

Company Announcement

31 May 2013

Bavarian Nordic's IMVANEX® Smallpox Vaccine Receives Positive Opinion from European Regulatory Authorities

KVISTGAARD, Denmark, May 31, 2013 - Bavarian Nordic A/S (OMX: BAVA) announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending the granting of a marketing authorization for IMVANEX® for active immunization against smallpox disease for the general adult population, including people with immunodeficiencies (people diagnosed with HIV or atopic dermatitis).

IMVANEX, a non-replicating smallpox vaccine known as IMVAMUNE outside the European Union (EU), was filed for marketing authorization through a centralized procedure, supported by clinical data in more than 3,400 people. Based on current evidence, the CHMP concluded that the benefit-risk balance of IMVANEX is favorable and recommended that it be used in accordance with official national recommendations for vaccination.

The CHMP's opinion on IMVANEX will now be referred to the European Commission for final marketing authorization. The European Commission generally delivers its final decision within three months of the CHMP recommendation. The decision will be applicable to all 27 EU member states and European Economic Area countries Iceland, Liechtenstein and Norway.

"We are pleased to receive a positive opinion from the European authorities and we look forward to the decision by the European Commission. This represents a significant milestone and scientific breakthrough for our company and our MVA-BN vaccine technology platform, which we have taken from early research through clinical development and the anticipated regulatory approval in just a decade," said Anders Hedegaard, President and CEO of Bavarian Nordic. "Final marketing authorization, once received, will enable us to make IMVANEX commercially available in the EU. We will continue our work with the European governments to address the requirements for their national preparedness plans, focusing on the advantages that IMVANEX brings in terms of safety and administration for people at risk."

Asger Aamund
Chairman of the Board

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About IMVANEX® Smallpox Vaccine

IMVANEX, known as IMVAMUNE outside the EU, is being developed as a safer smallpox vaccine for immune compromised individuals, such as people with atopic dermatitis (AD) and HIV. IMVANEX is the company's most advanced clinical program based on MVA-BN® - a robust and adaptable vaccine platform suitable for addressing a wide variety of infectious diseases and cancer.

IMVANEX has been developed since 2003 under contracts with the U.S. Government. It is the first new vaccine developed under the U.S. government's "Project BioShield" program to protect at risk populations from bioterrorism. Bavarian Nordic has manufactured and supplied 16 million doses of the vaccine for emergency use to the U.S. Strategic National Stockpile to-date. IMVANEX has also been supplied to other government stockpiles around the world.

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[®], a therapeutic vaccine candidate for advanced prostate cancer that is the subject of an ongoing pivotal Phase 3 clinical trial and is being developed under a collaboration agreement with the National Cancer Institute. In clinical Phase 1 and Phase 2 trials, PROSTVAC[®] has been tested in nearly 600 patients. In infectious diseases, the company's lead program is IMVAMUNE[®]/IMVANEX[®], a non-replicating 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. IMVAMUNE[®]/IMVANEX[®] is currently in clinical Phase 3 development and marketing authorization applications have been filed in EU and Canada.

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.

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.