



Bavarian Nordic Submits Supplemental BLA Seeking U.S. FDA Approval of Freeze-Dried Formulation of Smallpox and Mpox Vaccine

COPENHAGEN, Denmark, May 31, 2024 - Bavarian Nordic A/S (OMX: BAVA) today announced the submission of a supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) seeking approval of a freeze-dried formulation of JYNNEOS® for prevention of smallpox and mpox disease in adults 18 years of age and older.

The liquid-frozen formulation of JYNNEOS® was approved by the FDA in September 2019. It remains the only approved mpox vaccine anywhere in the world and the only non-replicating smallpox vaccine approved in the U.S. This formulation of JYNNEOS® has specific cold-chain requirements, while the freeze-dried formulation provides more flexibility in terms of transportation, storage conditions and shelf life, thus being more suitable for long-term stockpiling.

The sBLA submission is based on clinical data from a Phase 3 lot consistency study and data from a Phase 2 study that showed bioequivalence between the freeze-dried and liquid-frozen formulations, as well as other clinical and non-clinical data, including process development and manufacturing data. Following a standard review time of 10 months for the sBLA, approval of the freeze-dried formulation could be obtained in the first quarter of 2025.

“We are pleased to finalize this submission, marking a significant milestone in our development of this next generation of our smallpox/mpox vaccine and in our partnership with the U.S. government on developing a vaccine suited for addressing public health challenges, now and in the future. The licensure of this new formulation, which is ideally suited for long-term stockpiling, should ensure future orders beyond the current contract valued at almost USD 300 million with the U.S. government” said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic.

Bavarian Nordic has an ongoing contract with the U.S Biomedical Advanced Research and Development Authority (BARDA) valued at USD 299 million to supply a freeze-dried doses of JYNNEOS® for stockpiling. This contract allows the production of freeze-dried doses prior to the licensure of the formulation and the Company has started to manufacture vaccines under this contract in the first quarter of 2024, aiming to fulfil the first USD 119 million contract option during this year. This has already been included in the Company’s financial guidance for 2024, which therefore remains unchanged. Additional options valued at USD 180 million are pending exercise by BARDA. The bulk vaccine for manufacturing the freeze-dried vaccines were initially manufactured under previous contracts, however a significant part of this inventory was repurposed for manufacturing of liquid-frozen doses during the mpox outbreak in 2022-2023 and would thus need to be replaced via new orders to enable fulfilment of the remaining freeze-dried option.

About the smallpox/mpox vaccine

MVA-BN or Modified Vaccinia Ankara-Bavarian Nordic is a non-replicating smallpox vaccine and the only mpox vaccine approved in the U.S. and Switzerland (marketed as JYNNEOS®), Canada (marketed as IMVAMUNE®), the EU/EAA and United Kingdom (marketed as IMVANEX®). Originally developed in collaboration with the U.S. government to ensure the supply of a smallpox vaccine for the entire population, including immunocompromised individuals who are not recommended vaccination with traditional replicating smallpox vaccines, MVA-BN has been indicated for use in the general adult population in individuals considered at risk for smallpox or mpox infection.

Bavarian Nordic has been a long-term supplier of the vaccine to the U.S. and Canada, as well as numerous other countries as part of their national biological preparedness. During the 2022-2023 mpox outbreak, Bavarian Nordic

has furthermore supported governments and supranational organizations by expanding access to the vaccine to more than 70 countries worldwide.

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 vaccine company with a mission to protect and save lives through innovative vaccines. We are a global leader in smallpox and mpox vaccines, supplied to governments to enhance public health preparedness and have a strong portfolio of vaccines for travelers and endemic diseases. 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. 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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