Company Announcement

29 May 2013

Bavarian Nordic’s CV-301 Cancer Immunotherapy Candidate Shows Promise in Colorectal Cancer

KVISTGAARD, Denmark, May 29, 2013 - Bavarian Nordic A/S (OMX: BAVA) announced today that promising data from a Phase 2 trial of its CV-301 cancer immunotherapy candidate in patients with resected metastatic colorectal cancer were recently published in the Annals of Surgery.

In a study conducted at Duke University, 74 patients who were disease free after surgical resection of metastatic colon cancer received chemotherapy followed by immunotherapy with CV-301 (formerly designated as PANVAC-VF) either as CV-301 modified dendritic cells or in combination with GM-CSF. Compared to a group of contemporary control patients who were matched for key clinical features and had similar surgery and chemotherapy, the overall survival of the CV-301 treated patients was significantly longer (p < 0.0001). Treatment with CV-301 was well tolerated, with injection site reactions, fever, fatigue and muscle soreness as the most common side effects.

Michael Morse, MD, an oncologist with the Duke University Medical Center and lead author on the study, said, “With few treatment options available for patients with advanced colon cancer following complete surgical resection of metastases, there is a clear unmet medical need for better treatments. We believe that the encouraging data from this Phase 2 study support a late stage pivotal clinical trial of CV-301 in this patient population.”

The paper titled: “A Randomized Phase II Study of Immunization With Dendritic Cells Modified With Poxvectors Encoding CEA and MUC1 Compared With the Same Poxvectors Plus GM-CSF for Resected Metastatic Colorectal Cancer” can be found on the Annals of Surgery website:

http://journals.lww.com/annalsofsurgery/Abstract/publishahead/A_Randomized_Phase_II_Study_of_IMMunization_With.98439.aspx

Bavarian Nordic has expanded its license with the National Cancer Institute (NCI) for CV-301 to include colon cancer. The original collaboration agreement was executed in 2011, and involved multiple cancers including breast, lung, ovarian and other cancers. Colorectal cancer is the most frequently diagnosed cancer and second leading cause of cancer death in developed countries, according to the American Cancer Society.

“We are excited about exploring the potential of our cancer immunotherapy platform in colorectal cancer,” said James Breitmeyer, EVP of Bavarian Nordic and President of the Cancer Vaccine Division. “We are optimistic that CV-301 offers patients with colon cancer the same promise of extended survival with a favorable side effect profile that our other product candidate, PROSTVAC® offers patients with advanced prostate cancer. This provides an excellent opportunity to broaden our cancer immunotherapy clinical pipeline with yet another late-stage product candidate. We now look forward to assessing the complete CV-301 portfolio and expect to present the future development strategy later this year.”

This announcement does not affect the company’s expectations for the financial results for 2013.

Asger Aamund
Chairman of the Board
About CV-301
CV-301 (CEA-MUC-1-TRICOM) is an off-the-shelf immunotherapy product candidate for the treatment of multiple cancers. It originates from the same poxvirus technology platform as PROSTVAC®.

Both PROSTVAC® and CV-301 are prime-boost vaccines sequentially combining two different poxviruses (vaccinia and fowlpox). Collectively, these two product candidates, along with earlier generations of these vaccines, have been the subject of over 30 clinical trials with more than 1,100 patients actively treated for prostate, breast, lung, colorectal, gastric, pancreatic, ovarian and other cancers. These extensive clinical studies suggest that the product candidates are well-tolerated with the ability to induce specific immune responses directed against the relevant tumor-associated antigens.

While PROSTVAC® incorporates a single antigen over-expressed in prostate cancer (PSA), CV-301 incorporates two antigens (CEA and MUC-1) that are over-expressed in other major cancers, including breast, colon and other cancers, which makes CV-301 potentially applicable in various cancers.

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 clinical 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. IMVAMUNE® is currently in clinical Phase 3 development and marketing authorization applications have been filed in EU and Canada. 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.