Press Release

Bavarian Nordic Initiates Trial of CV301 in Combination with Nivolumab in Patients with Lung Cancer

- Study is exploring potential benefits of combining a cancer vaccine and PD-1 checkpoint inhibitor

COPENHAGEN, Denmark, December 29, 2016 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced the initiation of a clinical trial combining its proprietary cancer immunotherapy candidate, CV301, with the anti-PD-1 drug, OPDIVO® (nivolumab) from Bristol-Myers Squibb. The study is enrolling patients with non-small cell lung cancer (NSCLC) who have failed prior therapy.

The trial will begin with a Phase 1 safety component, enrolling up to 40 patients; the Phase 2 portion of the study will enroll 120 patients who will be randomized to receive either nivolumab (monotherapy) or a combination of CV301 and nivolumab. The study will enroll patients from up to 20 clinical sites throughout the United States. Detailed information on the trial can be found at [http://clinicaltrials.gov/ct2/show/NCT02840994](http://clinicaltrials.gov/ct2/show/NCT02840994).

The rationale for this combination approach is for the vaccine to generate a tumor specific T cell response and allow the checkpoint inhibitor to maintain that immune effect by preventing the tumor from turning that response off.

While the primary endpoint of the study is overall survival, numerous secondary endpoints including response rate, progression free survival and duration of response will be evaluated and offer the potential for an early efficacy signal, prior to an overall survival endpoint.

“We are pleased to announce the initiation of this study, which marks the entry for Bavarian Nordic into lung cancer. While CV301 has shown the ability to generate immune responses to tumor-associated antigens in a variety of cancers, this study is the first seeking proof-of-concept for a promising combination approach and we look forward to the results as well as to advance CV301 as combination therapy in additional indications over the next years,” said Paul Chaplin, President & CEO of Bavarian Nordic.

About CV301

CV301 is an immunotherapy candidate which is being developed under a CRADA with the National Cancer Institute (NCI).

CV301 targets two tumor-associated antigens, CEA and MUC-1, which are over-expressed in multiple solid tumors, including lung, bladder and colorectal cancer. Similar to PROSTVAC®, CV301 uses a prime/boost dosing schedule. CV301 incorporates a modified version of vaccinia (MVA-BN, a proprietary technology of Bavarian Nordic) as a priming dose, followed by multiple fowlpox boosts, and encodes the TRICOM costimulatory molecules.

A precursor version of CV301 has been tested in six NCI-sponsored clinical trials in various cancers, and a Phase 2 study in bladder cancer is currently ongoing. More than 300 patients have been treated with the product candidate.

About OPDIVO (nivolumab)

Marketed by Bristol-Myers Squibb, OPDIVO is an immune checkpoint inhibitor (anti-PD-1 therapy) approved for treatment of patients with advanced NSCLC in the second line setting, among other indications. OPDIVO has
demonstrated superior overall survival across histologies, versus chemotherapy, in two pivotal Phase 3 trials in patients with advanced NSCLC.

About Bavarian Nordic
Bavarian Nordic is a fully integrated biotechnology company focused on the development, manufacturing and commercialization of cancer immunotherapies and vaccines for infectious diseases, based on the Company’s live virus vaccine platform. Through long-standing collaborations, including a collaboration with the U.S. government, Bavarian Nordic has developed a portfolio of vaccines for infectious diseases, including the non-replicating smallpox vaccine, IMVAMUNE®, which is stockpiled for emergency use by the United States and other governments. The vaccine is approved in the European Union (under the trade name IMVANEX®) and in Canada. Bavarian Nordic and its partner Janssen are developing an Ebola vaccine regimen, which has been fast-tracked, with the backing of worldwide health authorities, and a vaccine for the prevention and treatment of HPV. Additionally, in collaboration with the National Cancer Institute, Bavarian Nordic has developed a portfolio of active cancer immunotherapies, including PROSTVAC®, which is currently in Phase 3 clinical development for the treatment of advanced prostate cancer. The company has partnered with Bristol-Myers Squibb for the potential commercialization of PROSTVAC. For more information visit www.bavarian-nordic.com or follow us on Twitter @bavariannordic.

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. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany the forward-looking statements. 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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