



BAVARIAN NORDIC

*Company Announcement*

## **Bavarian Nordic Updates on Phase 2 Study of CV301 in Bladder Cancer**

**COPENHAGEN, Denmark, October 18, 2019** - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today that the stage 1 of the Phase 2 study evaluating the combination therapy of its cancer immunotherapy, CV301, and Roche's checkpoint inhibitor, atezolizumab (TECENTRIQ®), for the treatment of patients with locally advanced or metastatic urothelial bladder cancer did not meet the efficacy threshold to progress into stage 2 with expanded enrollment. No serious adverse events were observed in the study to date.

In the first stage of the trial, 27 patients were enrolled into two cohorts: the first cohort was first-line treatment of patients (n=14) with urothelial bladder cancer who were not eligible for cisplatin-containing chemotherapy; and cohort 2 was a second-line treatment of patients (n=13) who had previously been treated with cisplatin-based chemotherapies. Despite the detection of clinical efficacy in a number of patients, neither cohort met the pre-defined criteria for clinical efficacy to expand enrollment into the second stage of the trial.

The study was sponsored by Bavarian Nordic, and two other, investigator-sponsored Phase 2 trials evaluating CV301 in combination with checkpoint inhibitors, are still ongoing in colorectal and pancreatic cancer. Bavarian Nordic will continue to follow and support these ongoing trials, while the Company's primary focus and resources will be directed towards BN-Brachyury and the new immuno-oncology strategy involving intravenous and intratumoral administration as well as new and more advanced constructs.

The Company's novel vaccine candidate, BN-Brachyury, is currently being evaluated in a Phase 2 trial in patients with advanced chordoma. This trial, which also uses a two-stage design, indicated clinical activity in the first stage, allowing for expansion of enrollment, which was recently completed. Conclusive data from this study are expected within 12 months. Another trial of BN-Brachyury administered intravenously is planned and will initiate shortly.

"We have diversified our immuno-oncology strategy over the past years, which is reflected in smaller studies seeking to evaluate different aspects of our technology. While the results of this study are disappointing, they contribute to our overall understanding of our platform and provide important learnings to refine our approach to equip the body's immune system with more weapons to fight cancer from within," said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic.

### **About Bavarian Nordic**

Bavarian Nordic is a fully integrated biotechnology company focused on the development of innovative therapies against infectious diseases and cancer. Using our live virus vaccine platform technology, MVA-BN®, we have created a diverse portfolio of proprietary and partnered product candidates intended to unlock the power of the immune system to improve public health with a focus on high unmet medical needs. In addition to our long-standing collaboration with the U.S. government on the development and supply of medical countermeasures, including the only FDA-approved, non-replicating smallpox vaccine, 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, 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 benefit-risk profile. 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

Page 1 of 2

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.

**Contacts**

Rolf Sass Sørensen  
Vice President Investor Relations (EU)  
Tel: +45 61 77 47 43

Graham Morrell  
Paddock Circle Advisors (US)  
[graham@paddockcircle.com](mailto:graham@paddockcircle.com)  
Tel: +1 781 686 9600

Company Announcement no. 18 / 2019