Xtandi® (enzalutamide) – New indication

- On December 16, 2019, Pfizer and Astellas Pharma announced the FDA approval of Xtandi (enzalutamide), for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).

- Xtandi is also approved for the treatment of patients with castration-resistant prostate cancer.

- Men are considered castration- (or hormone-) sensitive if their disease still responds to medical or surgical treatment to lower testosterone levels. The prevalence of mCSPC in the U.S. in 2019 is estimated to be just over 40,000.

- The approval of Xtandi for the new indication was based on ARCHES, a placebo-controlled, randomized study in 1,150 patients with mCSPC. The major efficacy outcome measure was radiographic progression-free survival (rPFS). Time to new antineoplastic therapy was an additional efficacy endpoint.

    — Xtandi demonstrated a statistically significant improvement in rPFS vs. placebo. Median rPFS was not reached with Xtandi vs. 19.4 months (95% CI: 16.6, not reached) with placebo (hazard ratio [HR] 0.39, 95% CI: 0.30, 0.50; $p < 0.0001$).
    — A statistically significant improvement was also reported with Xtandi vs. placebo in time to initiation of a new antineoplastic therapy (HR 0.28, 95% CI: 0.20, 0.40; $p < 0.0001$).
    — Overall survival data were not mature at the time of rPFS analysis.

- The recommended dose of Xtandi for all patients is 160 mg (four 40 mg capsules) administered orally once daily.