Company Announcement

Bavarian Nordic Initiates Phase 3 Trial of Freeze-dried MVA-BN® Smallpox Vaccine

COPENHAGEN, Denmark, June 19, 2019 – Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today the initiation of a pivotal Phase 3 trial of the freeze-dried formulation of MVA-BN® smallpox vaccine in 1,110 healthy, vaccinia-naïve subjects.

The randomized, double-blind, multicenter trial will evaluate the immunogenicity and safety of three consecutive vaccine lots of the freeze-dried formulation of MVA-BN® smallpox vaccine, similar to the prior completed Phase 3 study for the liquid-frozen MVA-BN formulation.

The Biologics License Application (BLA) for the liquid frozen formulation of MVA-BN is currently under review at the FDA, with anticipated completion and licensure in the second half of 2019. Upon completion of the current study, expectedly in 2021, the Company intends to submit a supplement to the BLA to extend the approval for both formulations of MVA-BN. The requirement for only one Phase 3 study of the freeze-dried formulation was confirmed at an End-of-Phase 2 meeting with the regulatory authorities, following a prior Phase 2 study showing bioequivalence between the freeze-dried and liquid-frozen formulations of MVA-BN.

Based on the successful completion of the study and subsequent regulatory process, the Company anticipates approval of the freeze-dried vaccine in 2022.

“We are excited to initiate this final study which, along with the anticipated approval of the liquid-frozen MVA-BN smallpox vaccine and the completion of our new fill and finish facility later this year, will reinforce our position as the global leader in smallpox vaccines, and also enable us to expand our market opportunities in the U.S. and the rest of the world,” said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic.

The Phase 3 study and regulatory activities towards licensure are funded through an option valued at USD 37 million, which was exercised in November 2017 as part of the ongoing USD 539 million contract with the Biomedical Advanced Research and Development Authority (BARDA) for development and supply of freeze-dried MVA-BN to the U.S. Strategic National Stockpile.

About the smallpox vaccine contracts with the U.S. Government
Since 2003, Bavarian Nordic has worked with the U.S. government on the development and production of MVA-BN smallpox vaccine and has to-date supplied 28 million doses of the liquid-frozen version to the U.S. Strategic National Stockpile (SNS) for emergency use. Concurrently, BARDA has supported the development of a freeze-dried version of the vaccine with longer shelf-life to replace the current stockpile that has expired. Manufacturing of bulk vaccine to support this transition was initiated in 2016 and by end of 2019, the Company will have manufactured and invoiced bulk vaccine worth USD 333 million. The fill-finish of this bulk will trigger additional contract options valued at USD 299 million. The ten-year contract, awarded in 2017, also includes pricing for additional orders of vaccine bulk and vaccine doses of either liquid-frozen or freeze-dried MVA-BN.

Federal funding acknowledgements
This project has been funded in whole or in part with federal funds from the HHS Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201700019C.

About Bavarian Nordic
Bavarian Nordic is a fully integrated biotechnology company focused on the development of innovative therapies against cancer and infectious diseases. Using our live virus vaccine platform technology, MVA-BN®, we have

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created a diverse portfolio of proprietary and partnered product candidates intended to unlock the power of the immune system to improve public health with a focus on high unmet medical needs. We supply our MVA-BN non-replicating smallpox vaccine to the U.S. SNS and other government stockpiles. The vaccine is approved in the European Union and in Canada (under the trade names IMVANEX® and IMVAMUNE® respectively). In addition to our long-standing collaboration with the U.S. government on the development of medical countermeasures, our infectious disease pipeline comprises a proprietary RSV program as well as vaccine candidates for Ebola, HPV, HBV and HIV, which are developed through a strategic partnership with Janssen. Additionally, in collaboration with the National Cancer Institute, we have developed a portfolio of active cancer immunotherapies, designed to alter the disease course by eliciting a robust and broad anti-cancer immune response while maintaining a favorable risk-benefit profile. Through multiple industry collaborations, we seek to explore the potential synergies of combining our immunotherapies with other immune-modulating agents, e.g. checkpoint inhibitors. 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. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany the forward-looking statements. 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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