



BAVARIAN NORDIC

PROSTVAC®

PROSTVAC (rilimogene galvacirepvec/rilimogene glafolivec) is Bavarian Nordic's off-the shelf targeted immunotherapy candidate for the treatment of metastatic castration-resistant prostate cancer (mCRPC). PROSTVAC is the subject of a Phase 3 clinical development program under a Special Protocol Assessment (SPA) from the FDA, and is being developed in collaboration with the National Cancer Institute (NCI).

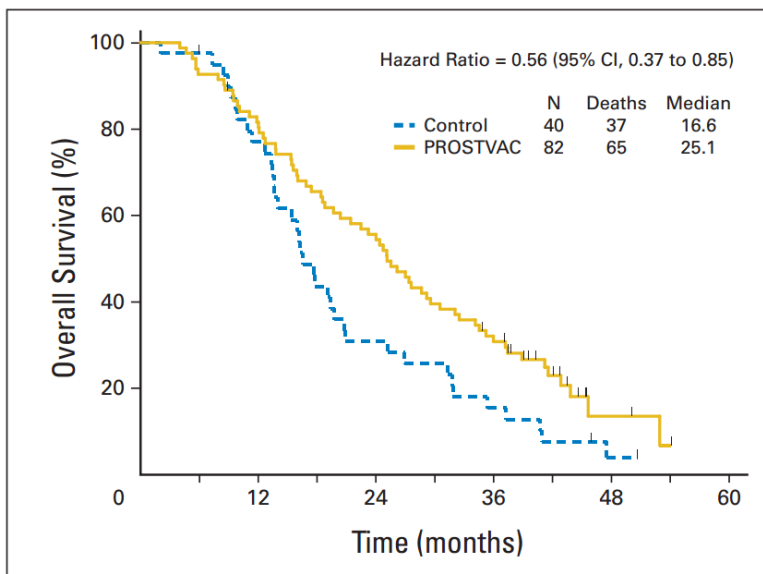
PROSTVAC has the potential to extend the lives of men with mCRPC, who have limited treatment options, and because it is a targeted immunotherapy with a favorable safety profile, it is predicted to do so with minimal impact on quality of life.

In contrast to products that require individual patient blood cell collection and manufacturing, PROSTVAC is ready to use, making a simple production and distribution process possible. PROSTVAC is administered subcutaneously, which provides ease of use to physician and patients.

Encouraging results to date have led to the initiation of the Phase 3 PROSPECT study currently underway. The randomized, double-blind, placebo controlled Phase 2 study of PROSTVAC in 125 asymptomatic or minimally symptomatic mCRPC patients demonstrated:

- Longer median survival by 8.5 months (25.1 v 16.6 months for the control group)
- 44% reduction in the risk of death (stratified log-rank P= .0061)*

*Kantoff, PW, et al. *J Clin Oncol.* 2010;28:1099-1105.



PROSTVAC

CLINICAL DEVELOPMENT PROGRAM

- 15 Phase 1 & 2 clinical trials
- Over 600 patients treated with PROSTVAC

SELECTED CLINICAL STUDIES

- PROSPECT - randomized, double-blind, placebo-controlled Phase 3 trial in mCRPC
Status: Ongoing
- Randomized, double-blind, placebo-controlled Phase 2 trial in mCRPC
Status: Completed

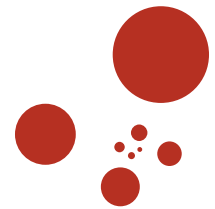
PLANNED STUDIES

- Combination trial with enzalutamide in M0 (biochemical recurrence) and mCRPC patients

For more information please visit www.bavarian-nordic.com.



To download a copy of the Phase 2 study results, scan the QR code with your mobile device.



BAVARIAN NORDIC

PROSPECT Trial

PROSPECT is a global, randomized, double-blind, placebo-controlled Phase 3 trial being conducted under a Special Protocol Assessment (SPA) from the FDA. PROSPECT is expected to enroll 1,200 asymptomatic or minimally symptomatic metastatic, castration-resistant prostate cancer (mCRPC) patients across as many as 250 clinical trial centers and up to 15 countries.

Eligible patients will be randomized to 1 of 3 study arms:

- PROSTVAC[®] and GM-CSF injections
- PROSTVAC and GM-CSF placebo injections
- PROSTVAC placebo and GM-CSF placebo injections

Key requirements for trial eligibility:

- Diagnosis of asymptomatic or minimally symptomatic mCRPC
- No prior treatment with chemotherapy

The primary endpoint is overall survival (OS); for the study outcome to be positive, either one or both of the treatment arms must demonstrate significantly better overall survival than placebo.

The PROSPECT trial analysis plan has been accepted by the FDA under the SPA to include pre-specified interim analyses of data to evaluate whether the trial should continue as planned or potentially be stopped early, either for efficacy or futility. If the trial exceeds the efficacy threshold during an interim analysis, a Biologics License Application may be filed at an earlier stage, potentially shortening the overall development time.

PROSTVAC: Proposed Mode of Action

PROSTVAC immunotherapy is based on triggering a specific and targeted immune response to prostate cancer cells and tissue by using viral vectors which carry the tumor-associated antigen PSA (prostate-specific antigen) along with three immune-enhancing costimulatory molecules known as TRICOM (B7.1, ICAM-1, and LFA-3). When PSA-TRICOM is presented to the immune system in the form of highly immunogenic viral vectors, cytotoxic T-lymphocytes (CTLs) are generated that recognize and kill PSA-expressing tumor cells. A cascade effect may also occur, overcoming the immune suppressive tumor microenvironment and leading to immune recognition of other tumor-associated antigens.

The PROSTVAC regimen consists of an initial priming administration with a PSA-TRICOM vaccinia-based vector, followed by six subsequent boosting administrations with a PSA-TRICOM fowlpox-based vector.

Study participation includes 9 study visits over 5 months, with follow up visits every 6 months until the end of the study. For more information about the PROSPECT trial, visit www.continueyourfight.com.

Prospect

TRIAL INVESTIGATORS



James L. Gulley, MD, PhD, FACP
Director, Clinical Trials Group &
Deputy Chief, Laboratory of Tumor
Immunology and Biology

Senior Investigator, Medical Oncology
Branch Center for Cancer Research,
National Cancer Institute National
Institutes of Health



Philip W. Kantoff, MD
Chief, Division of Solid Tumor Oncology;
Chief Clinical Research Officer; Director,
Lank Center for Genitourinary Oncology

Professor of Medicine,
Harvard Medical School