Press Release

Phase 3 Results of Bavarian Nordic's Smallpox Vaccine Published in The New England Journal of Medicine

COPENHAGEN, Denmark, November 14, 2019 – Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today that results from the pivotal Phase 3 efficacy trial of its smallpox vaccine, MVA-BN®, have been peer-reviewed and published in *The New England Journal of Medicine (NEJM)*, one of the world's leading medical journals.

The Phase 3 trial was the final clinical study to support the registration of the vaccine, which was approved in September by the U.S. Food and Drug Administration. The vaccine, marketed as JYNNEOS™, is indicated for prevention of smallpox and monkeypox disease in adults 18 years of age and older.

"We are very proud that our research has been acknowledged by The New England Journal of Medicine. The fact that the study results have been published by such an esteemed journal underpins the importance of the data to the medical community," said Paul Chaplin, President and CEO of Bavarian Nordic.

The study, which compared indicators of efficacy for Bavarian Nordic's non-replicating smallpox vaccine, MVA-BN to ACAM2000®, the U.S. licensed, replicating smallpox vaccine, successfully achieved both co-primary endpoints, while also demonstrating an improved safety profile versus ACAM2000. The results demonstrated that peak neutralizing antibodies induced by MVA-BN were statistically higher (almost 2-fold higher on average) than those stimulated by ACAM2000 and that primary vaccination with MVA-BN resulted in a highly attenuated take (reduction in lesion size), and in fact prevented the vaccine take in the majority of subjects re-vaccinated with ACAM2000. Importantly, a single dose of MVA-BN induced neutralizing antibody titers comparable with ACAM2000 at Day 14, indicating the potential for use of the vaccine to protect the general population.

The paper titled "*Phase 3 Efficacy Trial of Modified Vaccinia Ankara as a Vaccine against Smallpox*" was co-authored by Phillip R Pittman, MD, MPH, United States Army Medical Research Institute of Infectious Diseases (USAMRIID) who also led the Phase 3 trial in collaboration with the U.S. Defense Health Agency (DHA). The paper is available at: https://www.nejm.org/doi/full/10.1056/NEJMoa1817307.

Federal funding acknowledgments
The Phase 3 study comparing the safety and immunogenicity of MVA-BN to ACAM2000 has been partly funded with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. HHSO100200700034C.

About USAMRIID
USAMRIID is celebrating its 50th year of providing leading edge medical capabilities to deter and defend against current and emerging biological threat agents. The Institute is the only laboratory in the Department of Defense equipped to safely study highly hazardous viruses requiring maximum containment at Biosafety Level 4. Research conducted at USAMRIID leads to medical solutions-vaccines, drugs, diagnostics, and information-that benefit both military personnel and civilians. Established in 1969, the Institute plays a key role as the lead military medical research laboratory for the Defense Threat Reduction Agency's Joint Science and Technology Office for Chemical and Biological Defense. USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Development Command. For more information, visit www.usamriid.army.mil

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.

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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.

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