

Company Announcement

# Bavarian Nordic Announces a New Order for JYNNEOS Smallpox Vaccine from the U.S. Government Potentially Worth USD 200 Million

- The new order for up to 1.4 million liquid-frozen doses of JYNNEOS and additional vaccine bulk was placed under the existing 10-year contract awarded in 2017
- USD 106 million has been secured, with the majority being revenue recognized in 2020, while the remaining option is expected to be revenue recognized in 2021
- Company reaffirms 2020 financial guidance

**Copenhagen, Denmark, April 30, 2020** - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced that the U.S. Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, has placed a new order under the contract, awarded in 2017, for the manufacturing and supply of JYNNEOS® (Smallpox and Monkeypox Vaccine, Live, Non-replicating), at a total value of USD 202 million. This new order is in addition to the existing option to manufacture approximately 13 million freeze-dried doses worth USD 299 million that the Company expects to start manufacturing in 2022 and revenue recognize following approval by the U.S. Food and Drug Administration (FDA) of this vaccine formulation.

The contract expansion covers two years of performance and includes the manufacturing of additional bulk vaccine and the supply of up to 1.4 million doses of liquid frozen JYNNEOS. Most of these liquid frozen doses will be manufactured at Bavarian Nordic's new fill and finish facility, bringing the commercial production of both the liquid frozen and freeze-dried vaccine formulations in-house. This is the first order from the U.S. Government following the approval of JYNNEOS by the FDA in September 2019, which will ensure the availability of a licensed, non-replicating smallpox vaccine in the U.S. Strategic National Stockpile (SNS) for potential use by first-line responders.

While the first USD 106 million of the contract has been secured, with the majority being recognized as income in 2020, the second part is expected to be exercised during 2021. Based on this, Bavarian Nordic is able to reaffirm its financial guidance for 2020 with expected revenues of approximately DKK 1,900 million and an EBITDA of approximately DKK 675 million. The significant value of this order will compensate for the increased uncertainties from the COVID-19 situation in other parts of the business.

Paul Chaplin, President & CEO of Bavarian Nordic said: "We are very pleased to announce this new order for JYNNEOS, which shows the continued strong support and success of our public-private partnership with the US Government to supply biological countermeasures. As part of our commitment to supply vaccines to protect American citizens, we have invested more than USD 75 million in a state-of-the-art fill and finish facility, and with additional support from BARDA, we will be able to take control of the entire manufacturing cycle for both the liquid frozen and freeze-dried formulations of JYNNEOS and make this vaccine available to first-line responders for an improved preparedness against both smallpox and monkeypox."

"While BARDA and the world focuses on the current coronavirus pandemic, other threats to national health security remain," said BARDA Acting Director Gary Disbrow, Ph.D. "At BARDA, we are committed to meeting the needs of Americans and to engaging private partners in continually improving our nation's security."

## About JYNNEOS®

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. The vaccine was developed in partnership with the U.S. Government to ensure all populations can be Page 1 of 2

**Bavarian Nordic A/S** Philip Heymans Alle 3 DK-2900 Hellerup

Tel. +45 33 26 83 83 www.bavarian-nordic.com protected from smallpox, including people with weakened immune systems or who are at high risk of adverse reactions to traditional smallpox vaccines, which are based on replicating vaccinia virus strains. 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 other 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 (AESI) 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. None of the cardiac AESIs considered causally related to study vaccination were considered serious.

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

## 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, also for the protection against monkeypox. Our commercial product portfolio furthermore contains market-leading vaccines against rabies and tick-borne encephalitis. Using our live virus vaccine platform technology, MVA-BN<sup>®</sup>, 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 investigational 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 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.

#### Contacts

Europe: Rolf Sass Sørensen, Vice President Investor Relations, Tel: +45 61 77 47 43 US: Graham Morrell, Paddock Circle Advisors, <u>graham@paddockcircle.com</u>, Tel: +1 781 686 9600

Company Announcement no. 25 / 2020