

New Prostate Cancer Option

FDA approves Nubeqa for nonmetastatic prostate cancer

September 16, 2019 By [Liz Highleyman](#)

In July, the Food and Drug Administration approved Nubeqa (darolutamide) for [prostate cancer](#) that progresses despite a low testosterone level but that has not yet spread elsewhere in the body. Nubeqa is an androgen receptor inhibitor that interferes with the activity of male hormones in the body, including their ability to trigger prostate cancer growth.

The Phase III ARAMIS trial, which enrolled more than 1,500 men with high-risk prostate cancer, showed that Nubeqa doubled the time before cancer spread beyond the prostate (40 months versus 18 months with a placebo) and led to a 59% reduction in the risk of metastasis or death. Men in the Nubeqa group also went longer before they experienced worsening pain, developed skeletal problems (such as bone fractures) or needed to start chemotherapy.

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