Company Announcement

Bavarian Nordic Announces U.S. FDA Approval of JYNNEOS™ (Smallpox and Monkeypox Vaccine, Live, Non-replicating) for Prevention of Smallpox and Monkeypox Disease in Adults

- First FDA approved non-replicating smallpox vaccine
- Only FDA approved vaccine for prevention of monkeypox
- Company granted Priority Review Voucher
- Conference call and webcast tomorrow at 3:00 PM CEST

COPENHAGEN, Denmark, September 24, 2019 – Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) today announced that the U.S. Food and Drug Administration (FDA) has approved JYNNEOS™ (Smallpox and Monkeypox Vaccine, Live, Non-replicating) (MVA-BN®, liquid-frozen) 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 the only approved non-replicating smallpox vaccine in the U.S. and the only approved monkeypox vaccine anywhere in the world.

JYNNEOS is approved for use broadly, including in people with weakened immune systems and those with eczema or with household members with eczema. This approval is a major breakthrough in meeting the U.S. government's long-standing commitment to developing a vaccine that can be administered to people who are at high risk of adverse reaction to traditional, replicating smallpox vaccines.

"The licensure of this vaccine not only enhances domestic biodefense and global health security but also demonstrates what can be accomplished for the American people through public-private partnerships," said Rick Bright, Ph.D., HHS deputy assistant secretary for preparedness and response and director of the Biomedical Advanced Research and Development Authority (BARDA). "The years of dedication working with Bavarian Nordic on this vaccine ultimately mean that the U.S. is better prepared to save lives if an emergency occurs involving one of the deadliest diseases the world has ever known."

"The FDA approval of JYNNEOS is a tremendous milestone for both our company and the U.S. Department of Health and Human Services," said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic. "Together, we have shown that it is possible to develop a safe and effective medical countermeasure for national security threats like smallpox. JYNNEOS is the culmination of a fifteen-year partnership that started with a call from the NIH for a safer smallpox vaccine, successfully transitioned to BARDA and was delivered to the Strategic National Stockpile for use in an emergency. We are committed to the continued supply of vaccines to the U.S. and thank them for their global leadership on biodefense. We are also particularly pleased with the additional indication to protect against monkeypox that creates new commercial opportunities for JYNNEOS."

Concurrent with the approval, FDA granted Bavarian Nordic a Priority Review Voucher (PRV) under the Material Threat Medical Countermeasure PRV program. A PRV can be used to accelerate the FDA's review of a future human drug application and is also transferrable. The Company intends to sell the voucher to a third party.

Conference call and webcast
The management of Bavarian Nordic will host a conference call tomorrow, September 25, 2019 at 3 pm CEST (9 am EST) to discuss the FDA approval of JYNNEOS. Dial-in numbers and further details will be provided in advance of the call on: http://www.bavarian-nordic.com/investor/events.aspx?event=5713.

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About monkeypox
Monkeypox is a rare viral zoonotic disease (transmission from animals to humans) similar to human smallpox, whose causative agent, *variola virus*, is also a member of the *Orthopoxvirus* genus. However, monkeypox infection is less transmissible human-to-human than smallpox and also less deadly (case fatality estimates for monkeypox are up to 10%). Orthopoxvirus infections produce antibody responses that are cross-protective against other viruses within the genus. It is this property of orthopoxviruses that allows JYNNEOS to be used as a vaccine against both smallpox and monkeypox.

Until recently, infections of monkeypox in humans had mostly been limited to central and western regions of Africa, where the virus is naturally occurring. However, during the ongoing monkeypox outbreak in Nigeria, increased human-to-human transmission has been observed and the wide geographic spread, predominantly in urban areas, has raised concerns over the disease. The recent cases of monkeypox observed in the UK, Israel and Singapore all originated from Nigeria, demonstrating that the virus is no longer a domestic challenge only. Nigeria is Africa's largest country by both population and economy, including the large oil and gas industry, which employs a significant number of local and foreign employees. It is estimated that more than five million people travel to countries affected by monkeypox in Central Africa each year, suggesting a market potential for a monkeypox vaccine for travelers.

About smallpox
Smallpox is a highly contagious and deadly disease, which was eradicated worldwide by 1980 after a global vaccination campaign, and no longer occurs naturally. Unique to humans, the disease is caused by the *variola virus*, and is transmitted from person to person through direct contact with contaminated fluids and objects, as well as through the air. Historically, about 30% of those who became infected with smallpox died from the illness.

Despite being eradicated, smallpox is considered by many governments to be a significant bioterrorism threat and as routine vaccination stopped in the 1970's, the majority of the world's population today are highly vulnerable. Re-emergence of smallpox could occur as result of deliberate or accidental release of samples that are kept for research purposes or may be synthesized in a lab.

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 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 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.

Bavarian Nordic has received significant support during the development of JYNNEOS from the 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, the National Institutes of Health (NIH), the Department of Defense (DoD) and the Centers for Disease Control and Prevention (CDC).

Bavarian Nordic has to-date delivered 28 million doses of liquid-frozen MVA-BN to the U.S. Strategic National Stockpile for emergency use. The Company has an ongoing ten-year contract with BARDA to replenish and potentially expand the stockpile, which has expired, with a freeze-dried formulation of the vaccine. A Phase 3 lot consistency study of the freeze-dried formulation is currently ongoing to support the approval of this formulation.

MVA-BN is also approved in the EU under the trade name IMVANEX® for active immunization against smallpox of the general adult population, including people with weakened immune systems (people diagnosed with HIV or atopic dermatitis), and in Canada under the trade name IMVAMUNE® for active immunization against smallpox in a public health emergency for persons 18 years of age and older who are contraindicated to replicating smallpox vaccines.

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.

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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