

Bavarian Nordic Announces Initiation of Phase 2 Trial Evaluating the Combination Therapy of CV301 and Nivolumab in Metastatic Colorectal Cancer

- Investigator-led study has commenced dosing
- Immunotherapy candidate CV301 is being assessed in combination with checkpoint inhibitors in multiple solid tumors

COPENHAGEN, Denmark, July 11, 2018 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced that the first patient has been dosed in a Phase 2 study evaluating the combination therapy of its cancer vaccine, CV301, and Bristol Myers Squibb's checkpoint inhibitor, nivolumab (OPDIVO®), for the treatment of patients with resectable hepatic-limited metastatic colorectal cancer (mCRC).

Bavarian Nordic's CV301 is designed to create a T-cell response against the tumor antigens CEA and MUC1, which are overexpressed on multiple solid tumors, including colorectal cancers. Preclinical data supports the premise that CV301 is highly synergistic with checkpoint inhibitors and holds the potential to broaden their efficacy in cancers where monotherapy has been ineffective.

The randomized, multiple-site, Phase 2 trial is being led by Darren Carpizo, M.D., Ph.D., the Director of the Liver Cancer and Bile Duct Cancer Program at Rutgers Cancer Institute, with material support from Bavarian Nordic and Bristol Myers Squibb. The study is expected to enroll 78 patients. Prior to surgical removal of their tumors, patients will be randomized to receive four cycles of either chemotherapy plus nivolumab or a combination of chemotherapy, nivolumab, and CV301. After resection, patients will continue receiving respective treatments in each study arm. Overall survival (OS) and several secondary measures will be evaluated in each arm.

"We are thrilled to see the first dose administered in this trial to evaluate the combination therapy of CV301 and nivolumab in patients with resectable, oligometastatic, microsatellite stable colorectal cancer (MSS)," said Paul Chaplin, President and CEO of Bavarian Nordic. "While checkpoint inhibitors have been impressive in some tumors, there are hundreds of thousands of cancer patients in dire need of new treatments, particularly in MSS. We are eager to explore how CV301 enhances the overall survival and lowers the risk of recurrence in these patients."

For more information on how to take part in this trial, individuals should call Rutgers Cancer Institute's Office of Human Research Services at 732-235-8675 or e-mail cinjclinicaltrials@cinj.rutgers.edu.

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 MUC1, which are over-expressed in multiple solid tumors, including lung, bladder, colorectal and pancreatic cancers. CV301 is a poxvirus-based prime/boost vaccine that 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.

Preclinical data shows that MVA-BN vaccines encoding a tumor antigen transgene (like CEA and MUC-1) upregulate PD-L1 by mounting an immune response against a tumor target. The upregulation of PD-L1 is a marker indicating the tumor is under attack from T-cells, presenting an opportunity for a greater response in patients who might otherwise not benefit from treatment with a checkpoint inhibitor alone.

About Bavarian Nordic

Bavarian Nordic is a fully integrated biotechnology company focused on the development of innovative and safe therapies against cancer and infectious diseases. Using our live virus vaccine platform technology, MVA-BN®, we have created a diverse portfolio of proprietary and partnered product candidates intended to improve the health and quality of life for children and adults. We supply our IMVAMUNE® non-replicating smallpox vaccine to the U.S. Strategic National Stockpile and other government stockpiles. The vaccine is approved in the European Union (under the trade name IMVANEX®) and in Canada. Registration studies are currently underway in the U.S. In addition to our long-standing collaboration with the U.S. government on the development of IMVAMUNE® and other medical countermeasures, our infectious disease pipeline comprises a proprietary RSV program as well as vaccine candidates for Ebola, HPV, HBV and HIV, which are developed through a strategic partnership with Janssen. Additionally, in collaboration with the National Cancer Institute, we have developed a portfolio of active cancer immunotherapies, designed to alter the disease course by eliciting a robust and broad anti-cancer immune response while maintaining a favorable risk-benefit profile. Through multiple industry collaborations, we seek to explore the potential synergies of combining our immunotherapies with other immune-modulating agents, e.g. checkpoint inhibitors.

For more information visit www.bavarian-nordic.com or follow us on Twitter [@bavariannordic](https://twitter.com/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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