Company Announcement

Bavarian Nordic Receives U.S. FDA Approval of Freeze-Dried Smallpox and Mpox Vaccine

COPENHAGEN, Denmark, March 31, 2025 – Bavarian Nordic A/S (OMX: BAVA) today announced that the U.S. Food and Drug Administration (FDA) has approved the freeze-dried formulation of JYNNEOS® (Smallpox and Mpox Vaccine, Live, Non-replicating) for prevention of smallpox and mpox disease in adults 18 years of age and older. This approval will provide additional flexibility for stockpiling against a smallpox event or mpox outbreak.

The approval follows a standard review with the FDA of a supplemental Biologics License Application (sBLA) submitted in May 2024. The sBLA was primarily based on clinical data that showed comparability in terms of the immune responses and safety between the freeze-dried and liquid-frozen formulations, as well as other non-clinical and manufacturing data.

The current liquid-frozen formulation of JYNNEOS, approved by the FDA in September 2019, has specific cold-chain requirements, while the freeze-dried formulation provides advantages in terms of transportation, storage conditions and shelf life, all of which are important factors for long-term stockpiling.

"*Today's FDA approval represents a significant milestone in our development of this next generation of JYNNEOS and in our collaborative efforts with the U.S. government to strengthen public health security.*" said **Paul Chaplin, President and CEO of Bavarian Nordic**. "*As a long-term supplier of JYNNEOS to the U.S. biological preparedness, we are committed to continue supporting the government's efforts to protect its citizens against current and future public health threats.*"

About our contracts with the U.S. government
Since 2003, Bavarian Nordic has worked with the U.S. government on the development, manufacturing and supply of a non-replicating smallpox vaccine to ensure all populations can be protected from smallpox and mpox, 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.

Approved by the FDA in 2019, JYNNEOS was the first smallpox vaccine successfully developed under Project BioShield, a program created by the U.S. Congress in 2004 to accelerate the research, development, procurement, and availability of medical countermeasures against biological, chemical, radiological, and nuclear (CBRN) agents through public-private partnerships.

Bavarian Nordic has supplied a liquid-frozen version of JYNNEOS to the U.S. government for stockpiling since 2010 and in response to the mpox outbreak in 2022-2023.

The Company has been contracted by the U.S Biomedical Advanced Research and Development Authority (BARDA) to develop and supply a freeze-dried version of JYNNEOS for stockpiling. Manufacturing under this contract was initiated in 2024, and the first vaccines will be delivered later in 2025.

Federal funding acknowledgements
This project has been supported in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number HHSO100201700019C.

About JYNNEOS®
JYNNEOS (Smallpox and Mpox Vaccine, Live, Non-replicating) is approved for the prevention of smallpox and mpox disease in adults 18 years of age and older determined to be at high risk for smallpox and monkeypox infection.

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The vaccine was developed in collaboration with the U.S. government originally to ensure supply of a smallpox vaccine for the entire population, including immunocompromised individuals who are not recommended vaccination with traditional replicating smallpox vaccines.

JYNNEOS was approved by the U.S. Food and Drug Administration (FDA) in 2019 and in 2021, the Advisory Committee on Immunization Practices (ACIP) under the Centers for Disease Control and Prevention (CDC) voted to recommend JYNNEOS for pre-exposure vaccination of people at occupational risk for orthopoxvirus exposures.

In 2022, the CDC issued interim guidance, enabling pre- and post-exposure use of JYNNEOS during the mpox outbreak and an Emergency Use Authorization (EUA) was issued by the FDA allowing the use of JYNNEOS in people under 18 years. In October 2023, the CDC updated its guidance for use of JYNNEOS and now recommends routine use of the vaccine for at risk individuals 18 years and older.

Important Safety Information

Appropriate medical treatment must be available to manage possible anaphylactic reactions following administration of JYNNEOS. Anyone who has experienced a severe allergic reaction following a previous dose of JYNNEOS or following exposure to any component of JYNNEOS may be at increased risk for severe allergic reactions.

Syncope (fainting) has been reported following vaccination with JYNNEOS. Procedures should be in place to avoid injury from fainting.

Immunocompromised persons, including those receiving immunosuppressive therapy, may have a diminished immune response to JYNNEOS.

Vaccination with JYNNEOS may not protect all recipients.

In smallpox vaccine-naïve healthy adults, the most common (>10%) solicited injection site reactions were pain (84.9%), redness (60.8%), swelling (51.6%), induration (45.4%), and itching (43.1%); the most common solicited systemic adverse reactions were muscle pain (42.8%), headache (34.8%), fatigue (30.4%), nausea (17.3%) and chills (10.4%).

In healthy adults previously vaccinated with a smallpox vaccine, the most common (>10%) solicited injection site reactions were redness (80.9%), pain (79.5%), induration (70.4%), swelling (67.2%), and itching (32.0%); the most common solicited systemic adverse reactions were fatigue (33.5%), headache (27.6%), and muscle pain (21.5%).

The frequencies of solicited local and systemic adverse reactions among adults with HIV infection and adults with atopic dermatitis were generally similar to those observed in healthy adults.

Across all studies, a causal relationship to JYNNEOS could not be excluded for 5 serious adverse events (SAEs), all non-fatal, which included Crohn's disease, sarcoidosis, extraocular muscle paresis, throat tightness, and hemolytic anemia.

Cardiac adverse events of special interest (AESIs) considered causally related to study vaccination were reported in <0.1% 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.

To report SUSPECTED ADVERSE REACTIONS, contact Bavarian Nordic at 1-833-365-9596 or the US Department of Health and Human Services by either visiting www.vaers.hhs.gov/reportevent.html or calling 1-800-822-7967.

Please see full Prescribing Information.

About Bavarian Nordic

Bavarian Nordic is a global vaccine company with a mission to improve health and save lives through innovative vaccines. We are a preferred supplier of mpox and smallpox vaccines to governments to enhance public health preparedness and have a leading portfolio of travel vaccines. 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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