



BAVARIAN NORDIC

Company Announcement

22 November 2013

## Bavarian Nordic Receives Health Canada Approval of IMVAMUNE Smallpox Vaccine

**KVISTGAARD, Denmark, November 22, 2013** - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today that Health Canada has granted a Notice of Compliance approving IMVAMUNE® for active immunization against smallpox in a public health emergency. IMVAMUNE is indicated for persons 18 years of age and older who are contraindicated to replicating smallpox vaccines. This includes individuals with immune deficiencies and skin disorders.

Health Canada is the second regulatory body to approve the company's smallpox vaccine which earlier this year was approved by the European Commission for use in the general adult population in all 28 EU countries and Iceland, Liechtenstein and Norway, where it is marketed under the trade name IMVANEX®.

Since 2008, Bavarian Nordic has collaborated with the Canadian Government to address their biological preparedness requirements. The company was initially awarded a contract to supply 20,000 doses of IMVAMUNE to the Canadian armed forces, followed by a replacement order in 2012. The original contract also provided funding for filing a New Drug Substance application for IMVAMUNE.

"The approval of IMVAMUNE in Canada continues our track record of successfully working with governments to address their biological preparedness requirements. We have partnered with the U.S. government for more than a decade on the development of our smallpox vaccine and we are delighted that Canada now leverages on this successful partnership," said Anders Hedegaard, President and CEO of Bavarian Nordic. "This approval provides further validation of our MVA-BN vaccine technology platform which we have successfully developed and commercialized."

Asger Aamund  
Chairman of the Board

### Contacts

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### About IMVAMUNE (MVA-BN)

IMVAMUNE is based on the MVA-BN vaccine platform technology (Modified Vaccinia Ankara - Bavarian Nordic). MVA-BN is a robust and adaptable vaccine platform suitable for addressing a wide variety of infectious diseases, including biological threats. In addition to developing MVA-BN as a safer smallpox vaccine essential to protecting the immune-compromised population, Bavarian Nordic has conducted preclinical and clinical studies of recombinant MVA-BN-based vaccines for a variety of infectious diseases and numerous types of cancer. More than 7,300 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.

An advantage of MVA-BN is the virus' inability to replicate in a vaccinated individual. The replication cycle is blocked at a very late stage, which ensures that new viruses are not generated and released. This means that the virus cannot spread in the vaccinated person and none of the serious side effects normally associated with replicating vaccinia viruses have been seen with MVA-BN.

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CVR-nr: 16 27 11 87

Bavarian Nordic recently completed the delivery of the first 20 million doses of IMVAMUNE to the U.S. Strategic National Stockpile. The U.S. government has also exercised a contract option to purchase an additional 8 million doses in 2013 and 2014. Several other governments around the world have procured the vaccine for their preparedness stockpiles.

#### **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<sup>®</sup>.

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.