



BAVARIAN NORDIC

Company Announcement

September 4, 2014

## **Bavarian Nordic Announces Exercise of Contract Option by the U.S. Government for Continued Supply of IMVAMUNE® Smallpox Vaccine**

- *Option valued at USD 118 million will fund replenishment of existing doses in U.S. Strategic National Stockpile, and helps bridge to the next-generation freeze-dried formulation is available*

**KVISTGAARD, Denmark, September 4, 2014** - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today that the Biomedical Advanced Research and Development Authority (BARDA), a division of the U.S. Department of Health & Human Services (HHS) has exercised an option valued at USD 118 million for the continued delivery of IMVAMUNE smallpox vaccine to the U.S. Strategic National Stockpile (SNS).

This is the second option exercised to purchase additional doses of IMVAMUNE to maintain the stockpile in case of a public health emergency. The two replenishment options are valued at USD 228 million. Furthermore, the order will help sustain the unique manufacturing capabilities established by Bavarian Nordic that contribute to protecting the public against bioterrorism.

Paul Chaplin, President & CEO of Bavarian Nordic said: "This contract continues the successful collaboration between Bavarian Nordic and the U.S. Government on the development and supply of smallpox vaccines that started more than a decade ago. We are grateful that the U.S. Government has ordered another 4 million doses of IMVAMUNE to maintain the U.S. Strategic National Stockpile. We look forward to continuing this collaboration as we prepare to supply an improved, freeze-dried formulation of IMVAMUNE and develop additional countermeasures to serve the government's needs."

The cash flow from the option consists of an upfront milestone payment of USD 18 million and USD 100 million that will be recognized pro rata with the deliveries of 4 million doses of IMVAMUNE.

The exercise of the option does not change the Company's financial guidance for 2014.

Bavarian Nordic has been delivering IMVAMUNE to the SNS since 2010 in a liquid-frozen formulation. In parallel, the company has been developing a freeze-dried formulation of the vaccine under a second contract with BARDA. A freeze-dried formulation is expected to reduce life cycle management costs based on a longer shelf life. Earlier this year, BARDA exercised an option to fund the transfer of the manufacturing process to a commercial manufacturing line with a larger capacity. Data supporting the clinical requirements for emergency use of the freeze-dried vaccine in the U.S. are also currently being finalized and expected to be submitted to the FDA in 2015. These activities will potentially support the production and supply of freeze-dried IMVAMUNE in 2016. Procurement would need to be conducted through a new contract, on which the Company expects to initiate dialogue with the U.S. Government in 2014.

### **Contacts**

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### **About IMVAMUNE Smallpox Vaccine**

IMVAMUNE is being developed as a safer smallpox vaccine for immunocompromised individuals, such as people with atopic dermatitis (AD) and HIV. IMVAMUNE is the Company's most advanced clinical program based on MVA-BN<sup>®</sup> - a robust and adaptable vaccine platform suitable for addressing a wide variety of infectious diseases and cancer. Bavarian Nordic has conducted preclinical and clinical studies of recombinant MVA-BN<sup>®</sup>-based vaccines for a variety of infectious diseases and numerous types of cancer. Studies including more than 7,400 subjects, including people diagnosed with AD or infected with HIV in which replicating vaccines are contraindicated, suggest that MVA-BN<sup>®</sup>-based vaccines have a favorable safety profile. In 2013, the vaccine was approved in Canada under the trade name IMVAMUNE and in the European Union under the trade name IMVANEX<sup>®</sup>.

IMVAMUNE is the first vaccine successfully developed under Project BioShield, a U.S. program created by Congress in 2004 to develop and purchase medicines and vaccines to protect the American public from bioterrorism attacks. Bioterrorism experts are concerned about the possibility of an attack on the U.S. that exposes the population to the smallpox virus.

IMVAMUNE is being clinically developed and manufactured under contracts with BARDA as well as the National Institutes of Health (NIH).

### **About Bavarian Nordic**

Bavarian Nordic is an international biotechnology company developing and manufacturing novel cancer immunotherapies and vaccines for infectious diseases. Lead product candidates are PROSTVAC<sup>®</sup>, an immunotherapy product candidate for advanced prostate cancer that is the subject of an ongoing pivotal Phase 3 clinical trial, and IMVAMUNE<sup>®</sup>, a non-replicating smallpox vaccine candidate in Phase 3 development, which is being developed and supplied for emergency use to the U.S. Strategic National Stockpile under a contract with the U.S. Government. The vaccine is approved in Canada under the trade name IMVAMUNE and in the European Union under the trade name IMVANEX.

Bavarian Nordic's shares are listed on NASDAQ OMX Copenhagen under the symbol BAVA (Reuters: BAVA.CO, Bloomberg: BAVA.DC). The company has a sponsored Level 1 ADR program listed in the US (OTC) under the symbol BVNRY.

For more information, visit [www.bavarian-nordic.com](http://www.bavarian-nordic.com).

### **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.