Press Release

Bavarian Nordic Receives Positive CHMP Opinion for Including Mpox Real-world Effectiveness Data in European Marketing Authorization for Smallpox and Mpox Vaccine

- Real-world data demonstrating vaccine effectiveness against mpox of up to 90% after two MVA-BN doses and a significant reduction of the risk of mpox-related hospitalizations

COPENHAGEN, Denmark, July 26, 2024 – Bavarian Nordic A/S (OMX: BAVA) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended the approval of a type II variation for IMVANEX® (MVA-BN) smallpox and mpox vaccine, including real-world effectiveness data from the use of the vaccine during the global 2022 mpox outbreak in the marketing authorization.

In the absence of real-world data before the 2022 outbreak, the European marketing authorization of MVA-BN, granted in 2013 for smallpox prevention and extended in 2022 to include mpox, was based on efficacy data in non-human primates and immunogenicity data from numerous studies involving more than 4,000 healthy and immune-compromised individuals. These data demonstrated that MVA-BN had a favorable safety profile and induced immune responses that were non-inferior when compared to traditional smallpox vaccines, which are known to confer cross-protection against mpox and other orthopoxviruses.

After a systematic review and analysis of data from real-world observational studies conducted in vaccine-eligible individuals and published after the onset of the global mpox outbreak in 2022, Bavarian Nordic submitted an application to EMA in late 2023 for a type II variation, representing a major change to the marketing authorization for MVA-BN.

In the real-world studies, vaccine effectiveness against mpox disease was demonstrated at least 14 days after vaccination, with adjusted vaccine effectiveness estimates ranging from 35% (95% CI, -2-59) to 89% (95% CI, 76-95) after one MVA-BN dose and from 66% (95% CI, 47-78) to 90% (95% CI, 86-92) after two MVA-BN doses.

Furthermore, in a surveillance study, MVA-BN was shown to reduce the risks of mpox-related hospitalization. Compared with unvaccinated mpox patients, the odds of hospitalization were 0.27 (95% CI, 0.08-0.65) after one MVA-BN dose, and 0.20 (95% CI, 0.01-0.90) after two MVA-BN doses. The estimated relative risk reduction was 73% after one MVA-BN dose and 80% after two MVA-BN doses.

"The 2022 global mpox outbreak provided an opportunity to assess the effectiveness of our vaccine in at-risk populations across different geographies, both before and after exposure to the mpox virus, and we are pleased to receive the recommendation to include real-life data in our marketing authorization in Europe, which confirm a high effectiveness of up to 90% after two doses of the vaccine as recommended by the authorities. It is furthermore encouraging that data show the vaccine to significantly reduce the risk of hospitalizations, thus confirming our vaccine as an important and versatile tool in the fight against mpox globally," said **Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic.**

About the MVA-BN smallpox and mpox vaccine
MVA-BN or Modified Vaccinia Ankara-Bavarian Nordic (marketed under the brand names JYNNEOS®, IMVANEX® and IMVAMUNE®) is a non-replicating smallpox and mpox vaccine. The vaccine is approved by the FDA, EC, Health Canada, MHRA and Swissmedic and has also obtained emergency use authorization in other territories for use during the mpox outbreak. The vaccine was originally developed in collaboration with the U.S. government to ensure supply of a smallpox vaccine for the entire population, including immunocompromised individuals who are not recommended vaccination with traditional replicating smallpox vaccines.

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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.

For a full list of adverse events and information on dosage and administration, contraindications and other precautions when using IMVANEX, please refer to the Summary of Product Characteristics.

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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