*Press Release*

# Bavarian Nordic Receives European Approval of Extension of Vaccine Label to Include Monkeypox

**COPENHAGEN, Denmark, July 25, 2022** – Bavarian Nordic A/S (OMX: BAVA) announced today that the European Commission (EC) has extended the marketing authorization for the Company's smallpox vaccine, IMVANEX® to include protection from monkeypox and disease caused by vaccinia virus. The approval, which follows a positive opinion by the Committee for Medicinal Products for Human Use (CHMP) on July 22, 2022, is valid in all European Union Member States as well as in Iceland, Liechtenstein, and Norway.

The label extension was approved after submission of a rolling type-II variation application in June 2022, in alignment between Bavarian Nordic and the European Medicines Agency's Emergency Task Force (ETF), Rapporteurs and the European Health Emergency Preparedness and Response Authority (HERA). The EC approved the full IMVANEX indication as: Active immunisation against smallpox, monkeypox and disease caused by vaccinia virus in adults. The monkeypox indication approval is an example of great cooperation between Bavarian Nordic and the European regulators as such an indication extension normally takes at least 6-9 months to achieve.

Paul Chaplin, President and CEO of Bavarian Nordic said: "We are pleased to receive the approval from the European Commission, broadening the label of our vaccine to include monkeypox. The availability of an approved vaccine can significantly improve nations' readiness to fight emerging diseases, but only through investments and structured planning of the biological preparedness. The development of IMVANEX was made possible through significant investments from the U.S. government for the past two decades, leading the way for other governments to develop plans and prioritize for the future to protect their citizens against public health threats. With this approval, we look forward to working closer with the EU and its member states to solve this important task."

**About IMVANEX®**

IMVANEX® (MVA-BN or Modified Vaccinia Ankara-Bavarian Nordic) is a non-replicating smallpox vaccine 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. The vaccine was approved by the European Commission in 2013 for immunization against smallpox in adults aged 18 years and older and has subsequently gained regulatory approvals in Canada (marketed as IMVAMUNE®) and the U.S. (marketed as JYNNEOS®) where the approvals have been extended to include the monkeypox indication as the only vaccine having obtained this to-date.

Bavarian Nordic has ongoing supply contracts with USA and Canada and has delivered the vaccine to a number of undisclosed countries globally as part of their national biological preparedness. In recent years, smaller quantities of the vaccine have been supplied in response to sporadic cases of monkeypox. During the ongoing 2022 outbreak of monkeypox, Bavarian Nordic has worked with several governments to fulfil the immediate demand for the vaccine through a number of supply agreements and is working to secure manufacturing of vaccines to fulfil the demand in the medium- to long term.

**About Bavarian Nordic**

Bavarian Nordic is a fully integrated vaccines company focused on the development, manufacturing and commercialization of life-saving vaccines. We are a global leader in smallpox vaccines and have been a long-term supplier to the U.S. Government of a non-replicating smallpox vaccine, which has been approved by the FDA, also for the protection against monkeypox. The vaccine is also approved for protection against smallpox



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and monkeypox in Canada, and as a smallpox vaccine in Europe. Our commercial product portfolio furthermore contains market-leading vaccines against rabies and tick-borne encephalitis. Using our live virus vaccine platform technology, MVA-BN®, we have created a diverse portfolio of proprietary and partnered product candidates designed to save and improve lives by unlocking the power of the immune system, including an Ebola vaccine, which is licensed to the Janssen Pharmaceutical Companies of Johnson & Johnson. We are also committed to the development of a next generation COVID-19 vaccine. 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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