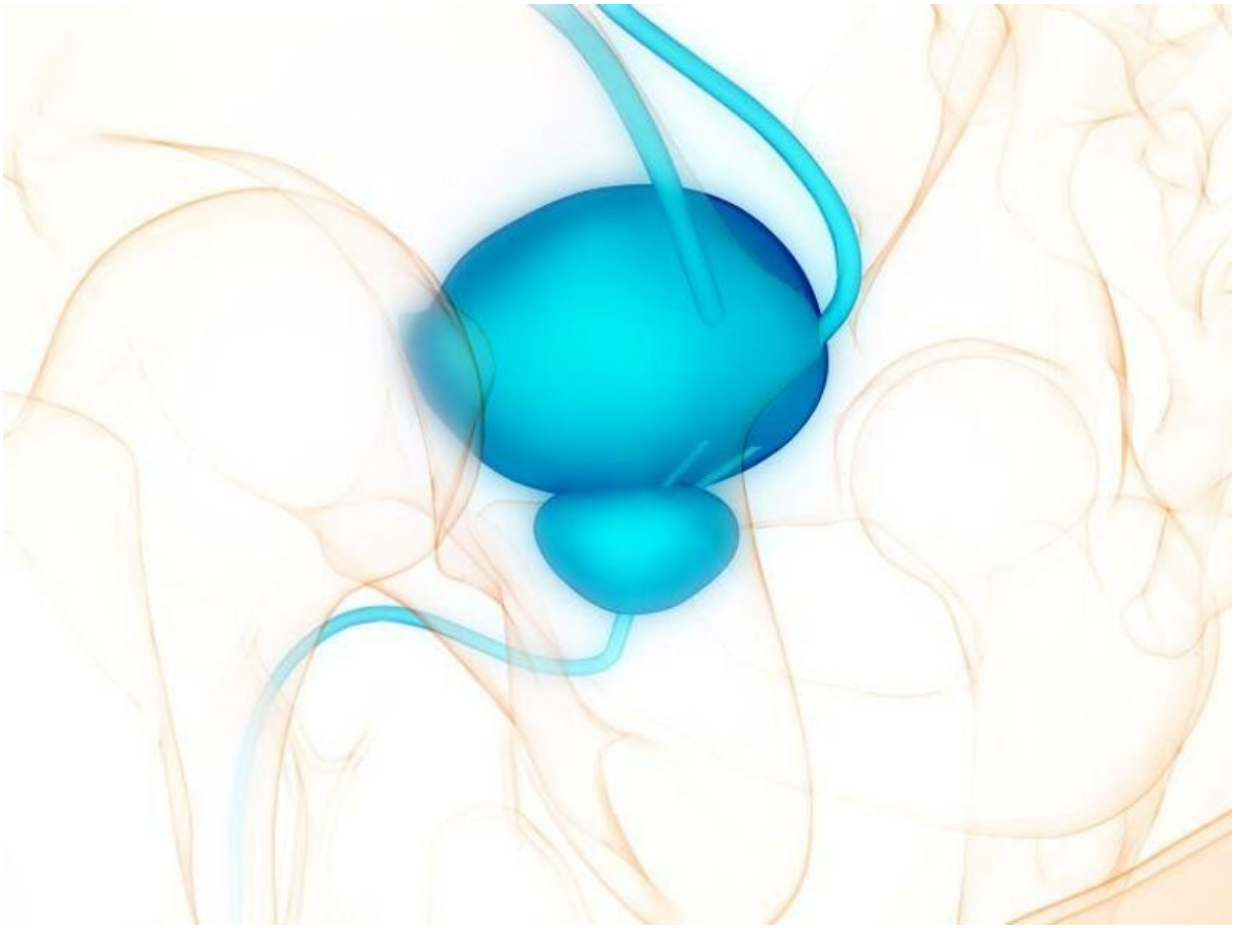
FDA approves Talzenna for metastatic, castration-resistant prostate cancer

June 27 2023, by Lori Solomon



The U.S. Food and Drug Administration has approved Talzenna

(talazoparib) with enzalutamide for homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).

The approval was based on a trial in which 399 patients with HRR gene-mutated mCRPC were randomly assigned (1:1) to receive enzalutamide 160 mg daily plus either talazoparib 0.5 mg or placebo daily.

The results of the trial showed statistically significant improvement in radiographic progression-free survival (rPFS) for Talzenna with enzalutamide versus placebo. Median rPFS was not reached in the Talzenna group versus 13.8 months with placebo (hazard ratio, 0.45; 95 percent confidence interval, 0.33 to 0.61; P BRCA-mutated mCRPC, the hazard ratio for rPFS was 0.20 (95 percent confidence interval, 0.11 to 0.36), but for HRR gene-mutated mCRPC without *BRCA* mutations, the hazard ratio was 0.72 (95 percent confidence interval, 0.49 to 1.07).

Recommended dosing is 0.5 mg orally once daily for Talzenna in combination with enzalutamide (160 mg orally daily) until disease progression or unacceptable toxicity. Patients receiving this combination should also receive a gonadotropin-releasing hormone analog concurrently or should have had bilateral orchiectomy.

The most common adverse reactions (≥10 percent) included decreased hemoglobin, neutrophils, lymphocytes, platelets, calcium, sodium, phosphate, magnesium, and potassium, as well as nausea, decreased appetite, fractures, dizziness, increased bilirubin, and dysgeusia. A blood transfusion was needed among 39 percent of patients treated with Talzenna with enzalutamide, including 22 percent who required multiple transfusions.

Approval of Talzenna was granted to Pfizer.

More information: More Information