

Nubeqa[®] (darolutamide) – New drug approval

- On July 30, 2019, [Bayer announced](#) the FDA approval of [Nubeqa \(darolutamide\)](#), for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC).
- In the U.S., over 73,000 men are estimated to be diagnosed with CRPC in 2019.
 - About 40% of these patients have prostate cancer that has not spread to other parts of the body and is also associated with a rising prostate-specific antigen level, despite a castrate testosterone level, which is known as nmCRPC.
 - About one-third of men with nmCRPC go on to develop metastases within two years.
- Nubeqa is an androgen receptor inhibitor (ARI) with a distinct chemical structure that competitively inhibits androgen binding, AR nuclear translocation, and AR-mediated transcription. Nubeqa decreased prostate cancer cell proliferation *in vitro* and tumor volume in mouse xenograft models of prostate cancer.
- The efficacy of Nubeqa was demonstrated in a placebo-controlled study (ARAMIS) conducted in 1,509 patients with nmCRPC. Patients received Nubeqa or placebo until radiographic disease progression, unacceptable toxicity or withdrawal. All patients received a gonadotropin-releasing hormone (GnRH) analog concurrently or had a bilateral orchiectomy. All patients received a gonadotropin-releasing hormone (GnRH) analog concurrently or had a bilateral orchiectomy. The major efficacy endpoint was metastasis free survival (MFS).
 - The median MFS was 40.4 months for Nubeqa-treated patients vs. 18.4 months for the placebo group (Hazard ratio 0.41; 95% CI: 0.34, 0.50; p < 0.0001).
- A warning and precaution of Nubeqa is embryo-fetal toxicity.
- The most common adverse reactions (≥ 2%) with Nubeqa use were fatigue, pain in extremity, and rash.
- The recommended dose of Nubeqa is 600 mg (two 300 mg film-coated tablets) orally, twice daily with food.
 - Patients receiving Nubeqa should also receive a GnRH analog concurrently or should have had a bilateral orchiectomy.
- Bayer's launch plans for Nubeqa are pending. Nubeqa will be available as a 300 mg tablet.