



BAVARIAN NORDIC

Company Announcement

9 March 2010

## Bavarian Nordic Successfully Completes End of Phase II Meeting for PROSTVAC™

- *Regulatory agencies endorse the overall Phase III plan for PROSTVAC™ in prostate cancer*
- *Bavarian Nordic will now finalise Phase III preparations and an SPA request for submission to the FDA, while preparing for production and continuing discussions with potential licensing partners*

*Kvistgård, Denmark, March 9, 2010* - Bavarian Nordic A/S (OMX: BAVA) announced today that the company has received Scientific Advice from the European Medicines Agency and concluded an end of Phase II meeting with the US Food and Drug Administration (FDA) for the PROSTVAC™ programme. Both agencies expressed general agreement with the proposed Phase III clinical programme of PROSTVAC™. Based on the consolidated feedback Bavarian Nordic will proceed to assemble a clinical trial protocol and submit it to the Special Protocol Assessment (SPA) process with the FDA within a few months. The final clinical protocol will be based on the outcome of this process.

Based on the consolidated feedback, Bavarian Nordic is planning to achieve marketing approval for PROSTVAC™ via a single global, strongly powered clinical trial that is expected to enrol about 1,200 patients. The study will be placebo-controlled and enrol patients with minimally symptomatic, castration-resistant metastatic prostate cancer, similar to the patient population studied in the company's placebo-controlled Phase II study.

The previously conducted Phase II study was a prospective randomized, double-blind, placebo-controlled 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). The study was published in *Journal of Clinical Oncology* in January 2010.

Anders Hedegaard, President & CEO of Bavarian Nordic, said: *"We are delighted with the outcome of our dialogue with both FDA and EMEA, as both agencies expressed general agreement with our clinical strategy to register PROSTVAC™. Although the final protocols still have to be formally agreed with both agencies, there is now a clear path to registering PROSTVAC™ in the US and Europe."*

### Contact

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### About PROSTVAC™

PROSTVAC™ is a 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 limited survival rates and is often associated with serious side effects. In contrast, PROSTVAC™ has the potential to extend survival with minimal toxicity. 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 clinical trials to date PROSTVAC™ and related PSA containing poxviral vaccines have been investigated and in more than 500 patients.

**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.

**About Bavarian Nordic**

Bavarian Nordic A/S 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 pipeline is focused in the three areas; cancer, biodefence and infectious diseases, and includes seven development programmes. Two programmes are 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](http://www.bavarian-nordic.com)