

## **Bavarian Nordic Announces Initiation of Clinical Trial Evaluating the Combination Therapy of CV301 and Durvalumab in Metastatic Colorectal and Pancreatic Cancers**

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

**COPENHAGEN, Denmark, November 2, 2018** - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced that the first patient has been dosed in a clinical study evaluating CV301, the Company's targeted immunotherapy candidate, and durvalumab, AstraZeneca's PD-L1 inhibitor, in combination with maintenance chemotherapy for patients with metastatic colorectal or pancreatic cancers.

Bavarian Nordic's CV301 targets tumor-associated antigens, CEA and MUC1, which are overexpressed on multiple solid tumors, including colorectal and pancreatic cancers. Preclinical data has shown that vaccination resulted in the induction of tumor specific T-cells that infiltrated the tumor resulting in the upregulation of PD-L1 on tumor cells. 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.

CV301 is administered in an innovative manner designed to generate a potent and durable T-cell response. Patients receive an enhanced priming regimen of the highly attenuated, non-replicating vaccinia virus MVA-BN-CV301 in 4 different injection sites on days 1 and 29, followed by boosters of the recombinant fowlpox virus FPV-CV301 at tapering intervals during the course of the treatment with durvalumab and maintenance chemotherapy.

The investigator-sponsored trial is being led by Dr. Michael Pishvaian, Associate Professor in the Department of Hematology/Oncology at the Lombardi Comprehensive Cancer Center at Georgetown University Medical Center in Washington, D.C., with material support from Bavarian Nordic and AstraZeneca. The clinical trial is being conducted at several other top cancer centers including the Mayo Clinic, Indiana University and Emory University. The trial will begin with a small 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 maintenance chemotherapy. The Phase 2 portion of the study will consist of two parallel trials, enrolling up to 26 patients with metastatic disease 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).

"We are excited 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. The combination of a targeted cancer vaccine with a checkpoint inhibitor could result in a novel approach to fighting colorectal and pancreatic cancers, which are among the most difficult-to-treat malignancies to date," said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic.

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

### **About CV301**

CV301 is an active immunotherapy candidate that targets two tumor-associated antigens, CEA and MUC1, long known to be overexpressed in most solid tumors. The poxvirus-based prime/boost vaccine 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 antigen specific vaccination results in T cell infiltration into areas of antigen expression and upregulation of PD-L1 on antigen expressing tumor cells. 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 MVA-BN® non-replicating smallpox vaccine to the U.S. Strategic National Stockpile and other government stockpiles. The vaccine is approved in the European Union and in Canada (under the trade names IMVANEX® and IMVAMUNE® respectively). In addition to our long-standing collaboration with the U.S. government on the development of 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](http://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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