



## Bavarian Nordic's Mpx Vaccine Receives Recommendation from U.S. CDC Advisory Committee for Routine Use in Adults at Risk

COPENHAGEN, Denmark, October 25, 2023 - Bavarian Nordic A/S (OMX: BAVA) announced today that the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) has voted in favor of recommending the routine use of JYNNEOS<sup>®</sup>, the Company's FDA-approved mpx vaccine, in adults at risk of mpx infection. Specifically, the ACIP voted to recommend that individuals 18 years and older with certain risk factors<sup>1</sup> should receive the two-dose regimen of JYNNEOS. Previously, ACIP had recommended JYNNEOS for individuals at risk of mpx only during an outbreak.

The recommendations will be forwarded to the Director of the CDC and the U.S. Department of Health and Human Services for review and following approval, the recommendations will be published in the *Morbidity and Mortality Weekly Report*.

The CDC estimates that 2 million U.S. individuals are eligible for vaccination against mpx under these recommendations<sup>2</sup>. To date, approximately 23% of this group has received the recommended two doses of JYNNEOS during the 2022/2023 outbreak, leaving a significant number of people vulnerable to infection with mpx. Pending approval of the updated recommendations, Bavarian Nordic is targeting a commercial launch of JYNNEOS in the U.S. in the first half of 2024.

This represents the second national recommendation for Bavarian Nordic's mpx vaccine in adult risk groups following a similar endorsement by the Standing Committee for Vaccination (STIKO) in Germany during 2022. More recently, the European AIDS Clinical Society (EACS) also recommend the use of the vaccine for adults infected with HIV, or on pre-exposure prophylaxis (PrEP) treatment<sup>3</sup>, which may support additional national recommendations for the use of the vaccine in the future.

"Since the outbreak of mpx last year, Bavarian Nordic has supplied millions of doses of our vaccine to more than 70 countries worldwide, which has had a positive impact on controlling this unprecedented outbreak of mpx. Despite the best efforts of numerous governments and health agencies around the world a large proportion of individuals at risk remain unvaccinated and vulnerable to mpx infections. The broadened ACIP recommendation recognizes the significance of maintaining a high awareness of the disease among risk groups and the importance of ensuring broader access to the vaccine beyond an outbreak situation. Entering the private mpx vaccine market in the U.S offers an opportunity to provide improved access to JYNNEOS and to build a steady commercial business segment, complimenting the existing smallpox stockpiling business with the U.S. government. With our unwavering commitment to improving public health, we look forward to working with healthcare professionals to make our vaccine available for all individuals at risk," said Paul Chaplin, President and CEO of Bavarian Nordic.

### About JYNNEOS<sup>®</sup>

JYNNEOS<sup>®</sup> (Smallpox and Monkeypox Vaccine, Live, Nonreplicating) is approved for the prevention of smallpox and mpx disease in adults 18 years of age and older determined to be at high risk for smallpox and mpx infection. 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, ACIP 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 mpx outbreak and an Emergency Use Authorization (EUA) was issued allowing the use of JYNNEOS in people under 18 years.

Visit [www.jynneos.com](http://www.jynneos.com) for full prescribing information.

### **About Bavarian Nordic**

Bavarian Nordic is a fully integrated vaccine company focused on the research and development, manufacturing and commercialization of life-saving vaccines. We are a global leader in smallpox and mpox vaccines, which have been developed through our long-standing partnership with the U.S. Government to enhance the public health preparedness and have a strong portfolio of vaccines for travelers and endemic diseases. For more information visit [www.bavarian-nordic.com](http://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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Company Announcement no. 35 / 2023

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<sup>1</sup> Persons at risk include gay, bisexual, and other men who have sex with men, transgender or nonbinary people who in the past 6 months have had one of the following: A new diagnosis of  $\geq 1$  sexually transmitted disease; More than one sex partner; Sex at a commercial sex venue; Sex in association with a large public event in a geographic area where mpox transmission is occurring, sexual partners of persons with the aforementioned risks, and persons who anticipate experiencing any of the aforementioned.

<sup>2</sup> CDC. JYNNEOS Vaccine Coverage by Jurisdiction as of September 26, 2023. <https://www.cdc.gov/poxvirus/mpox/cases-data/mpx-jynneos-vaccine-coverage.html>

<sup>3</sup> <https://www.eacsociety.org/media/guidelines-12.0.pdf>