# RESTRICTED BUSINESS PROPRIETARY



Company Announcement no. 18 / 2015

# Bavarian Nordic Receives Order for IMVAMUNE<sup>®</sup> Smallpox Vaccine from the U.S. Government Valued at USD 133 Million

Bulk supply order will help maintain current stockpile and serves as a precursor for future contracts for freeze-dried formulation of IMVAMUNE

Deliveries and revenues to occur in 2016 and 2017

**COPENHAGEN, Denmark** - **July 7, 2015** - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced that the Biomedical Advanced Research and Development Authority (BARDA), a division of the U.S. Department of Health & Human Services, has ordered a bulk supply of IMVAMUNE® non-replicating smallpox vaccine, valued at USD 133 million.

Under this new order, which is an extension of an existing contract, Bavarian Nordic will manufacture and store a bulk supply of IMVAMUNE. This bulk material could be converted into freeze-dried IMVAMUNE at a later date, once the freeze-drying manufacturing process has been transferred to a commercial line, and is approved by the U.S. authorities.

"This order was made possible by previous BARDA funding, which allowed us to identify a new process to extend the shelf-life of the bulk vaccine. This process now offers greater flexibility for stockpiling our vaccines by Governments. The bulk supply could represent the initial transition to a freeze-dried formulation of IMVAMUNE, once an Emergency Use Authorization has been granted," said Paul Chaplin, President & Chief Executive Officer of Bavarian Nordic. "Our successful decade-long partnership with BARDA paves the way for improved public health preparedness, ensuring all Americans are protected from smallpox, including those people with compromised immune systems and skin disorders like eczema."

The freeze-dried version of IMVAMUNE is expected to reduce the life cycle management costs based on a longer shelf life and will replace the liquid-frozen version that is currently stockpiled in the U.S. Strategic National Stockpile (SNS). The freeze-dried version is well positioned to fulfill the U.S. Government's long-term requirements for sufficient non-replicating smallpox vaccine to protect 66 million Americans, comprising those for whom a replicating smallpox vaccine is not recommended and their household contacts.

Bavarian Nordic recently reported positive results from a pivotal Phase 2 study, which demonstrated that the freeze-dried and the liquid-frozen versions of the vaccine induced an equivalent immune response in people. With the clinical development now completed, the only outstanding activity to support the stockpiling of this next-generation of the vaccine by the U.S government is the finalization of the transfer of the manufacturing process, which is expected by the end of the year.

This bulk vaccine order will be produced and revenue recognized in 2016 and into 2017, and thus does not affect the Company's expectations for the financial results for 2015.

### **Contacts**

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Federal funding acknowledgments

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Procurement and development of IMVAMUNE 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.

The development of a freeze-dried formulation of IMVAMUNE 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. HHSO100201000011C.

#### **About Bavarian Nordic**

Bavarian Nordic is a biopharmaceutical company focused on the development and manufacturing of cancer immunotherapies and vaccines for infectious diseases. Through a long-standing collaboration with the U.S. Government, Bavarian Nordic has developed a portfolio of biological countermeasures, including the non-replicating smallpox vaccine, IMVAMUNE®, which is stockpiled for emergency use by the U.S. and other governments. The vaccine is approved in the EU (under the trade name IMVANEX®) and in Canada. Bavarian Nordic and its partner Janssen are pioneering the development of an Ebola vaccine, which has been fast-tracked by authorities in response to the current situation in West Africa. Additionally, in collaboration with the National Cancer Institute, Bavarian Nordic has developed a portfolio of active cancer immunotherapies based on its versatile pox-virus based technologies, including PROSTVAC®, 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 <a href="https://www.bavarian-nordic.com">www.bavarian-nordic.com</a> or follow us on Twitter <a href="https://www.bavarian-nordic.com">www.bavarian-nordic.com</a> or follow us on Twitter <a href="https://www.bavarian-nordic.com">www.bavarian-nordic.com</a>

### 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. 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.