Xtandi® (enzalutamide) – Expanded indication and new warnings

- On July 13, 2018, Astellas Pharma and Pfizer announced the FDA approval of Xtandi (enzalutamide), for the treatment of patients with castration-resistant prostate cancer (CRPC).
    - This expands the approval of Xtandi to include patients with non-metastatic CRPC.
    - Previously, Xtandi was only approved for metastatic CRPC.
- According to the American Cancer Society, prostate cancer is the second most common cancer in American men. About 164,690 men are estimated to be newly diagnosed with prostate cancer and 29,430 deaths are expected in the U.S. in 2018.
- The expanded indication is based on safety and efficacy data from the PROSPER trial which enrolled 1,401 patients with non-metastatic CRPC. Patients were randomized to receive either Xtandi or placebo. The primary endpoint was metastasis-free survival (MFS).
    - The median MFS was 36.6 months for men who received Xtandi vs. 14.7 months with placebo (HR = 0.29 [95% CI: 0.24, 0.35]; $p < 0.0001$).
    - Overall survival data were not mature at the time of final MFS analysis.
- In addition, new updates have been added to the *Warnings and Precautions* section of the Xtandi drug label regarding hypersensitivity reactions, ischemic heart disease, falls and fractures, and embryo-fetal toxicity.
    - Consult the Xtandi drug label for detailed information about the new warnings.
- The recommended dose of Xtandi for CRPC is 160 mg (four 40 mg capsules) administered orally once daily.
    - Swallow capsules whole. Do not chew, dissolve, or open the capsules.
    - Patients receiving Xtandi should also receive a gonadotropin-releasing hormone analog concurrently or should have had a bilateral orchiectomy.