Company Announcement

Bavarian Nordic Announces Phase 2 Trial Investigating Combination of Its Immunotherapy CV301 and Nivolumab in Microsatellite Stable Colorectal Cancer

- Bavarian Nordic and Bristol-Myers Squibb agree to supply clinical material for the trial
- Investigator-led study represents the fourth clinical combination of CV301 with a checkpoint inhibitor

COPENHAGEN, Denmark, March 8, 2018 – Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced a new Phase 2 study, exploring the combination of its cancer vaccine, CV301 and Bristol-Myers Squibb's nivolumab (OPDIVO®) in patients with metastatic colorectal cancer (mCRC). CV301 is specifically designed to elicit T-cells against the tumor antigens CEA and MUC1, both of which are highly overexpressed in colorectal cancers.

The Phase 2 randomized trial will enroll up to 74 patients with oligometastatic, microsatellite stable mCRC eligible for complete resection. 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. The trial, anticipated to begin enrolment before mid-year, will be led by Darren R. Carpizo, M.D., Ph.D., Director of the Liver Cancer and Bile Duct Cancer Program at Rutgers Cancer Institute in New Jersey.

"In about 80 percent of colorectal cancer patients whose disease has spread to the liver, the cancer returns after complete resection. By exploring unique combinations of vaccine therapy and checkpoint inhibition along with standard of care, we believe it is possible to improve overall survival and risk of recurrence in this patient population," said Dr. Carpizo.

"To date, there are no checkpoint inhibitors approved for the treatment of microsatellite stable colorectal cancer. This trial marks an important step in exploring indications where checkpoint inhibitors have not been successful as a monotherapy," said Paul Chaplin, President and CEO of Bavarian Nordic remarked. "We believe that CV301 - with its ability to elicit T-cells against specific tumor antigens - has the potential to address cancers in which monotherapy checkpoint inhibition may not be possible, and we are happy to further explore how we can best serve patients in need of new therapies."

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 CV301 upregulates 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.

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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.

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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