

Company Announcement

30 March 2011

# Bavarian Nordic submits market application to Health Canada for IMVAMUNE®

Kvistgård, Denmark, March 30, 2011 - Bavarian Nordic A/S (OMX: BAVA) announced today that it has submitted a marketing authorization application (MAA) in Canada for its smallpox vaccine candidate IMVAMUNE®. The MAA has been filed as a standard New Drug Substance (NDS) submission to Health Canada based on clinical indicators of efficacy.

## Background of the NDS submission in Canada

Bavarian Nordic was awarded a Request for Proposal (RFP) in December 2008 by the Canadian Government to supply IMVAMUNE® to the Canadian armed forces. As part of this contract, Bavarian Nordic was requested to evaluate the potential for licensing IMVAMUNE® in Canada. In October 2009, Bavarian Nordic consulted with the agency during a pre-NDS advice meeting. Based on the data presented, Health Canada encouraged Bavarian Nordic to submit a standard NDS application, outlining the clinical indicators of efficacy for IMVAMUNE®.

If found acceptable by Health Canada following a standard NDS review time of approximately one year, IMVAMUNE® will be indicated for active immunization against smallpox infection and disease in persons 18 years of age and older. The indication will include individuals with immune deficiencies and skin disorders such as those who are Human Immunodeficiency Virus (HIV) infected and those who have Atopic Dermatitis (AD). The vaccine may be used for both primary vaccination and re-vaccination, both in an emergency and non-emergency setting.

Anders Hedegaard, President & CEO of Bavarian Nordic said: "We are extremely excited about this licensing application in Canada which represents the first marketing authorization application for the company. It emphasizes the potential of IMVAMUNE® as a third generation smallpox vaccine and we are looking forward to collaborating with the Canadian authorities to complete a successful review cycle, which may turn into the first vaccine license for the company."

Asger Aamund Chairman of the Board

### Contact

Anders Hedegaard, President & CEO. Phone +45 23 20 30 64

### About Bavarian Nordic

Bavarian Nordic is a leading industrial biotechnology company developing and producing novel vaccines for the treatment and prevention of life-threatening diseases with a large unmet medical need. The company's clinical pipeline targets cancer and infectious diseases, and includes seven development programmes. Two programmes under preparation for Phase III: PROSTVAC®, a therapeutic vaccine for advanced prostate cancer is being developed under a collaboration agreement with the National Cancer Institute, and IMVAMUNE®, a third-generation smallpox vaccine is being developed under a contract with the US government.

Bavarian Nordic is listed on NASDAQ OMX Copenhagen under the symbol BAVA.

For more information please visit <u>www.bavarian-nordic.com</u>

PROSTVAC® is a registered trademark in the U.S.

## 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.

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 Bavarian Nordic A/S
 Hejreskovvej 10A
 Tel:
 +45 33 26 83 83
 www.bavarian-nordic.com
 CVR-no: 16 27 11 87

 DK-3490 Kvistgaard
 Fax:
 +45 33 26 83 80

Denmark