Company Announcement no. 14 / 2015

Bavarian Nordic Announces Positive Results from Two Pivotal Clinical Studies of IMVAMUNE® Smallpox Vaccine

- Completion of first Phase 3 study to support a Biologics License Application for liquid-frozen IMVAMUNE
- Completion of clinical development to support stockpiling of the next-generation freeze-dried version of IMVAMUNE

KVISTGAARD, Denmark, May 13, 2015 – Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced results from the first of two pivotal Phase 3 studies of the liquid-frozen formulation of IMVAMUNE® supporting a Biologics License Application for U.S. approval of the vaccine. In addition, the Company announced results from a pivotal Phase 2 study of freeze-dried IMVAMUNE smallpox vaccine supporting the clinical requirements for an Emergency Use Authorization, which would allow for stockpiling of this next-generation of the vaccine.

The Phase 3 was designed as a randomized, double-blind, placebo-controlled study in 4,000 vaccinia-naïve subjects. Three thousand (3,000) subjects were vaccinated with three different manufacturing lots of the liquid-frozen IMVAMUNE formulation (1,000 subjects per lot) and compared to 1,000 subjects that received placebo. The three lots of IMVAMUNE induced equivalent antibody responses, meeting the primary endpoint of the study, while the favorable safety profile of IMVAMUNE was confirmed in this largest clinical study performed to date. Despite close cardiac monitoring of all subjects, no serious adverse reactions were reported among the 3,000 subjects vaccinated with IMVAMUNE, confirming the results of a smaller Phase 2 placebo controlled study that was recently published[i] and clearly differentiates the safety profile of IMVAMUNE when compared to traditional smallpox vaccines (e.g. ACAM2000® approved in the U.S.) that have recorded high rates of cardiac complications in healthy vaccinees (5.73 events per thousand immunizations[ii]).

The Phase 2 study compared the safety and immunogenicity of a freeze-dried and a liquid-frozen formulation of IMVAMUNE and enrolled 650 vaccinia-naïve healthy subjects who were randomized to receive either formulation of IMVAMUNE. The freeze-dried vaccine induced an equivalent antibody response as the liquid-frozen version, meeting the primary endpoint of the study. Also both formulations recorded a similar safety profile, confirming that the clinical data generated cumulatively in more than 7,600 vaccinated subjects is relevant for both formulations of IMVAMUNE.

The results provide the final clinical data required to support stockpiling of the freeze-dried version of IMVAMUNE in the U.S. Strategic National Stockpile. Supported by a contract option of USD 22 million exercised by the Biomedical Advanced Research and Development Authority (BARDA) in 2014, Bavarian Nordic is currently working to transfer the freeze-drying process to a new manufacturing line with a larger commercial capacity. These manufacturing activities remain on-track to be finalized this year, which is the final step towards meeting the regulatory requirements to stockpile the freeze-dried version of IMVAMUNE.

Paul Chaplin, President & Chief Executive Officer of Bavarian Nordic, said: "Completing this pivotal Phase 2 study is a significant step in the transition to the freeze-dried version of the vaccine, which provides a number of advantages for the future procurement and stockpiling, thereby broadening the commercial potential. We remain on track to complete the transfer of the manufacturing process which will enable us to start deliveries in 2016, as we look forward to continuing our successful long-standing collaboration with the U.S. Government on their public health preparedness."

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Federal funding acknowledgments
The Phase 2 study comparing the safety and immunogenicity of a freeze-dried and a liquid-frozen formulation of IMVAMUNE has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201000011C.

The Phase 3 study evaluating the immunogenicity and safety of three consecutive production lots of IMVAMUNE has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100200700034C

About Bavarian Nordic
Bavarian Nordic is a biopharmaceutical company focused on the development and manufacturing of cancer immunotherapies and vaccines for infectious diseases. Through a long-standing collaboration with the U.S. Government, Bavarian Nordic has developed a portfolio of biological countermeasures, including the non-replicating smallpox vaccine, IMVAMUNE®, which is stockpiled for emergency use by the U.S. and other governments. The vaccine is approved in the EU (under the trade name IMVANEX®) and in Canada. Bavarian Nordic and its partner Janssen are pioneering the development of an Ebola vaccine, which has been fast-tracked by authorities in response to the current situation in West Africa. Additionally, in collaboration with the National Cancer Institute, Bavarian Nordic has developed a portfolio of active cancer immunotherapies based on its versatile pox-virus based technologies, including PROSTVAC®, which is currently in Phase 3 clinical development for the treatment of advanced prostate cancer. The company has partnered with Bristol-Myers Squibb for the potential commercialization of PROSTVAC. For more information visit www.bavarian-nordic.com or follow us on Twitter @bavariannordic.

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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[i] PLoS ONE: *Zitzmann-Roth E-M, von Sonnenburg F, de la Motte S, Arndtz-Wiedemann N, von Krempelhuber A, Uebler N, et al. (2015) Cardiac Safety of Modified Vaccinia Ankara for Vaccination against Smallpox in a Young, Healthy Study Population. PLoS ONE 10(4): e0122653. doi:10.1371/journal.pone.0122653*

[ii] ACAM2000 Vaccines and Related Biological Products Advisory Committee (VRBPAC) Briefing Document, April 2007 http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4292B2-00-index.htm

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