Darolutamide boosts survival in nonmetastatic prostate cancer

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(HealthDay)—For men with nonmetastatic, castration-resistant prostate cancer, the risk for death is significantly lower for those receiving darolutamide versus placebo, according to a study published in the Sept. 10 issue of the *New England Journal of Medicine*.

Karim Fizazi, M.D., from the University of Paris-Saclay, and colleagues randomly assigned 1,509 men in a 2:1 ratio to receive either darolutamide or placebo (955 and 554 patients, respectively) while they continued to receive androgen-deprivation therapy. Unblinding of the treatment assignments occurred after the primary end point analysis was found to be positive, and patients from the placebo group were permitted to cross over and receive open-label darolutamide.

At the time of unblinding, all 170 patients who were still receiving placebo crossed over to receive darolutamide; 137 who had discontinued placebo before unblinding received at least one other life-prolonging therapy. The researchers found that at three years, overall survival was 83 and 77 percent in the darolutamide and placebo groups, respectively. The risk for death was significantly lower in the darolutamide group versus the placebo group (hazard ratio, 0.69). With respect to all secondary end points, including time to first skeletal event and time to first use of cytotoxic chemotherapy, darolutamide was associated with significant benefit.

"An overall survival benefit was observed even though more than half the patients in the placebo group received subsequent treatment with darolutamide or another life-prolonging therapy," the authors write.

Several authors disclosed financial ties to pharmaceutical companies, including Bayer, which manufactures darolutamide and funded the study.

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