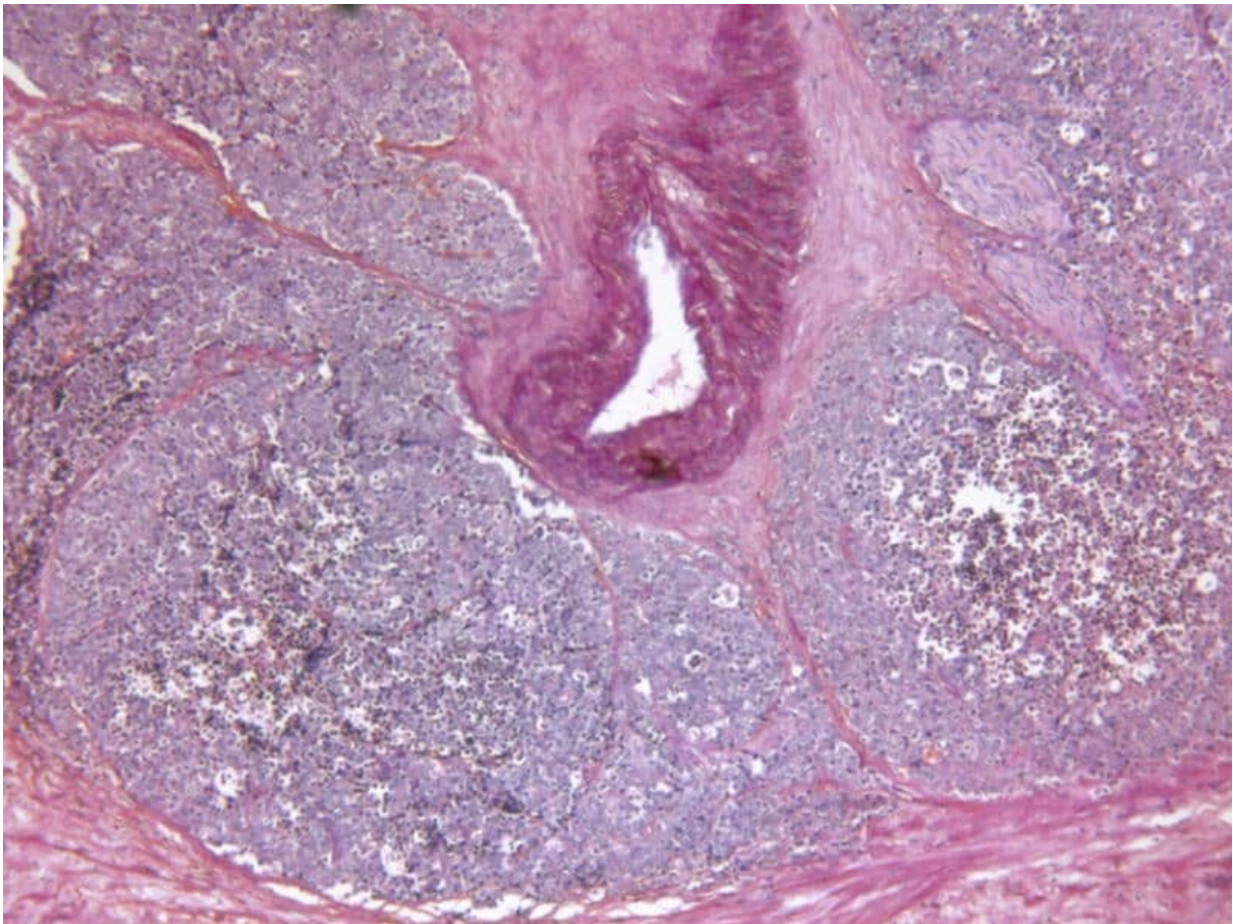


Darolutamide slows spread of castration-resistant prostate cancer

February 19 2019



(HealthDay)—Metastasis-free survival is significantly longer among men

with nonmetastatic, castration-resistant prostate cancer treated with darolutamide versus placebo, according to a phase 3 study published online Feb. 14 in the *New England Journal of Medicine* to coincide with the American Society of Clinical Oncology annual Genitourinary Cancers Symposium, held from Feb. 14 to 16 in San Francisco.

Karim Fizazi, M.D., from the Université Paris-Sud, and colleagues randomly assigned men with nonmetastatic, [castration-resistant prostate cancer](#) and a [prostate-specific antigen](#) doubling time of ≤ 10 months (2:1) to receive either darolutamide (955 participants; 600 mg twice daily) or placebo (554 participants) while continuing androgen-deprivation therapy.

The researchers found that in the planned primary analysis, median metastasis-free survival was 40.4 months with darolutamide and 18.4 months with placebo (hazard ratio for metastasis or death in the darolutamide group, 0.41). Darolutamide also offered benefits related to secondary end points, including [overall survival](#), time to pain progression, time to cytotoxic chemotherapy, and time to a symptomatic skeletal event. The groups were similar with regard to the incidence of adverse events with a frequency of ≥ 5 percent and a grade ≥ 3 . The percentage of patients who discontinued the study due to adverse events was also similar in the two groups (8.9 percent in the darolutamide group versus 8.7 percent in the placebo group).

"The risk of metastasis or death from any cause was reduced by 59 percent, and the benefit was consistent across all subgroups, including the subgroup of patients with lower-risk disease," the authors write.

Bayer HealthCare and Orion Pharma, the manufacturers of darolutamide, supported the trial.

More information: [Abstract/Full Text](#)

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Citation: Darolutamide slows spread of castration-resistant prostate cancer (2019, February 19)
retrieved 7 May 2024 from
<https://medicalxpress.com/news/2019-02-darolutamide-castration-resistant-prostate-cancer.html>

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