



BAVARIAN NORDIC

Company Announcement

Bavarian Nordic Announces Positive Topline Results from Phase 3 Clinical Study of Freeze-dried Smallpox Vaccine

COPENHAGEN, Denmark, August 24, 2020 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today topline results from the pivotal Phase 3 study of the freeze-dried formulation of its MVA-BN[®] smallpox vaccine.

The Phase 3 lot-consistency study was agreed with the U.S. Food and Drug Administration (FDA) as the only Phase 3 study required to support licensure of the freeze-dried formulation. The liquid-frozen formulation of the vaccine was approved by the FDA in September 2019 under the name JYNNEOS[®], and a prior Phase 2 study has showed bioequivalence between the freeze-dried and liquid-frozen formulations.

The Phase 3 study, which has been fully funded by the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, was a randomized, double-blind, multi-center study in 1,129 vaccinia-naïve subjects evaluating the immunogenicity and safety of three consecutive vaccine lots of the freeze-dried formulation of MVA-BN smallpox vaccine. The three lots of MVA-BN induced equivalent antibody responses, meeting the primary endpoint of the study, while the favorable safety profile, in line with the cumulative safety experience of the approved liquid-frozen formulation, was also confirmed with no serious adverse reactions reported among the subjects.

Completion of the study will enable the Company to submit a supplement to the BLA to extend the approval for both formulations of MVA-BN. The extension would cover both the smallpox and the monkeypox indication.

Paul Chaplin, President & Chief Executive Officer of Bavarian Nordic, said: “We are pleased to report positive results from the Phase 3 study, which is a significant step towards approval of the freeze-dried version of JYNNEOS and key to unlocking the future revenues from our existing supply contract with the U.S. government.”

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, manufacture and commercialization of life-saving vaccines. We are a global leader in smallpox vaccines and have been a long-term supplier to the U.S. Strategic National Stockpile of a non-replicating smallpox vaccine, which has been approved by the FDA under the trade name JYNNEOS[®], also for the protection against monkeypox. The vaccine is approved as a smallpox vaccine in Europe under the trade name IMVANEX[®] and in Canada under the trade name IMVAMUNE[®]. Our commercial product portfolio furthermore contains market-leading vaccines Rabipur[®]/RabAvert[®] against rabies and Encepur[®] against tick-borne encephalitis. Using our live virus vaccine platform technology, MVA-BN[®], we have created a diverse portfolio of proprietary and partnered product candidates designed to save and improve lives by unlocking the power of the immune system, including an Ebola vaccine, licensed to Janssen. 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

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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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