

## **Bavarian Nordic announces positive mature Phase II results from newly acquired prostate cancer vaccine**

**125 patient, prospective randomized placebo-controlled phase II study shows statistically significant improved overall survival.**

Bavarian Nordic has now evaluated the mature phase II data from the therapeutic prostate cancer vaccine candidate PROSTVAC™ that had been obtained as part of the recently entered partnership with the National Cancer Institute (NCI) in the US.

The results from the Phase II prospective randomized placebo-controlled study of 125 patients with advanced prostate cancer after 4 years of follow-up show that patients receiving PROSTVAC™ had a statistically significantly longer median overall survival by 8.5 months ( $p=0.015$ ) compared to the control group. Currently the only approved treatment for advanced prostate cancer extends median overall survival by an average of approximately 2 months. In addition, PROSTVAC™ also had a favourable safety and tolerability profile.

Based on these promising results, Bavarian Nordic expects to initiate confirmatory Phase III studies for PROSTVAC™ together with NCI in the first half of 2010 that will form the basis of approval for this therapy.

Prostate cancer is the most common form of cancer with more than 500,000 new diagnosed patients globally per year and only limited treatment options. With estimated more than 140,000 related deaths annually, prostate cancer is the third leading cause of cancer related deaths in men.

Philip Kantoff MD, Professor of Medicine, Harvard Medical School, the principal investigator of the study, said *"There are few available treatments for advanced prostate cancer. To see this extent of improvement in overall survival is very encouraging. These phase II data with PROSTVAC™ warrant confirmation with a phase III study and when confirmed this product has the potential to fulfil an unmet medical need for these patients."*

Anders Hedegaard, President and Chief Executive Officer, Bavarian Nordic A/S, said *"We are delighted with these promising results from this Phase II study, which will be published in full over the coming months. Based on these data we believe that PROSTVAC™ offers a potential breakthrough and real hope for patients suffering from advanced prostate cancer. Furthermore, unlike other current prostate cancer vaccines in development, PROSTVAC™ is an off-the shelf product that does not require complex individualised therapy. These results provide a full endorsement for our decision to strengthen our presence in cancer vaccine research, as announced earlier this year in connection with our newly launched strategy."*

This announcement does not change Bavarian Nordic's previously announced financial guidance for 2008. The decision to take PROSTVAC™ into phase III trials will have a limited financial impact on year 2009, which will be covered by the company's net free liquidity.

Kvistgård, 7 October 2008

Asger Aamund  
Chairman

**Contact:**

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**Conference call**

A conference call will be held today, 7 October 2008 at 10:30 am (CEST). Anders Hedegaard, President & CEO and Reiner Laus MD and CEO of BN ImmunoTherapeutics Inc. will present. The accompanying presentation will be available on the company's website: [www.bavarian-nordic.com](http://www.bavarian-nordic.com) in advance.

Dial-in numbers for the conference call are:

UK: +44 (0)20 7162 0025

US: +1 334 323 6201

### **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.*

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### **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 business strategy is focused in three areas: biodefence, cancer and infectious diseases. Bavarian Nordic's proprietary and patented technology MVA-BN<sup>®</sup> is one of the world's safest, multivalent vaccine vectors. Bavarian Nordic has ongoing contracts with the US government for the late-stage development and procurement of the company's third-generation smallpox vaccine, IMVAMUNE<sup>®</sup>.

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

For more information please visit [www.bavarian-nordic.com](http://www.bavarian-nordic.com)

### **About the NCI**

The National Cancer Institute (NCI) is part of the National Institutes of Health (NIH) and is the United States federal government's leading cancer research organization. NCI has played an active role in the development of drugs for cancer treatment for over 50 years. This is reflected in the fact that approximately one half of the chemotherapeutic drugs currently used by oncologists for cancer treatment were discovered and/or developed at NCI. The organisation has supported the research efforts of at least 20 Nobel Prize winners. For approximately half of these Nobel laureates, NCI supported the awarded research. According to a 1996 NCI analysis of drugs approved by the FDA, two-thirds of the anti-cancer drugs approved as of the end of 1995 were NCI-sponsored Investigational New Drugs.

### **About PROSTVAC<sup>™</sup>**

PROSTVAC<sup>™</sup> (Vaccinia-PSA-TRICOM and Fowlpox-PSA-TRICOM) 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 metastatic cells in the prostate. Conventional chemotherapy currently used to treat prostate cancer has limited survival rates and is often associated with numerous side effects. In contrast, PROSTVAC<sup>™</sup> has the potential to extend survival with improved quality of life.

In clinical trials to date PROSTVAC<sup>™</sup> has been investigated in 464 patients over 10 years. The Phase III programme is currently being planned.

### **About prostate cancer**

Prostate cancer had an incidence of more than 500,000 cases worldwide in 2007. It has thus become the most frequent cancer in men and has become more frequent than lung cancer and colon cancer. With estimated more than 140,000 related deaths annually, prostate cancer is the third leading cause of cancer related deaths in men. The age adjusted cancer death rates for prostate cancer have doubled since 1930; among other leading malignant diseases only lung cancer has shown a worse development in this century. These tendencies developed even though the five year survival rates for localized prostate cancer have been continuously improved. However, the treatment for metastatic prostate cancer has not been improved in recent years. Prostate cancer is resistant to conventional chemotherapy. The only mechanism that has been used so far in disseminated disease with some effect is hormone treatment. Hormone therapy slows the tumor growth by stopping or blocking testosterone from entering the cancer cells. Prostate cancer cells are typically dependent on testosterone or other androgens as growth factors. Thus, although initially effective, hormone therapy becomes ineffective after a period of time. Chemotherapy for disseminated disease at this stage is very limited with only one chemotherapeutic agent approved for the treatment of metastatic prostate cancer that extends survival by ~ 2 months, with toxic side effects. All other therapies for this stage of disseminated prostate cancer are palliative and do not prolong survival. Thus, improved therapies for prostate cancer are urgently needed.