Bavarian Nordic Announces Collaboration to Evaluate CV301 in Combination with durvalumab in Colorectal and Pancreatic Cancers

- Third evaluation of CV301 in combination with a checkpoint inhibitor
- Multicenter investigator-sponsored trial to be led by Georgetown University

COPENHAGEN, Denmark, February 26, 2018 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced a new collaboration that will investigate CV301, the Company’s targeted immunotherapy candidate, and durvalumab (IMFINZI™), AstraZeneca’s PD-L1 inhibitor, in combination with maintenance chemotherapy for patients with metastatic colorectal or pancreatic cancers.

Under the collaboration with Georgetown University, both Bavarian Nordic and AstraZeneca will contribute clinical trial material and provide financial support for a planned Phase 1/2 clinical study. The trial, which is being sponsored by Georgetown University, will be led by Dr. Michael Pishvaian, Assistant Professor in the Department of Hematology/Oncology at the Lombardi Comprehensive Cancer Center at Georgetown University Medical Center.

The Phase 1/2 trial will begin with a lead-in study to determine the safety and tolerability of the combination, as well as the recommended Phase 2 dose of durvalumab in combination with CV301 and chemotherapy. The Phase 2 portion of the study will consist of two parallel trials, enrolling up to 26 patients for each disease setting. The primary endpoint for both arms of the study will be progression-free survival (PFS) with multiple secondary endpoints, including objective response rate (ORR), overall survival (OS), and disease control rate (DCR).

“Colorectal and pancreatic cancers are among the most difficult-to-treat malignancies to date. While therapeutic options for these patients remain limited, combining a targeted cancer vaccine with a checkpoint inhibitor could result in a novel approach to fighting these diseases, as well as improved patient outcomes,” said Dr. Michael Pishvaian, Georgetown University.

“With this trial, we are hopeful to continue demonstrating CV301’s potential in multiple cancers and combinations, particularly in a treatment setting in which checkpoint inhibition alone has yet to show significant benefit. We are very grateful to both the investigators and AstraZeneca for their support, and look forward to learning more as the data becomes available,” said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic.

In addition to durvalumab, CV301 is being investigated in combination with other immune checkpoint inhibitors such as KEYTRUDA® (pembrolizumab) from Merck in non-small cell lung cancer and TECENTRIQ® (atezolizumab) from Roche in bladder cancer.

Additional information on the study is available at: https://clinicaltrials.gov/ct2/show/NCT03376659.

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 the ability of CV301 to 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.

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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