

Company Announcement

8 December 2010

Bavarian Nordic Receives Special Protocol Assessment Agreement from the FDA for Phase 3 Trial of PROSTVAC®

Kvistgård, Denmark, December 8, 2010 - Bavarian Nordic A/S (OMX: BAVA) announced today that the company has received a letter of concurrence from the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for a Phase 3 study required for product registration for its product candidate, PROSTVAC®, for the treatment of patients with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer. This agreement reached with the FDA on this SPA means that the Phase 3 study can proceed as designed and, if successful, could form the primary clinical basis of product approval under a Biologics Licence Application.

"We are very pleased with the agreement on the Special Protocol Assessment with FDA. It not only represents a significant milestone in the development of PROSTVAC®, but also marks the key step in the regulatory process before the initiation of the Phase 3 study, anticipated to start enrolment late summer 2011, upon release of clinical trial material. We believe that PROSTVAC® will provide important benefits in survival and quality of life, compared to existing treatments in advanced prostate cancer", commented Anders Hedegaard, President & CEO of Bavarian Nordic.

A conference call is held today, Wednesday, December 8 at 4 p. m. CET with the participation of Anders Hedegaard, President and CEO, and Reiner Laus, Division President Cancer Vaccines. Dial-in numbers for the conference call are: Denmark: +45 3271 4611, UK: +44 (0)20 7162 0077, US: +1 334 323 6203.

About the Phase 3 program

The Phase 3 program will include a single global, strongly powered, randomized, double-blind, placebo-controlled study that 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 (which was included in Phase 2). 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 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. The phase 3 trial is sized so that each comparison requires 534 deaths with sensitivity for estimated death hazard ratios of 0.82 or less.

About Special Protocol Assessments

The Special Protocol Assessment (SPA) process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a Biologics License Application or New Drug Application (BLA, NDA). Final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 trial.

About PROSTVAC®

PROSTVAC® is an "off-the-shelf" therapeutic vaccine moving into late stage clinical development 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. 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. In 13 completed clinical trials to date, PROSTVAC[®] and related PSA containing poxviral vaccines have been investigated in more than 570 patients.

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).

Asger Aamund
Chairman of the Board

Contact

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

About Bavarian Nordic

Bavarian Nordic is a leading industrial 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 clinical pipeline targets cancer and infectious diseases, and includes seven development programmes. Two programmes under preparation for Phase III: PROSTVAC[®], a therapeutic vaccine for advanced prostate cancer is being developed under a collaboration agreement with the National Cancer Institute, and IMVAMUNE[®], a third-generation smallpox vaccine is being developed under a contract with the US government.

Bavarian Nordic is listed on NASDAQ OMX Copenhagen under the symbol BAVA.

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

PROSTVAC[®] is a registered trademark in the U.S.

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.