

Company Announcement no. 31 / 2015

# Bavarian Nordic Announces Results of a Phase 1 Trial Investigating Brachyury Specific Cancer Vaccine in Patients with Advanced Cancers

• Novel Vaccine Induced Brachyury Specific T-cells in ~80% of Patients at Higher Dose Levels

**COPENHAGEN, Denmark, November 3, 2015** - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today results from an NCI-sponsored Phase 1 study investigating its novel cancer vaccine, MVA-BN<sup>®</sup> Brachyury. Data from this study demonstrate for the first time that an MVA-BN based vaccine targeting brachyury can induce brachyury-specific T-cell immune responses in advanced cancer patients.

Led by the study's principal investigator Dr. Christopher R. Heery, M.D., Director of the Clinical Trials Group, Laboratory of Tumor Immunology and Biology, Center for Cancer Research, National Cancer Institute, the Phase 1 dose-escalation study enrolled 13 patients with chordoma, a rare and slow growing tumor which expresses brachyury, and 25 patients with other, metastatic solid cancers. Brachyury is reported to play a key role in tumor metastasis. Patients were enrolled in groups of three receiving escalating doses of MVA-BN Brachyury in three cycles, every four weeks. Once safety was established, additional patients were enrolled at the two highest doses.

MVA-BN Brachyury was well tolerated with no dose limiting toxicities. The maximal tolerated dose was not reached. No serious adverse vaccine-related events were observed. Immune responses were analyzed in 29 patients. Brachyury-specific T-cell responses were observed at each dose level: 66% of patients at dose level 1, 80% at dose level 2, and 90% at dose level 3. At the two highest dose levels, approximately 80% of the patients that developed brachyury-specific T-cells demonstrated responses in both CD4 and CD8 T-lymphocytes.

"This is very positive news on many levels," said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic. "For one, we now have confirmation that an MVA-BN based cancer immunotherapy can elicit a T-cell response against a specific tumor target. Additionally, finding a therapeutic approach to treating brachyury expression, which is not normally found on a tumor cell surface, has to date proven to be quite difficult. The creation of a vaccine-based, immunotherapy approach could be a unique solution to targeting a tumor antigen which has been associated with high rates of metastasis and multi-drug resistance. We thank our partners at the NCI for conducting this study, and look forward to working with them to advance this program in the coming years,"

The results will be presented as a poster at the Society for Immunotherapy of Cancer's Annual Meeting in National Harbor, Maryland, on Saturday, November 7<sup>th</sup>, from 12:45-2:00 pm ET. An abstract entitled "Phase 1, dose escalation, clinical trial of MVA-Brachyury-TRICOM Vaccine demonstrating safety and brachyury-specific T cell responses" is available online at <a href="http://www.immunotherapyofcancer.org/supplements">www.immunotherapyofcancer.org/supplements</a>.

# Contacts

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

Seth Lewis Vice President Investor Relations (US) Tel: +1 978 341 5271

Bavarian Nordic A/S

Hejreskovvej 10A DK-3490 Kvistgård Tel. +45 33 26 83 83 CVR-no. 16 27 11 87 info@bavarian-nordic.com www.bavarian-nordic.com

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#### About MVA-BN Brachyury

MVA-BN Brachyury is a novel, active immunotherapy candidate designed to induce a robust T-cell immune response against brachyury, a tumor-associated antigen which is overexpressed in every major solid tumor setting. Brachyury is believed to play a key role in both the metastasis and progression of tumors. Tumors which overexpress brachyury are believed to be highly resistant to current therapies and are associated with decreased survival rates.

MVA-BN Brachyury is being developed using Bavarian Nordic's proprietary validated MVA-BN (Modified Vaccinia Ankara Bavarian Nordic) platform. In clinical studies comprising more than 7,600 subjects, including cancer patients, MVA-BN has been shown to be well-tolerated and to induce a strong immune response.

## 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<sup>®</sup>, 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<sup>®</sup>) 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. 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 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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