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Vaccine for Advanced Prostate Cancer Promising

[John Schieszer](#)

January 28, 2010

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A vaccine of harmless poxviruses engineered to spur an immune system attack on tumor cells could offer hope to men symptomatic castration-resistant metastatic prostate cancer (mCRPC).

Researchers reported on phase 2 trial results showing that Prostavac-VF immunotherapy is well tolerated and associated with a 44% reduction in death rate over a three-year period, with a median overall survival increase of 8.5 months in men with mCRPC.

The success of this new form of immunotherapy paves the way for a Phase 3 trial that may include up to 1,000 patients with mCRPC.

In the double-blind trial, investigators randomly assigned patients to receive Prostavac or an inactive control. Subjects received these study agents on days 1, 14, 28, 56, 84, 112, and 140. Of the 122 subjects in the trial, 82 patients received Prostavac-VF, which is now owned by BN ImmunoTherapeutics, Inc., Mountain View, Calif., and 40 received the control.

Prostavac combines two weakened poxviruses that have been genetically engineered to produce slightly irregular versions of PSA and three co-stimulatory molecules that stimulate the immune system to mount a more vigorous attack on prostate tumor cells.

After three years of follow-up, 30% of the patients in the Prostavac arm were alive compared with 17% in the control group. The median survival of the vaccine group was 24.5 months compared with 16 months for the control group. "Although this study is relatively small, it offers encouraging evidence of a clinically meaningful benefit from this vaccine approach," said principal investigator Philip Kantoff, MD, Professor of Medicine at Harvard Medical School and the Director of the Lank Center for Genitourinary Oncology at Dana-Farber Cancer Institute, both in Boston. Study findings are scheduled to be published in the *Journal of Clinical Oncology*.

The two study arms had mostly similar clinical characteristics, but the mean age of the men in the Prostavac arm was 72.6 years compared with 76.8 years for controls. The researchers noted, however, that age is not a

significant prognostic factor in prostate cancer. In addition, the median PSA level in the vaccine group was lower than that of control subjects (36 vs. 45 ng/mL). The two groups showed no difference in Gleason scores.

Prostvac was well tolerated and most adverse events (AEs) were injection site reactions. However, a subset of patients experienced fatigue, fevers, and nausea. Two patients in the Prostvac arm discontinued therapy because of treatment-related AEs. One patient had recurrent lip edema after his second and third vaccinations and the other patient had multiple AEs, including thrombotic thrombocytopenic purpura and myocardial infarction (MI). The researchers reported that the thrombotic thrombocytopenic purpura was possibly related to treatment even though it has not been associated previously with vaccinia immunization.

“The patients being treated have advanced disease. I think this is a significant observation but it has to be validated,” said Dr. Kantoff told *Renal & Urology News*. “It is still probably a few years away. Nonetheless, it is very exciting step in delivering immunotherapy.”

A randomized phase 3 trial that may include up to 1,000 patients is expected to begin next year, he said.

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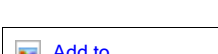


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