

Company Announcement

8 April 2013

## **Bavarian Nordic Agrees on Interim Analysis with the FDA and Provides an Update on its PROSPECT Phase 3 Trial**

**KVISTGAARD, Denmark, April 8, 2013** - Bavarian Nordic A/S (OMX: BAVA) today announced that the Company plans to conduct an interim analysis of the on-going PROSPECT Phase 3 trial of PROSTVAC® in prostate cancer patients with metastatic disease. The updated statistical analysis plan for the trial, which was recently accepted by the FDA, now includes pre-specified interim analyses of data that will be performed to evaluate whether the trial should continue as planned or potentially be stopped early for efficacy. In such case, a Biologics License Application may be filed at an earlier stage, potentially shortening the overall development time.

Enrollment in the trial is currently ongoing at almost 100 sites in 10 countries, and continues to expand into new countries and sites. As previously communicated, the initiation of new sites has been delayed due to a lengthier and more arduous regulatory process than anticipated in certain countries. Bavarian Nordic has responded to this delay by implementing a number of measures, aimed at completing enrollment within approximately one year.

Dr. James Breitmeyer, who was recently appointed President of BN Immunotherapeutics, Inc. said, "Enrollment in the PROSPECT study has been my first priority since I joined the company in February. Several enhancements to study conduct have been made to catch up on enrollment. Specifically, we have refocused our efforts towards high-performing clinical trial sites, an awareness program has been implemented, and we have hired additional internal and external resources to allow for a closer dialogue with the increasing number of clinical trial sites."

Two abstracts have been accepted for the American Society of Clinical Oncology (ASCO) Annual Meeting on May 31-June 4, 2013 in Chicago, Illinois, covering clinical safety data for PROSTVAC®, and the rationale for and design of two new studies of PROSTVAC® given in combination with enzalutamide. In connection with the conference, Bavarian Nordic will also be hosting a PROSTVAC® update and reception. Further information will follow shortly.

Asger Aamund  
Chairman of the Board

### **Contact**

Anders Hedegaard, President & CEO. Phone +45 23 20 30 64

### **About PROSTVAC®**

PROSTVAC® (PSA-TRICOM) is an off-the-shelf product candidate for the treatment of prostate cancer. In 19 ongoing and completed clinical Phase 1 and Phase 2 trials, more than 600 patients have been treated with the immunotherapy candidate, which has been well-tolerated. PROSTVAC® is a 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. The data from a larger Phase 2 trial demonstrated PROSTVAC®'s ability to extend the median overall survival of patients with advanced

prostate cancer by 8.5 months, a nearly 50% increase compared to the placebo group. This promising data led to the initiation of a confirmatory Phase 3 trial (PROSPECT).

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, Inc.

#### **About the PROSPECT Phase 3 Program**

PROSPECT is a single global, randomized, double-blind, placebo-controlled Phase 3 trial and is expected to enroll 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 but who have not yet received other treatment options such as chemotherapy will be eligible to enroll 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 demonstrate a better overall survival than placebo.

For more information about the trial, visit <http://www.continueyourfight.com>

#### **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 clinical Phase 1 and Phase 2 trials, PROSTVAC® has been tested in more than 600 patients. In infectious diseases, the company's lead program is IMVAMUNE®, a non-replicating 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](http://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.