Generic Name:
Darolutamide
Trade Name:
Nubeqa
Company:
Bayer HealthCare Pharmaceuticals
Notes:

On July 30, FDA approved darolutamide for nonmetastatic, castration-resistant prostate cancer.

Approval was based on ARAMIS, a multicenter, double-blind, placebo-controlled clinical trial in 1,509 patients with nonmetastatic, castration-resistant prostate cancer. Patients were randomized (2:1) to receive either 600 mg darolutamide orally twice daily (n = 955) or matching placebo (n = 554). All patients received a gonadotropin-releasing hormone (GnRH) analog concurrently or had a previous bilateral orchiectomy. Twelve patients with previous seizure histories were treated in the darolutamide arm.

The primary endpoint was metastasis free survival (MFS), defined as the time from randomization to first evidence of distant metastasis or death from any cause within 33 weeks after the last evaluable scan, whichever occurred first. The median MFS was 40.4 months (95% CI 34.3?not reached) for patients treated with darolutamide compared with 18.4 months (95% CI 15.5?22.3) for those receiving placebo (hazard ratio 0.41 [95% CI 0.34?0.50; P < 0.0001). Overall survival data were not mature.

The most common adverse reactions (?2%) in patients who received darolutamide were fatigue, pain in extremity, and rash. Ischemic heart disease (4.3%) and heart failure (2.1%) were more common in the darolutamide arm. The seizure incidence was similar in the two arms (0.2%).

The recommended darolutamide dose is 600 mg (two 300-mg tablets) administered orally twice daily with food. Patients should also receive a GnRH analog concurrently or should have had bilateral orchiectomy.

Medication Monitor Categories:
New Drug Approvals