



BAVARIAN NORDIC

Company Announcement

1 March 2012

## **Bavarian Nordic Submits a Marketing Application for its Smallpox Vaccine to the European Medicines Agency**

*KVISTGAARD, Denmark, March 1, 2012* - Bavarian Nordic A/S (OMX: BAVA) announced today that it has submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for its smallpox vaccine (IMVAMUNE®) that will be marketed under the trade name IMVANEX® in Europe. The MAA has been filed for consideration under the centralized procedure and following a successful review could potentially lead to the market authorization of IMVANEX® in Europe (EAA countries) during 2013.

If found acceptable by EMA, IMVANEX® 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 diagnosed with Atopic Dermatitis (AD).

This submission to EMA follows the New Drug Submission (NDS) filed with Health Canada during 2011, which is currently undergoing the review process and still expected to result in a market approval for IMVAMUNE® in Canada during 2012.

*"The submission of the application for Marketing Authorization for IMVANEX® in Europe marks yet an important milestone for the company, and from a regulatory point of view, things are currently progressing well. We have entered into the registration phase in both Canada and Europe and if both applications successfully lead to market approval for IMVAMUNE® / IMVANEX®, this will greatly expand the market opportunities worldwide beyond the current sales to the US government.,"* stated Anders Hedegaard, President & CEO of Bavarian Nordic.

Asger Aamund  
Chairman of the Board

### **Contact**

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### **About IMVAMUNE® / IMVANEX® - smallpox vaccine candidate**

IMVAMUNE® is positioned as a new and superior third-generation smallpox vaccine for protection of the general population (18-55 years old). The likely use of IMVAMUNE® by governments would include: individuals contraindicated for conventional smallpox vaccines: e.g. individuals with HIV, people with atopic dermatitis (AD) and members of their households: First-line responders (military, police, health care workers, etc.) and the general population.

IMVAMUNE® has fast-track status with the US authorities and has completed clinical Phase 2 development. Although unlicensed, the vaccine is already in production and available for governments globally under their national emergency rules, due to the need for a safer smallpox vaccine.

In clinical trials to date, more than 3,400 individuals have been vaccinated with IMVAMUNE®, which has demonstrated a favourable safety profile. The vaccinated subjects include almost 1,000 individuals with compromised immune systems who are currently ineligible for conventional smallpox vaccines.

The development of IMVAMUNE® is funded by the US government through contracts with BARDA (Biomedical Advanced Research and Development Authority) and the NIH (National Institutes of Health).

**About Bavarian Nordic**

Bavarian Nordic is a vaccine-focused 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 pipeline targets cancer and infectious diseases, and includes ten development programs. In oncology, the company's lead program is PROSTVAC<sup>®</sup>, a therapeutic vaccine candidate for advanced prostate cancer that is the subject of an ongoing pivotal Phase 3 trial and is being developed under a collaboration agreement with the National Cancer Institute. In clinical Phase 1 and Phase 2 trials, PROSTVAC<sup>®</sup> has been tested in nearly 600 patients. In infectious diseases, the company's lead program is IMVAMUNE<sup>®</sup>, a third-generation smallpox vaccine candidate that is being developed and supplied for emergency use to the U.S. Strategic National Stockpile under a contract with the U.S. Government. 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.