Nubeqa® (darolutamide) – Expanded indication

- On August 5, 2022, the FDA announced the approval of Bayer's Nubeqa (darolutamide), for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel.
    - Nubeqa was previously approved for the treatment of adult patients with non-metastatic castration-resistant prostate cancer (mCRPC).
- The approval of Nubeqa for the expanded indication was based on ARASENS, a double-blind, placebo-controlled study in 1,306 patients with mHSPC. Patients received Nubeqa 600 mg orally twice daily or placebo, concomitantly with docetaxel for 6 cycles. The major efficacy outcome measure was overall survival (OS).
    - The OS was not reached (NR) (95% CI: NR, NR) in the Nubeqa group vs. 48.9 months (95% CI: 44.4, NR) in the placebo group (Hazard ratio 0.68; 95% CI: 0.57, 0.80; $p < 0.0001$).
- The most common adverse reactions (≥ 10% with a ≥ 2% increase over placebo with docetaxel) with Nubeqa use in mHSPC were constipation, decreased appetite, rash, hemorrhage, weight increased, and hypertension.
- The most common laboratory test abnormalities (≥ 30%) with Nubeqa use in mHSPC were anemia, hyperglycemia, decreased lymphocyte count, decreased neutrophil count, increased aspartate transferase, increased alanine transaminase, and hypocalcemia.
- The recommended dose of Nubeqa for the treatment of mHSPC and mCRPC is 600 mg (two 300 mg tablets) taken orally, twice daily, with food.
    - For patients with mHSPC treated with Nubeqa in combination with docetaxel, administer the first of 6 cycles of docetaxel within 6 weeks after the start of Nubeqa treatment.
    - Refer to docetaxel prescribing information for additional dosing information.
    - Treatment with Nubeqa should be continued until disease progression or unacceptable toxicity occurs.