

Apalutamide delays progression of nonmetastatic, castration-resistant prostate cancer

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Treatment with an investigational androgen receptor inhibitor significantly delayed the development of metastasis in patients with prostate cancer that had become resistant to standard androgen-deprivation therapy. The results of a multi-institutional, phase 3 clinical trial of apalutamide - led by investigators from Massachusetts General Hospital (MGH) and University of California, San Francisco (UCSF) - are receiving early release publication in the *New England Journal of Medicine* to coincide with a presentation today at the American Society for Clinical Oncology Genitourinary Cancers (ASCO-GU) Symposium.

"Our study found that apalutamide treatment markedly improved metastasis-free survival and other clinical outcomes in men with castration-resistant prostate cancers and no detectable metastases," says Matthew Smith, MD, PhD, of the MGH Cancer Center, corresponding author of the NEJM report. "At this time, there are no approved treatments for men in that situation, so we need to wait until their disease progresses to add the standard therapies that have been approved for metastatic disease."

Senior author Eric Small, MD, deputy director of the Helen Diller Family Comprehensive Cancer Center at UCSF, who presented the data at the ASCO-GU Symposium, says, "This trial's results suggest that the availability of apalutamide should offer men with nonmetastatic, castration-resistant prostate [cancer](#) a treatment that can delay or prevent

the development of metastases and other complications associated with disease progression."

Androgen-deprivation therapy, either through surgical removal of the testicles or the use of drugs that suppress testosterone production, is standard treatment for men with [metastatic prostate cancer](#) and is also used for nonmetastatic cancer. Unfortunately, androgen deprivation stops working for almost all patients, leading to what is called castration-resistant disease. In such patients whose cancer has not yet spread, a rapid rise in prostate-specific antigen (PSA) levels warns of the near-term development of metastases, the major cause of complications and death from prostate cancer.

Apalutamide binds to the androgen receptor, blocking its activation by testosterone and other androgens. Apalutamide is being developed by The Janssen Pharmaceutical Companies of Johnson & Johnson, which sponsored this study. A previous phase 2 clinical trial of apalutamide for men with nonmetastatic, castration-resistant [prostate](#) cancer at high risk of progression showed that the drug was well tolerated and achieved responses in most patients.

The current trial was conducted at 322 sites in 26 countries in North American, Europe and the Asia-Pacific. More than 1,200 patients enrolled in the trial between October 2013 and December 2016. All participants had nonmetastatic [prostate cancer](#) that had stopped responding to androgen-deprivation therapy and a rapid PSA doubling time, indicating an elevated risk for metastasis. Participants were randomized to receive a daily oral dose of either apalutamide or a placebo and were evaluated every 16 weeks for signs of disease progression.

The NEJM study reports results based on data gathered by May 19, 2017. The average progression-free survival - the time from

randomization to the first evidence of metastasis - was 40.5 months for participants receiving apalutamide, compared with 16.2 months for those taking a placebo. Taking apalutamide also reduced other signs of [disease progression](#) - including development of imaging-confirmed metastasis or symptoms such as bone pain - and death from any cause. Members of the apalutamide group who continued to benefit from the drug were able to continue treatment, and members of the placebo group could begin receiving apalutamide on an open-label basis.

More information: *New England Journal of Medicine* (2018). [DOI: 10.1056/NEJMoa1715546](https://doi.org/10.1056/NEJMoa1715546)

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