide Approved for Late-Stage Prostate Cancer

The FDA has approved enzalutamide to treat men with late-stage castration-resistant prostate cancer that has spread or recurred, even with medical or surgical therapy to minimize testosterone. The drug was approved under the priority review program, nearly 3 months ahead of the action date.

In a randomized clinical study, 800 patients with metastatic castration-resistant prostate cancer who had received treatment with docetaxel received enzalutamide 160 mg/d for a median of 8.3 months; 399 were given placebo for a median of 3 months. All patients continued androgen depriva-

tion therapy. Roughly half of both groups received glucocorticoids as well. Study treatment continued until disease progression, new systemic antineoplastic treatment, unacceptable toxicity, or withdrawal.

Enzalutamide extended survival by a median of 18 months compared with 14 months for patients on placebo. Enzalutamide is an androgen receptor inhibitor that acts on different steps in the androgen receptor signaling pathway. In *in vitro* studies, it reduced proliferation and induced cell death of prostate cancer cells.

The most common adverse effects for the drug were weakness or fatigue, back pain, diarrhea, and joint and muscle pain. Fifteen per-

cent of patients on enzalutamide developed grade 1 to 4 neutropenia compared with 6% of patients taking placebo. About 1% of patients taking enzalutamide had seizures; those patients withdrew from treatment. The drug's safety is unknown for patients with a history of seizure, underlying brain injury, stroke, or brain metastases, or patients taking medications that may lower the threshold for seizures. ●

Source: U.S. Food and Drug Administration. FDA approves new treatment for a type of late stage prostate cancer [news release]. U.S. Food and Drug Administration website. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm317838.htm>. Updated 8/31/2012. Accessed October 18, 2012.

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