

Company Announcement

13 February 2013

Bavarian Nordic Presents New Clinical Data on PROSTVAC® at the 2013 Genitourinary Cancers Symposium

KVISTGAARD, Denmark - February 13, 2013 - Bavarian Nordic A/S (OMX: BAVA) today announced that four abstracts on the Company's therapeutic cancer vaccine candidates for the treatment of prostate cancer, PROSTVAC® and MVA-BN® PRO will be the subject of four clinical presentations at the 2013 Genitourinary Cancers Symposium on February 14-16, 2013 in Orlando, Florida.

Two posters feature clinical data of PROSTVAC® evaluated as monotherapy or in combination with a radiopharmaceutical. A third poster reviews the safety profile of poxviral vaccines from 8 different clinical trials of PROSTVAC® and CV-301. The final poster reviews results from the Phase 1 dose escalation trial of MVA-BN® PRO. The preliminary results from these studies support the further clinical investigation in patients suffering from advanced prostate cancer.

Anders Hedegaard, President & CEO of Bavarian Nordic, said: "We are pleased that the clinical trial results of our immunotherapy candidates, including PROSTVAC®, are being presented at a major medical conference. These preliminary data provide insight into the tolerability and unique profile of our poxviral platform for developing innovative cancer immunotherapies."

The abstracts can be seen in full at Genitourinary Cancers Symposium's website: <http://gucasym.asco.org/>

Abstract #57: Effect of PSA-TRICOM, a pox-viral vaccine in prostate cancer (PCa), on tumor growth rates within 80 days after initiation in non-metastatic PCa.

Presenter: James L. Gulley, M.D., Ph.D., F.A.C.P.-Laboratory of Tumor Immunology and Biology, Medical Oncology Branch, National Cancer Institute (NCI)

In this NCI sponsored study, the effect of PSA-TRICOM (PROSTVAC®) vaccination was evaluated in 50 hormone naïve patients with non-metastatic prostate cancer in a multi-center trial (ECOG 9802). Prostate specific antigen (PSA) values were used to calculate tumor growth rate within the first 100 days of treatment.

The preliminary data from this study suggest that PROSTVAC® can alter the tumor growth rate significantly within 3 months after therapy initiation. The slowing of tumor growth rate could potentially translate to an improved overall survival, which will be evaluated in the ongoing global PROSPECT Phase 3 trial of PROSTVAC®, in asymptomatic or minimally symptomatic, metastatic castration-resistant prostate cancer that is currently enrolling patients.

Abstract # 102: A Phase II randomized clinical trial of Samarium-153 EDTMP (Sm-153) with or without PSA-TRICOM vaccine in metastatic castration-resistant prostate cancer (mCRPC) after docetaxel.

Presenter: Christopher Ryan Heery, MD - Laboratory of Tumor Immunology and Biology, Medical Oncology Branch, National Cancer Institute

This NCI-sponsored Phase 2 multi-center trial was designed to evaluate the progression-free survival (PFS) in metastatic castration-resistant prostate cancer patients receiving either Sm-153 alone (Arm A) or in combination with PROSTVAC® (Arm B). Of 44 patients enrolled, 39 were evaluable. At four months, the PFS for evaluable patients in Arm A was 11.1% (2/18 patients) compared to 23.8% (5/21 patients) in Arm B. Median PFS for patients in Arm A was 1.7 months compared to 3.7 months in Arm B. (Hazard ratio 0.502, p=0.045)

This final analysis suggests the combination of PROSTVAC® and Sm-153 has a similar toxicity profile to Sm-153 alone. Also, it appears to demonstrate improvement in PFS with the combination. This may indicate potential synergy between PROSTVAC® and bone-seeking radiopharmaceuticals.

Abstract #85: Safety profile of poxviral vaccines: NCI experience.

Presenter: Joseph W. Kim, MD - Laboratory of Tumor Immunology and Biology, Medical Oncology Branch, National Cancer Institute

This abstract evaluates data from a total of 1,343 subcutaneous poxviral injections from 215 patients in 8 NCI-sponsored clinical trials. Each vaccine consisted of recombinant vaccinia and recombinant fowlpox encoded with 3 human costimulatory molecules (TRICOM), and prostate specific antigen (PSA) - PROSTVAC®, or carcinoembryonic antigen (CEA) and mucin-1 (MUC-1) which is CV-301 (CEA-MUC-1-TRICOM).

No contact transmissions, inadvertent inoculations, or any serious adverse events related to vaccinia were observed in these eight studies. Grade 2 injection site reactions were reported in 31% (423 poxviral injections). These preliminary data suggest that poxviral vaccines are well-tolerated at a broad range of doses, in combination with other treatments, and in various tumor types.

Abstract #193: Phase I dose escalation trial of MVA-BN® PRO in men with non-metastatic castration-resistant prostate cancer.

Presenter: David G. McLeod, MD - Walter Reed National Military Medical Center

In this open label Phase 1 dose escalation multi-center trial, MVA-BN® PRO, an investigational prostate cancer immunotherapy designed to express sequences that control immunity to prostate specific antigen (PSA) and Prostatic Acid Phosphatase (PAP), was administered to twenty-four subjects with non-metastatic castration-resistant prostate cancer. All subjects completed the initial 3 vaccinations (treatment) and 21 subjects received 6 vaccinations (re-treatment). Seven responders received additional vaccinations during the extended treatment.

MVA-BN® PRO was well-tolerated across all dose regimens and no dose-limiting toxicities or severe adverse events were reported. The preliminary study results indicate MVA-BN® PRO may have the ability to induce a tumor-specific immune response that may play a role in reducing disease progression.

Asger Aamund
Chairman of the Board

Contact

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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 nearly 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

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.