Nubeqa® (darolutamide) – Expanded indication

- On June 3, 2025, the FDA announced the approval of Bayer's Nubeqa (darolutamide), for the **treatment of adult patients with metastatic castration-sensitive prostate cancer (mCSPC).**

- Nubeqa is also approved for the treatment of mCSPC, in combination with docetaxel, and for the treatment of non-metastatic castration resistant prostate cancer (nmCRPC).

- The approval of Nubeqa for the expanded indication was based on ARANOTE, a double-blind, placebo-controlled study in 669 patients with mCSPC. Patients were randomized to receive Nubeqa or placebo. The major outcome measure was radiographic progression-free survival (rPFS), defined as the time from randomization to radiological disease progression or death. An additional efficacy outcome measure was overall survival (OS).

    — Treatment with Nubeqa resulted in a statistically significant improvement in rPFS compared to placebo. Median rPFS was not reached with Nubeqa vs. 25 months with placebo (hazard ratio 0.54, 95% C: 0.41, 0.71; $p < 0.0001$).
    — There was no statistically significant improvement in OS.

- The recommended dose of Nubeqa is **600 mg (two 300 mg tablets) taken orally, twice daily**. Treatment should be continued until disease progression or unacceptable toxicity occurs.

    — Patients receiving Nubeqa should also receive a gonadotropin-releasing hormone (GnRH) agonist or antagonist concurrently or have had a bilateral orchiectomy.