



## Bavarian Nordic Announces Commercial Launch of Mpox Vaccine in the U.S.

**COPENHAGEN, Denmark, April 2, 2024** - Bavarian Nordic A/S (OMX: BAVA) announced today that JYNNEOS®, the only FDA-approved mpox vaccine, is now commercially available in the U.S., marking a significant expansion for access to JYNNEOS® by establishing additional pathways for vaccine procurement, distribution, and reimbursement by both public and private payers.

Since 2022, in response to the global mpox outbreak, JYNNEOS has been made available through public health channels for individuals at risk of mpox infection. This was made possible through Bavarian Nordic's long-standing partnership with the U.S. government to supply the vaccine for the national stockpile and enabled by interim guidance from the Centers for Disease Control and Prevention (CDC), recommending pre- and post-exposure use of the vaccine for individuals at risk during the outbreak. These recommendations were updated in October 2023 by unanimous vote by the CDC's Advisory Committee on Immunization Practices (ACIP), and JYNNEOS is now recommended for routine use in individuals 18 years and older with certain risk factors<sup>1</sup>.

While mpox no longer constitutes a public health emergency, infections are still occurring throughout the U.S., with around 200 cases every month on average and transmission of the virus having been reported across most of the states in 2024 to-date<sup>2</sup>. Since the beginning of the outbreak in 2022, more than 32,000 cases have been reported in the U.S., representing a third of all cases reported globally<sup>3</sup>.

According to estimates from the CDC, two (2) million U.S. individuals are eligible for vaccination against mpox<sup>4</sup>. Recent data shows 60% of this population remains completely unvaccinated, and 15% have received only one dose of the vaccine<sup>5</sup>. Real-world data show that protection against mpox disease is superior in vaccinees who received the full schedule of two vaccinations as recommended by the CDC, compared to those who are unvaccinated or have only received one dose of the vaccine<sup>6</sup>.

Through its existing nationwide vaccine distribution structure, Bavarian Nordic is now making the mpox vaccine commercially available across the nation. As of April 1, health care providers can order JYNNEOS through their preferred wholesaler and distribution partners to make it available for at-risk individuals at local pharmacies and physician offices in addition to public health clinics.

Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic, commented: "From the beginning of the mpox outbreak, almost two years ago, the prompt availability of an approved vaccine combined with a strong public health response have helped to significantly reduce the impact of this debilitating disease, but unfortunately, mpox has not gone away completely. Building on the trust and reliability as a supplier of vaccines to the U.S. government for more than a decade, we are proud to extend our commitment to improving the nation's public health by making our mpox vaccine widely available to at-risk individuals through the regular channels. We look forward to working with healthcare providers across the nation to increase awareness and availability of the mpox vaccine."

Brian Hujdich, Executive Director, National Coalition for LGBTQ Health, commented: "The expanded availability of JYNNEOS is a vital step toward ensuring equitable access to healthcare for the LGBTQ+ community and marks a significant stride in preventing the spread of mpox. We must continue to advocate for equitable policies that protect and support the health and well-being of all individuals and encourage those at risk to consult with their healthcare providers regarding vaccination."

**About mpxx**

Visit the CDC website for comprehensive information about mpxx:

<https://www.cdc.gov/poxvirus/mpox/about/index.html>

**About Bavarian Nordic**

Bavarian Nordic is a fully integrated vaccine company with a mission to protect and save lives through innovative vaccines. We are a global leader in travel vaccines and a preferred partner with governments on vaccines for public preparedness. For more information visit [www.bavarian-nordic.com](http://www.bavarian-nordic.com).

**About JYNNEOS®**

JYNNEOS® (Smallpox and Monkeypox Vaccine, Live, Nonreplicating) is approved for the prevention of smallpox and mpxx disease in adults 18 years of age and older determined to be at high risk for smallpox and mpxx 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 mpxx outbreak and an Emergency Use Authorization (EUA) was issued 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 4 serious adverse events (SAEs), all non-fatal, which included Crohn's disease, sarcoidosis, extraocular muscle paresis and throat tightness.

Cardiac adverse events of special interest (AESIs) considered causally related to study vaccination 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. To report SUSPECTED ADVERSE REACTIONS, contact Bavarian Nordic at 1-844-4BAVARIAN or the US Department of Health and Human Services by either visiting [www.vaers.hhs.gov/reportevent.html](http://www.vaers.hhs.gov/reportevent.html) or calling 1-800-822-7967.

[Please see full Prescribing Information](#)

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Media are also encouraged to visit <https://www.bavarian-nordic.com/media/mpox> for additional background information and media kit, including photos and b-roll.

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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, weekly data. Accessed April 1, 2024. <https://wonder.cdc.gov/nndss/static/2024/12/2024-12-table968-H.pdf>.

<sup>3</sup> CDC. Ongoing 2022 Global Outbreak Cases and Data. Accessed April 1, 2024.

<https://www.cdc.gov/poxvirus/mpox/response/2022/index.html>.

<sup>4</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>5</sup> [https://www.cdc.gov/poxvirus/mpox/response/2022/vaccines\\_data.html](https://www.cdc.gov/poxvirus/mpox/response/2022/vaccines_data.html)

<sup>6</sup> CDC. 2022/2023 Mpox outbreak: situational awareness and updates (October 25, 2023, ACIP meeting presentation).

Accessed April 1, 2024. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2023-10-25-26/02-MPOX-Minhaj-508.pdf>