Erleada® (apalutamide) – New indication

- On September 17, 2019, Janssen announced the FDA approval of Erleada (apalutamide), for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).

- Erleada is also approved for the treatment of patients with non-metastatic castration-resistant prostate cancer.

- Patients with mCSPC have prostate cancer that still responds to androgen deprivation therapy and has spread to other parts of the body.

- The approval of Erleada for the new indication was based on TITAN, a double-blind study in 1,052 patients with mCSPC. Patients were randomized to receive either Erleada or placebo. The major efficacy outcome measures of the study were overall survival (OS) and radiographic progression-free survival (rPFS).

    — Erleada significantly extended OS vs. placebo with a 33% reduction in the risk of death (hazard ratio [HR] = 0.67; 95% CI: 0.51, 0.89; p = 0.0053).
    — Erleada also significantly improved rPFS vs. placebo with a 52% lower risk of radiographic progression or death (HR = 0.48; 95% CI: 0.39, 0.60; p < 0.0001).

- The *Warnings and Precautions* section of the labeling was also updated, including the addition of two new warnings for ischemic cardiovascular events and embryo-fetal toxicity.

- The recommended dose of Erleada for both indications is 240 mg (four 60 mg tablets) administered orally once daily.

    — Patients should also receive a gonadotropin-releasing hormone analog concurrently or should have had a bilateral orchiectomy.