

Bavarian Nordic Completes Enrollment of Phase 3 Lot-Consistency Trial of Freeze-dried Smallpox Vaccine

COPENHAGEN, Denmark, November 11, 2019 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today the completion of enrollment of 1,110 subjects for the fully-funded Phase 3 lot-consistency trial to support U.S. licensure of a longer-lasting, freeze-dried formulation of MVA-BN® smallpox vaccine.

In September, the U.S. Food and Drug Administration (FDA) approved the liquid-frozen formulation of the vaccine (under the trade name JYNNEOS™) for prevention of smallpox and monkeypox disease.

A prior Phase 2 study showed bioequivalence between the freeze-dried and liquid-frozen formulations of MVA-BN, and the lot-consistency trial was agreed with the FDA as the only Phase 3 study required to support licensure of the freeze-dried formulation.

Upon successful completion of the current study, expectedly in 2021, the Company plans to submit a supplement to the BLA to extend the approval for both formulations of MVA-BN, anticipated in 2022.

Federal funding acknowledgements

This project has been funded with federal funds from the HHS Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority (BARDA), under Contract No. HHSO100201700019C.

About our 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 as a non-replicating smallpox vaccine to ensure all populations can be protected from smallpox, including people with weakened immune systems who are at high risk of adverse reactions to traditional smallpox vaccines, which are based on replicating vaccinia virus strains. To-date, the Company has supplied 28 million doses of the liquid-frozen version to the U.S. Strategic National Stockpile (SNS) for emergency use, which have now expired.

Since 2009, BARDA has supported the development of a freeze-dried version of the vaccine with longer shelf-life to replace the stockpile and in 2017 awarded the Company a ten-year contract valued at USD 539 million for supply of freeze-dried vaccines to the SNS. Part of this contract (USD 37 million) has funded the Phase 3 study. Also, under this contract Bavarian Nordic is producing bulk vaccine worth of USD 100 million which will add to the existing stock of bulk manufactured under previous orders, collectively resulting in approximately 13 million doses for future delivery. The majority of the contract (USD 299 million), however, will be realized upon supply of the freeze-dried doses, which will be manufactured from 2020 onwards once the new fill-finish facility is operational.

The ten-year contract also includes pricing for additional orders of vaccine bulk and vaccine doses of either liquid-frozen or freeze-dried MVA-BN formulations to expand the U.S. stockpile, or for vaccination of first-line responders (military and healthcare workers).

About JYNNEOS™

JYNNEOS™ (Smallpox and Monkeypox Vaccine, Live, Non-replicating) is indicated for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.

JYNNEOS is a suspension for subcutaneous injection (0.5 mL) based on a live, attenuated vaccinia virus (Modified Vaccinia Ankara, MVA-BN), incapable of replicating in the body, yet still capable of eliciting a potent immune response.

Typical severe adverse reactions known for replicating vaccinia virus strains, such as myocarditis, encephalitis, generalized vaccinia or eczema vaccinatum, were not observed during the clinical development program of JYNNEOS.

The approval of JYNNEOS for smallpox is based on a comprehensive development program, comprising a total of 7871 individuals aged 18 through 80 years who received at least 1 dose (7109 smallpox vaccine-naïve and 762 smallpox vaccine-experienced individuals) in 22 clinical trials, including two Phase 3 studies, the latter of which showed non-inferiority in terms of immunogenicity measured by plaque reduction neutralization test of JYNNEOS compared to ACAM2000, the U.S. licensed, replicating smallpox vaccine.

The approval for monkeypox is based on survival data obtained in lethal monkeypox virus challenge studies in non-human primates. Overall survival in various models ranged from 80% to 100% of JYNNEOS-vaccinated animals compared to 0-40% in control animals.

The safety of JYNNEOS was evaluated in smallpox vaccine-naïve healthy adults, in healthy adults previously vaccinated with a smallpox vaccine, in HIV-infected adults, and in adults with atopic dermatitis.

The most common (>10%) adverse reactions associated with JYNNEOS were injection site reactions (pain, redness, swelling, induration, itching) and systemic adverse reactions such as muscle pain, headache, fatigue, nausea, myalgia and chills. Serious adverse reactions were reported in 0.05% of subjects who received JYNNEOS and included Crohn's disease, sarcoidosis, extraocular muscle paresis and throat tightness. Cardiac adverse reactions of special interest were reported in 0.08% of subjects who received JYNNEOS and included tachycardia, electrocardiogram T wave inversion, electrocardiogram abnormal, electrocardiogram ST segment elevation, electrocardiogram T wave abnormal, and palpitations.

For full Prescribing Information, visit <http://www.jynneos.com>.

About Bavarian Nordic

Bavarian Nordic is a fully integrated biotechnology company focused on the development of innovative therapies against infectious diseases and cancer. Using our live virus vaccine platform technology, MVA-BN®, we have 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. In addition to our long-standing collaboration with the U.S. government on the development and supply of medical countermeasures, including the only FDA-approved, non-replicating smallpox vaccine, 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, 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 benefit-risk profile. For more information visit www.bavarian-nordic.com or follow us on Twitter [@bavariannordic](https://twitter.com/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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Press Release