



BAVARIAN NORDIC

Company Announcement

1 October 2012

Bavarian Nordic Reports Preliminary Data from Phase 2 Trial of CV-301 in Metastatic Breast Cancer

KVISTGAARD, Denmark, October 1, 2012 - Bavarian Nordic A/S (OMX: BAVA) today announced preliminary results from a randomized, open-label, multi-center Phase 2 study of CV-301 (CEA/MUC-1/TRICOM), an immunotherapy product candidate, in combination with docetaxel versus docetaxel alone for the treatment of metastatic breast cancer. The data were presented at the ESMO 2012 Congress (European Society for Medical Oncology) in Vienna, Austria, by Christopher R. Heery, MD, and colleagues from the National Cancer Institute (NCI).

An abstract of the study is available online at:

<http://abstracts.webges.com/myitinerary/publication-3526.html?congress=esmo2012#.UGVN3cJyjAc>

A preliminary analysis of the study showed progression-free survival (PFS) of 6.6 months in the CV-301 group versus 3.8 months among those receiving docetaxel alone. The clear separation of the curves indicates potential benefit. Because of its size the study was not designed to reach statistical significance. Accordingly, the p-value of (p=0.12) is considered to be a successful outcome, even though it does not meet criteria for statistical significance.

“The results we have seen to date from this NCI sponsored Phase 2 study are encouraging and support exploring options for further clinical development of CV-301 in metastatic breast cancer,” said Reiner Laus, MD, President of the Cancer Vaccine Division of Bavarian Nordic A/S. “We are excited by the growing body of clinical evidence which validates our immunotherapy platform for the treatment of cancer.”

The Phase 2 study enrolled 48 patients with metastatic breast cancer to receive CV-301 in combination with docetaxel or docetaxel alone. Enrolment completed in February 2012 (CV-301, n=25; control, n=23) and 5 patients remained on study at the time of the analysis (2 in the CV-301 group, 3 in the control). The primary study endpoint was PFS, while secondary endpoints included overall survival and immunologic correlative studies. Demographics were well matched and toxicity was similar in both arms. Immune analysis and correlation to patient clinical outcomes is ongoing.

As previously announced, final study data are expected during fourth quarter 2012, whereupon Bavarian Nordic will determine its future development strategy for CV-301.

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About Breast Cancer

According to the GLOBOCAN Report released in December 2011 by the International Agency for Research on Cancer at the World Health Organization, breast cancer is the most common cancer among women, with nearly 1.4 million new cancer cases diagnosed worldwide in 2008 (23% of all cancers). Breast cancer is also the most frequent cause of cancer death in women (estimated 458 000 deaths in 2008) in both developing and developed regions of the world.

About CV-301

Evaluated in clinical trials with more than 400 patients to date, CV-301 is an off-the-shelf cancer immunotherapy product candidate incorporating two antigens (CEA and MUC-1) that are overexpressed in major cancers, including breast, lung, and ovarian cancer. Similar to PROSTVAC[®], the Company's lead product candidate, CV-301 is a prime-boost vaccine, sequentially combining two different poxviruses (vaccinia and fowlpox).

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 third-generation 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.