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[Make an Appointment](#)
[Back](#)

[Press Releases](#)
[Learn About Cancer & Treatment](#)

ABOUT US

[Our mission, vision & core values](#)

[Leadership](#)

[History](#)

[Inclusion & belonging](#)

[Annual report](#)

[Give to MSK](#)

[FOR THE MEDIA](#)

"Abiraterone acetate provides an important and safe option for men with castration resistant prostate cancer that can prolong their lives. This trial also establishes a new category of treatment for men who have progressed on conventional hormone therapies as well as chemotherapy. It proves that these previously treated patients have tumors that are still hormonally responsive. Previously, this was the point in the illness where hormonal agents were typically not considered," said senior author [Howard I. Scher, MD](#), Chief of the Genitourinary Oncology Service at Memorial Sloan Kettering, who noted that this is the first hormonal agent to show a clear survival benefit in this group of patients.

The randomized, double-blind, placebo-controlled phase III trial included 1,195 men with metastatic prostate cancer whose disease had progressed after docetaxel-based chemotherapy. Patients were randomized to receive prednisone with either abiraterone acetate or placebo. After a little more than a year, overall survival for the abiraterone acetate plus prednisone group was 14.8 months versus 10.9 months for the placebo plus prednisone group, a reduction in mortality of more than 34 percent. In September 2010, the data monitoring committee recommended unblinding the study to allow the placebo group to switch to abiraterone acetate. The drug was approved by the FDA in April 2011.

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Howard I. Scher, MD, senior author and Chief of the Genitourinary Oncology Service at Memorial Sloan Kettering

Prostate cancer is driven by male hormones called androgens, and for the past seventy years, depleting or blocking the action of androgens has been the standard of care for men whose cancers have advanced beyond the prostate itself. This approach is successful initially, but most men eventually progress. Abiraterone acetate works by blocking the synthesis or production of testosterone by inhibiting an enzyme called CYP17 that is involved in the formation of DHEA and androstenedione, which are metabolized into testosterone.

"Abiraterone acetate is an oral medication that targets one of the specific mechanisms that enable prostate cancers to become resistant to conventional hormones: the increased production of androgens in the tumor itself. This drug blocks the enzymes that produce androgens, resulting in androgen levels that are significantly lower than what is achieved with conventional treatments," added Dr. Scher.

In addition to improving overall survival in men with metastatic disease, patients receiving abiraterone acetate plus prednisone had higher PSA response

rates and were more likely to show an improvement in disease- related symptoms than placebo-treated patients. The time to PSA progression and disease progression by imaging was also prolonged. Side effects that occurred more frequently with abiraterone acetate included fluid retention, hypertension, and hypokalemia (a drop in potassium levels in the blood).

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