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on Drugs and Therapeutics

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Online Article

IN THIS ISSUE

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IN BRIEF

A New Prostate Cancer Indication for Darolutamide *(Nubeqa)*

The androgen receptor inhibitor darolutamide (*Nubeqa* – Bayer) has been approved by the FDA for use in combination with docetaxel for treatment of metastatic hormone-sensitive prostate cancer (mHSPC). The drug was previously approved for treatment of nonmetastatic castration-resistant prostate cancer (nmCRPC).[1]

Pronunciation Key	
Darolutamide: dar" oh loo' ta mide	***Nubeqa*:** noo' be ka

MECHANISM OF ACTION — Androgen receptors are involved in the growth, differentiation, and survival of prostate cancer cells. Darolutamide inhibits androgen binding, androgen receptor nuclear translocation, and androgen receptor-mediated transcription.

CLINICAL STUDIES — FDA approval of the new indication was based on the results of a double-blind trial (ARASENS) in 1306 patients with mHSPC who were randomized to receive oral darolutamide 600 mg or placebo twice daily, each in addition to docetaxel (75 mg/m^2 IV administered every 3 weeks for up to 6 cycles). All patients were receiving a gonadotropin-releasing hormone (GnRH) analog concurrently or had a bilateral orchiectomy. Median overall survival was 48.9 months in the placebo arm and was not yet reached in the darolutamide arm. Overall survival at 4 years was 50.4% in the placebo arm and 62.7% in the darolutamide arm.[2]

ADVERSE EFFECTS — The most common adverse effects of darolutamide in the ARASENS trial were alopecia, neutropenia, fatigue, and anemia. Hyperglycemia, decreases in lymphocyte and neutrophil counts, increased AST and ALT levels, and hypocalcemia have been reported.

PREGNANCY — Based on its mechanism of action, darolutamide could cause fetal harm and pregnancy loss. Male patients with female partners of reproductive potential should use effective contraception during treatment with darolutamide and for one week after the last dose.

DOSAGE, ADMINISTRATION, AND COST — *Nubeqa* is supplied as 300-mg tablets. The recommended dosage for treatment of mHSPC is 600 mg taken twice daily with food until unacceptable toxicity or disease progression occurs, in addition to docetaxel 75 mg/m^2 IV every 3 weeks for up to 6 cycles. The first dose of docetaxel should be administered within 6 weeks after starting darolutamide treatment. Patients should also receive a GnRH analog or have had a bilateral orchiectomy. The dosage of darolutamide should be reduced to 300 mg twice daily in patients with moderate hepatic impairment or severe renal impairment. The wholesale aquisition cost of a 30-day supply of *Nubeqa* costs is $12,866.[3] ■

1. Darolutamide (Nubeqa) for prostate cancer. Med Lett Drugs Ther 2019; 61:201.
2. MR Smith et al. Darolutamide and survival in metastatic, hormone-sensitive prostate cancer. N Engl J Med 2022; 386:1132.
3. Approximate WAC. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. June 5, 2023. Reprinted with permission by First Databank, Inc. All rights reserved. ©2023. www.fdbhealth.com/policies/drug-pricing-policy.

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