Press Release

Bavarian Nordic Receives EMA Approval of Mpox Vaccine for Adolescents

- MVA-BN approved for use against mpox and smallpox in adolescents 12-17 years of age after expedited review with EMA
- Represents the second EMA approval of an MVA-BN-based vaccine for a younger population

COPENHAGEN, Denmark, September 19, 2024 – Bavarian Nordic A/S (OMX: BAVA) announced today that the European Commission has adopted the Committee for Medicinal Products for Human Use (CHMP) recommendation for the approval of a type II variation for IMVANEX® (MVA-BN) smallpox and mpox vaccine, extending the current marketing authorization to include adolescents 12 to 17 years of age.

The CHMP recommendation follows the submission last month to EMA of data from a clinical study (NCT05740982), sponsored by the U.S. National Institutes of Health's (NIH) National Institutes of Allergy and Infectious Diseases (NIAID), in 315 adolescents 12-17 years of age and 211 adults aged 18 years and older, demonstrating non-inferiority of the immune responses as well as a similar safety profile between both age groups after vaccination with two standard doses of the MVA-BN vaccine.

While this represents the first approval of MVA-BN as a smallpox/mpox vaccine for adolescents, a recombinant version of MVA-BN (Mvabea®) was approved by EMA in 2020 as part of a prime-boost vaccine regimen[1] for the prevention of disease caused by Ebola virus in individuals ≥1 year of age. Clinical studies supporting this approval encompass more than 3,300 individuals across Europe, USA, and Africa including over 800 children and adolescents 1-17 years of age in Africa[2]. The safety profile of Mvabea in children 1-17 years of age was generally similar to that observed in adults and similar to the safety profile of MVA-BN in individuals 12 years and older.

Paul Chaplin, President & CEO of Bavarian Nordic, said: "We applaud EMA for their expedited review and decision to recommend approval of MVA-BN for adolescents. This represents an important milestone in our efforts to make our vaccine available for all populations and will help improve access for some of the most vulnerable individuals mostly impacted by the ongoing mpox outbreak in Africa."

Bavarian Nordic is preparing for a clinical trial (NCT06549530) to assess the immunogenicity and safety of MVA-BN in children 2-12 years of age, aiming to further extend the indication of the vaccine into younger populations. The trial, partially funded by the Coalition for Epidemic Preparedness Innovations (CEPI), is expected to start next month.

CEPI has also co-funded a clinical study (NCT05745987), led by McMaster University in Canada, to assess post-exposure vaccination with MVA-BN, i.e. if the vaccine helps reduce the risk of secondary mpox cases, or, in case of mpox infection, can reduce the severity of illness. The study will include over 1.500 participants including children in households with a laboratory-confirmed mpox infection at sites in the DRC, Uganda and Nigeria. Results of the study could provide important findings to inform vaccination strategies in areas impacted by the mpox outbreak.

About the mpox vaccine

MVA-BN or Modified Vaccinia Ankara-Bavarian Nordic is the only non-replicating mpox vaccine approved in the U.S., Switzerland, Singapore and Mexico (marketed as JYNNEOS®), Canada (marketed as IMVAMUNE®), and the EU/EAA and United Kingdom (marketed as IMVANEX®). Originally developed as a smallpox vaccine 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 in individuals considered at risk for smallpox or mpox infection.

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Bavarian Nordic has been a long-term supplier of the vaccine to national stockpiles, and during the 2022-2023 mpox outbreak, the Company 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] Mvabea® was licensed in 2014 to Johnson & Johnson as part of a prime-boost vaccine regimen.
[2] https://www.ema.europa.eu/en/documents/assessment-report/mvabea-epar-public-assessment-report_en.pdf