



BAVARIAN NORDIC

*Company Announcement*

## **Bavarian Nordic Announces FDA Acceptance and Priority Review of Biologics License Application for MVA-BN Smallpox Vaccine**

**COPENHAGEN, Denmark, December 21, 2018** - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced that the U.S. Food and Drug Administration (FDA) has accepted its Biologics License Application (BLA) for the liquid-frozen version of the MVA-BN<sup>®</sup> for active immunization against smallpox in adults age 18 years and older. The FDA has granted priority review to the BLA, which means that the agency is targeting completion of the review in six months rather than the standard time of ten months. Priority review is granted by the FDA to applications for medicines that, if approved, would offer a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. If approved, MVA-BN would be the first and only approved non-replicating smallpox vaccine in the U.S.

“The acceptance of our BLA is a significant milestone for Bavarian Nordic, and for our long-standing collaboration with the U.S. Government on the development of MVA-BN to address public health threats, such as smallpox,” said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic. “While MVA-BN has already been approved in the EU and in Canada, an FDA approval would represent an important acknowledgment of our core platform technology, which we are actively investigating across multiple infectious disease and cancer indications.”

The regulatory submission for the MVA-BN smallpox vaccine is based on a comprehensive development program, comprising 22 clinical studies, including two Phase 3 studies, the latter of which showed non-inferiority of MVA-BN compared to ACAM2000, the current U.S. licensed, replicating smallpox vaccine. In addition, no serious adverse events related to MVA-BN were reported, and the frequency of Grade 3 or higher related adverse events was less in MVA-BN (1.2%) in comparison to the replicating smallpox vaccine (10.3%).

If approved, Bavarian Nordic would also be eligible to receive a Priority Review Voucher, which provides incentives to developers of medical countermeasures among others. The voucher can be used to accelerate the review of a future BLA and is also transferrable. The Company intends to sell the voucher to a third party.

### **About the MVA-BN Smallpox Vaccine**

The MVA-BN smallpox vaccine is based on a live, attenuated vaccinia virus, unable to replicate in humans. The liquid-frozen version of the vaccine is currently approved in the EU under the trade name IMVANEX<sup>®</sup> for active immunization against smallpox of the general adult population, including people with weakened immune systems (people diagnosed with HIV or atopic dermatitis), and in Canada under the trade name IMVAMUNE<sup>®</sup> for active immunization against smallpox in a public health emergency of persons 18 years of age and older who are contraindicated to replicating smallpox vaccines. The regulatory approval in these territories were based on Phase 2 clinical data.

Bavarian Nordic has to-date delivered 28 million doses of the liquid-frozen MVA-BN smallpox vaccine to the U.S. Strategic National Stockpile for emergency use in people with compromised immune systems. The Company has ongoing contracts with the Biomedical Advanced Research and Development Authority (BARDA) to replenish the stockpile, which has expired, with a freeze-dried formulation of the vaccine. In 2019, the Company will initiate a Phase 3 lot consistency study of the freeze-dried formulation to support the approval of this formulation.

### **Federal funding acknowledgments**

The Phase 3 program has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100200700034C.

Page 1 of 2

### **About Bavarian Nordic**

Bavarian Nordic is a fully integrated biotechnology company focused on the development of innovative and safer therapies against cancer and infectious diseases. Using our live virus vaccine platform technology, MVA-BN<sup>®</sup>, 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<sup>®</sup> 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<sup>®</sup> and IMVAMUNE<sup>®</sup> 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.

### **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. 26 / 2018