Xtandi® (enzalutamide) – New formulation approval

- On August 4, 2020, the FDA approved Astellas' Xtandi (enzalutamide) tablets, for the treatment of patients with castration-resistant prostate cancer or metastatic castration-sensitive prostate cancer.
    - Previously, Xtandi was approved as 40 mg capsules for the same indications.
- Following a single dose administration of 160 mg enzalutamide in healthy male volunteers, enzalutamide extent of absorption (AUC) was comparable between Xtandi tablet and Xtandi capsule, but the mean Cmax was 10%-28% lower than that of Xtandi capsules. The steady-state pharmacokinetic profiles (AUC and Cmax) of enzalutamide and N-desmethyl enzalutamide are similar for Xtandi tablet and Xtandi capsule.
- Warnings and precautions for Xtandi include seizure, posterior reversible encephalopathy syndrome, hypersensitivity, ischemic heart disease, falls and fractures, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 10% and ≥ 2% over placebo) with Xtandi use were asthenia/fatigue, back pain, hot flush, constipation, arthralgia, decreased appetite, diarrhea, and hypertension.
- The recommended dose of Xtandi is 160 mg (two 80 mg tablets or four 40 mg tablets or four 40 mg capsules) administered orally once daily.
    - Patients receiving Xtandi should also receive a gonadotropin-releasing hormone analog concurrently or should have had bilateral orchiectomy.
- Astellas' launch plans for Xtandi tablets are pending. Xtandi will be available as 40 mg and 80 tablets.