



BAVARIAN NORDIC

Company Announcement

15 November 2011

Bavarian Nordic Initiates Pivotal Phase 3 Trial of PROSTVAC® Prostate Cancer Immunotherapy

Kvistgaard, Denmark - November 15, 2011 - Bavarian Nordic A/S (OMX: BAVA) today announced that its subsidiary, BN ImmunoTherapeutics has initiated the pivotal Phase 3 trial of PROSTVAC® for patients with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer. The trial is being conducted under a Special Protocol Assessment agreement with the FDA.

The first site in the U.S. has opened for enrolment of patients into the study, with a number of other sites and countries to follow soon.

“The trial represents the first-ever Phase 3 study in the history of Bavarian Nordic, and we are extremely proud to have achieved this significant milestone in our cancer vaccine division in our efforts to advance novel vaccines for the treatment of cancer,” stated Anders Hedegaard, President & CEO of Bavarian Nordic. *“We are encouraged by the results we have seen to date with PROSTVAC® and hope that this product may provide a more effective and convenient therapy for patients with prostate cancer.”*

PROSTVAC® is an “off-the-shelf” therapeutic vaccine candidate that has the potential to extend the lives of people with advanced prostate cancer. Administered subcutaneously, it induces a specific, targeted immune response that attacks prostate cancer cells.

James L. Gulley, M.D., Ph.D., Director of the Clinical Trials Group at the Laboratory of Tumor Immunology and Biology at the National Cancer Institute (NCI), and Philip Kantoff M.D., Professor of Medicine at Harvard Medical School, will act as principal investigators on the trial.

According to Dr. Gulley, the Phase 2 clinical trial data of PROSTVAC® demonstrated a very promising 44% reduction in the rate of death with an 8.5 month improvement in median overall survival, a level of clinical benefit that compares favorably to other currently approved agents for advanced prostate cancer. Dr. Gulley hopes to confirm this improvement in survival in the trial.

About the Phase 3 trial

The single global, randomized, double-blind, placebo-controlled Phase 3 study is based on the promising findings from a previous randomized, placebo-controlled Phase 2 trial of the vaccine in 125 patients with advanced prostate cancer and is expected to enrol about 1,200 patients in three study arms. Patients in the two active study arms will receive either PROSTVAC® alone or PROSTVAC® with adjuvant doses of GM-CSF. Patients who have metastatic disease and have failed hormone therapy will be eligible to enrol in the study. The primary endpoint is overall survival (OS). For the study outcome to be positive, either one or both of the treatment arms must be superior to placebo. About 300 clinical trial centers in more than 20 countries are expected to participate in the trial. Patient enrolment in the trial is expected to take up to twenty-four months.

For more information about the trial, visit: <http://www.bavarian-nordic.com/prostvac>.

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About Prostate Cancer

Prostate cancer is the most frequently diagnosed cancer in men. The disease affects approximately one in six men and an estimated 600,000 new cases of prostate cancer are expected in the U.S. and Europe during 2011. With an estimated more than 100,000 deaths in 2011, prostate cancer is also the second-leading cause of cancer death in men. Approximately 4 million men are living in the U.S. and Europe today who have been diagnosed with prostate cancer. *Sources: American Cancer Society and Evaluate Pharma.*

About PROSTVAC®

PROSTVAC® is an "off-the-shelf" prime-boost vaccine that sequentially combines two different poxviruses (vaccinia and fowlpox). Administered subcutaneously, it induces a specific, targeted immune response that attacks prostate cancer cells. Conventional chemotherapy currently used to treat prostate cancer has shown limited improvement in OS and is often associated with serious side effects. In contrast, PROSTVAC® has the potential to extend survival with minimal toxicity.

In a large, prospective randomized, double-blind, placebo-controlled Phase 2 study of 125 patients with metastatic prostate cancer, patients in the PROSTVAC® group had a significantly longer median overall survival by 8.5 months compared to the control group (p=0.006). The hazard ratio estimate for overall survival from the study is 0.56 (95% CI 0.37-0.85).

PROSTVAC® is being developed in collaboration with the National Cancer Institute under a Cooperative Research and Development Agreement with Bavarian Nordic's U.S.-based subsidiary, BN ImmunoTherapeutics. To date, PROSTVAC® and related PSA containing poxviral vaccines have been investigated in 19 ongoing and completed clinical trials involving more than 850 patients. PROSTVAC® is currently the subject of six NCI sponsored clinical Phase 1 and 2 studies in different settings.

In April 2010, PROSTVAC® was granted Fast Track designation by the FDA for the treatment of men with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer (mCRPC).

About Poxviruses and Immunotherapy

Although increased expression of tumor associated antigens, such as prostate-specific antigen (PSA), is associated with advanced disease these they do not sufficiently activate the immune system to attack cancer cells. To overcome this poor responsiveness, recombinant poxvirus vectors, including vaccinia, fowlpox and modified vaccinia Ankara (MVA), can be genetically engineered to express one or more tumor-associated antigens to greatly enhance the immune system's ability to recognize and destroy cancer cells bearing any of the targeted antigens. Bavarian Nordic's vaccine candidates containing vaccinia and fowlpox have been the subject of over 30 clinical trials in more than 1,000 patients with prostate, breast, lung, colorectal, gastric, pancreatic, ovarian, and other cancers. These extensive clinical studies suggest a favorable safety and tolerability profile along with immunologic responses directed against the relevant tumor-associated antigens.

About Bavarian Nordic

Bavarian Nordic is a vaccine-focused biotechnology company developing and producing novel vaccines for the treatment and prevention of life-threatening diseases with a large unmet medical need. The company's pipeline targets cancer and infectious diseases, and includes ten development programs. In oncology, the company's lead program is PROSTVAC®, a therapeutic vaccine candidate for advanced prostate cancer that is the subject of an ongoing pivotal Phase 3 trial and is being developed under a collaboration agreement with the National Cancer Institute. In infectious diseases, the company's lead program is IMVAMUNE®, a third-generation smallpox vaccine candidate that is being developed and supplied for emergency use to the U.S. Strategic National Stockpile under a contract with the U.S. Government. For more information, visit www.bavarian-nordic.com

Forward-looking statements

This announcement includes "forward-looking statements" that involve risks, uncertainties and other factors, many of which are outside of our control that could cause actual results to differ materially from the results discussed in the forward-looking statements. Forward-looking statements include statements concerning our plans, objectives, goals, future events, performance and/or other information that is not historical information. We undertake no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.