Company Announcement

Bavarian Nordic Announces FDA Delay in the Review of the Biologics License Application for MVA-BN Smallpox Vaccine

COPENHAGEN, Denmark, March 11, 2019 – Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced that it has received information from the U.S. Food and Drug Administration (FDA) that the review of the Company's Biologics License Application (BLA) for the liquid-frozen formulation of the MVA-BN® smallpox vaccine will be extended by three months.

The BLA was granted a priority review in December 2018, originally targeting a six months review process. However, the FDA has assessed that due the amount of data submitted during the review phase, the agency now requires more time and has extended the target PDUFA action date to September 2019.

The BLA maintains priority review status with the FDA, and thus Bavarian Nordic would still be eligible to receive a Priority Review Voucher when MVA-BN is approved.

"The BLA for MVA-BN is unusual as we have already manufactured 28 million doses prior to a full regulatory approval and the development involved generating safety and immunogenicity data from 22 clinical studies. So while the review process has not raised any significant concerns to date, we understand that the MVA-BN BLA is unusually large and that the FDA requires more time to complete the review," said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic.

The delay will not impact the Company's operations.

About the MVA-BN Smallpox Vaccine
The MVA-BN smallpox vaccine is based on a live, attenuated vaccinia virus, unable to replicate in humans. The liquid-frozen version of the vaccine is currently approved in the EU under the trade name IMVANEX® for active immunization against smallpox of the general adult population, including people with weakened immune systems (people diagnosed with HIV or atopic dermatitis), and in Canada under the trade name IMVAMUNE® for active immunization against smallpox in a public health emergency of persons 18 years of age and older who are contraindicated to replicating smallpox vaccines. The regulatory approval in these territories were based on Phase 2 clinical data.

Bavarian Nordic has to-date delivered 28 million doses of the liquid-frozen MVA-BN smallpox vaccine to the U.S. Strategic National Stockpile for emergency use in people with compromised immune systems. The Company has ongoing contracts with the Biomedical Advanced Research and Development Authority (BARDA) to replenish the stockpile, which has expired, with a freeze-dried formulation of the vaccine. In 2019, the Company will initiate a Phase 3 lot consistency study of the freeze-dried formulation to support the approval of this formulation.

About Bavarian Nordic
Bavarian Nordic is a fully integrated biotechnology company focused on the development of innovative and safer therapies against cancer and infectious diseases. Using our live virus vaccine platform technology, MVA-BN®, we have created a diverse portfolio of proprietary and partnered product candidates intended to improve the health and quality of life for children and adults. We supply our MVA-BN non-replicating smallpox vaccine to the U.S. Strategic National Stockpile 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

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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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