

Company Announcement no. 35 / 2015

# Bavarian Nordic Enters Licensing and Collaboration Agreement with Janssen for $MVA-BN^{\otimes}$ in the Development of a Therapeutic HPV Vaccine

- Total potential agreement value USD 171 million including upfront and milestone payments
- Janssen to develop a potential new therapeutic prime-boost vaccine for human papillomavirus (HPV)
- Represents a novel approach for early treatment and interception of HPV-induced cancers

**COPENHAGEN, Denmark, December 18, 2015** - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today that it has entered into a license and collaboration agreement with Janssen Pharmaceuticals, Inc. ("Janssen"). Under the agreement, Janssen will acquire exclusive rights to Bavarian Nordic's MVA-BN<sup>®</sup> technology for use in a prime-boost vaccine regimen together with Janssen's own AdVac<sup>®</sup> technology with the purpose of targeting all cancers induced by human papillomavirus (HPV).

Under the terms of the agreement, Janssen will make an upfront payment of USD 9 million to Bavarian Nordic as well as potential future payments upon reaching development and commercial milestones, together totaling up to USD 171 million. Janssen will fund all development costs, and Bavarian Nordic will undertake all manufacturing related to MVA-BN. Furthermore, Bavarian Nordic is entitled to receive single-digit tiered royalties on future product sales.

The agreement builds upon the existing collaboration entered in October 2014 between Bavarian Nordic and Janssen, under which Janssen would evaluate MVA-BN for certain infectious disease targets. Janssen also retains an exclusive option to license MVA-BN for two additional undisclosed infectious disease targets and for which economic terms remain independent of those for HPV.

Janssen intends to study MVA-BN in a prime-boost vaccine regimen with its AdVac technology, similar to that used in the Ebola vaccine regimen which is currently in Phase 3 clinical trials. The prime-boost approach has shown to induce a strong and longer-lasting immune response, demonstrated by both increased antibodies and T cell responses. The goal is to develop a vaccine, which aims to treat chronic HPV infections as well as intercept precancerous stages of cancer.

HPV is known to be the primary cause of cervical cancer and certain types of head and neck cancer, in addition to a number of more rare cancers. Although vaccines have become available to protect against various high-risk HPV subtypes that can cause cancer, there is an unmet need for a therapeutic approach for chronic infections that may lead to precancerous cell changes. It is estimated, that high-risk HPV types cause approximately 5 percent of all cancers worldwide<sup>i</sup>.

"We are excited to expand our collaboration with Janssen on the evaluation of MVA-BN as a therapeutic approach to HPV, which represents a significant opportunity to transform the treatment paradigm in cervical and other cancers induced by the virus," said Paul Chaplin, Ph.D. and Chief Executive Officer of Bavarian Nordic. "Through the ongoing collaboration on Ebola, we have already made significant advances with our MVA-BN technology, demonstrating its potential to enhance and prolong immune responses induced by Janssen's AdVac technology, and we look forward to expanding the partnership to explore the same concept for HPV."

The content of this announcement does not affect Bavarian Nordic's expectations for the financial results for 2015 and the Company therefore maintains expected full-year revenue at the level of DKK 1,000 million and a

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break even result before interest and tax (EBIT). The cash preparedness at year end is expected to be in the level of DKK 1,450 million.

## About MVA-BN®

MVA-BN (Modified Vaccinia Ankara - Bavarian Nordic) is a proprietary and patented vaccine platform technology of Bavarian Nordic, originally developed through a successful public-private partnership with the U.S. Government. MVA-BN is a robust and adaptable platform suitable for addressing a wide variety of infectious diseases and cancers.

In addition to developing MVA-BN as a safer smallpox vaccine (approved in the EU and Canada) essential to protecting the immune-compromised population, and through a partnership with Janssen as an Ebola vaccine, Bavarian Nordic has conducted more than a dozen preclinical and clinical studies of recombinant MVA-BN-based vaccines. More than 7,600 individuals, nearly 1,000 of whom are immunocompromised, have been vaccinated with MVA-BN-based vaccines, showing the platform displays high immunogenicity and a favorable safety profile.

## 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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<sup>&</sup>lt;sup>i</sup> de Martel C, Ferlay J, Franceschi S, et al. Global burden of cancers attributable to infections in 2008: A review and synthetic analysis. Lancet Oncology 2012; 13(6):607-615.