



Bavarian Nordic Joins Global Efforts to Fight Mpox Outbreak in Africa

- Bavarian Nordic is committed to support global efforts to address the mpox situation in Africa through a donation of 15,000 doses of mpox vaccine
- Emergency Use Authorization for the MVA-BN vaccine has been issued in the DR Congo

COPENHAGEN, Denmark, June 28, 2024 - Bavarian Nordic A/S (OMX: BAVA) today announced an extended commitment to help fight the current mpox outbreak in Africa. The Company's MVA-BN vaccine, the only FDA and EMA-approved mpox vaccine, which served as an important tool during the 2022-2023 mpox outbreak, could soon also become available in the DR Congo (DRC) and other countries in Africa.

Mpox is on the rise in African countries with increasing incidence of the more severe clade I. So far in 2024, more than 9,000 mpox cases and over 400 deaths have been reported across seven African countries of which the vast majority (96%) having occurred in the DRC¹. Earlier this week, the regulatory authorities in the DRC, ACOREP (Autorité Congolaise de Réglementation Pharmaceutique), issued an Emergency Use Authorization allowing for the use of the MVA-BN vaccine for individuals at risk of mpox.

Locally, in the DRC, clinical studies are also planned to support a full regulatory approval of the MVA-BN vaccine, as recently [announced](#) by Bavarian Nordic.

To further strengthen the response in the DRC and throughout the African region, Bavarian Nordic will collaborate with global health partners, including WHO, UNICEF and Gavi. Bavarian Nordic applauds Gavi's Board decision to approve a new Vaccine Investment Strategy which includes the establishment of a global mpox vaccine stockpile. In the near term, Bavarian Nordic is committed to work in partnership with Gavi, WHO and UNICEF to coordinate dose donations in response to the ongoing outbreak in the DRC and other African countries.

To support these efforts, Bavarian Nordic has committed to donating 15,000 doses of its MVA-BN mpox vaccine to the African response.

"The spread of mpox in the Democratic Republic of the Congo and elsewhere is highly concerning and could pose a global threat if it is not urgently contained," said **Dr Sania Nishtar, CEO of Gavi, the Vaccine Alliance**. "Gavi and its partners welcome Bavarian Nordic's resolve to help fight this outbreak and its contribution in doses. Our Alliance welcomes the availability of new vaccines for countries and is committed to working with Bavarian Nordic and the relevant authorities to facilitate their arrival and timely administration in line with country plans."

"Mpox has been a public health threat in several African countries for more than 50 years and is now spreading across the continent with higher incidence and severity. Global partners are uniting to build a stronger public health response throughout the affected region. and we are proud to contribute through a donation of our mpox vaccine," said **Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic**.

About mpox in the DRC and other African countries

Africa is currently tackling one of the largest and deadliest known mpox outbreak to date. Over 8,700 mpox cases and 408 deaths have been reported in the DRC this year alone, with children accounting for the majority of infections and deaths. Cases have also been confirmed in the Republic of Congo, Cameroon, Central African Republic, Ghana, Liberia and South Africa.

Mpox was first identified in the DR Congo in 1970. In most cases, mpox symptoms - typically fever and headache, followed by painful lesions - resolve within a few weeks. However, for some, mpox can lead to medical complications,

such as bronchopneumonia, sepsis, encephalitis, loss of vision, or death. The mpox virus strain behind the current outbreak, known as clade I, is estimated to be fatal in up to 10% of cases.

About the smallpox/mpox vaccine

MVA-BN or Modified Vaccinia Ankara-Bavarian Nordic is a non-replicating smallpox vaccine and the only mpox vaccine approved in the U.S. and Switzerland (marketed as JYNNEOS®), Canada (marketed as IMVAMUNE®), and the EU/EEA and United Kingdom (marketed as IMVANEX®). Originally developed in collaboration with the U.S. government to ensure the supply of a smallpox vaccine for the entire population, including immunocompromised individuals who are not recommended vaccination with traditional replicating smallpox vaccines, MVA-BN has been indicated for use in the general adult population (18 years and older) in individuals considered at risk for smallpox or mpox. During the 2022-2023 mpox outbreak, the vaccine was granted an Emergency Use Authorization by the U.S. FDA for both pre- and post-exposure use in adolescents.

Bavarian Nordic has been a long-term supplier of the vaccine to the U.S. and Canada as well as several other countries as part of their national biological preparedness. During the 2022-2023 mpox outbreak, Bavarian Nordic has furthermore supported governments and supranational organizations by expanding access to the vaccine to more than 70 countries worldwide.

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 smallpox and mpox vaccines, supplied to governments to enhance public health preparedness and have a strong portfolio of vaccines for travelers and endemic diseases. 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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¹ <https://africacdc.org/download/africa-cdc-weekly-event-based-surveillance-report-june-2024/>