



BAVARIAN NORDIC

*Company Announcement*

## **Bavarian Nordic Announces Collaboration to Evaluate CV301 and Tecentriq in Bladder Cancer**

- Collaboration is the second to evaluate a combination of CV301 with a checkpoint inhibitor

**COPENHAGEN, Denmark, March 10, 2017** - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced an agreement with F. Hoffmann-La Roche Ltd (Roche) whereby Roche has agreed to supply their PD-L1 blocking antibody Tecentriq® (atezolizumab) for a clinical study combining Bavarian Nordic's cancer vaccine, CV301, and Tecentriq in patients with urothelial carcinoma, or bladder cancer.

Bavarian Nordic plans to conduct a phase 2 study in patients with locally advanced or metastatic urothelial carcinoma (mUC) who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy, a patient population where Tecentriq has accelerated approval in the U.S. CV301 is designed to generate a T cell response to both CEA and MUC1, two tumor antigens that are highly over expressed in bladder cancers. This study will evaluate the hypothesis that combining a checkpoint inhibitor with a cancer vaccine such as CV301 could be synergistic by enhancing the immune response seen in this patient population to date. The study is anticipated to initiate around the end of 2017.

"In keeping with our strategy to expand the potential of CV301, we are extremely pleased to enter into this collaboration with Roche. This represents our second collaboration in the advancement of CV301 as combination therapy in multiple cancers. We look forward to the initiation of this study and to explore the potential synergy of our programs for the benefit of patients with bladder cancer," said Paul Chaplin, President and CEO of Bavarian Nordic.

Under the terms of the agreement, Roche has committed to supplying Tecentriq to Bavarian Nordic during the phase 2 trial. Bavarian Nordic will be responsible for conducting the clinical trial, and both companies will share data from the trial. Bavarian Nordic continues to retain all commercial rights to CV301.

### **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 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. In December 2016, the MAGNI-lung-01 study was initiated. This Phase 1b/2 study evaluates the combination of CV301 and OPDIVO® (nivolumab) from Bristol-Myers Squibb in patients with non-small cell lung cancer.

### **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

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HPV. Additionally, in collaboration with the National Cancer Institute, Bavarian Nordic has developed a portfolio of active cancer immunotherapies, including PROSTVAC<sup>®</sup>, 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](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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