



BAVARIAN NORDIC

Press Release

Health Canada Extends Approval of IMVAMUNE to Immunization against Monkeypox and Orthopox Viruses

COPENHAGEN, Denmark, November 12, 2020 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today that Health Canada has expanded the approval of the Company's non-replicating smallpox vaccine, IMVAMUNE® to include additional indications - specifically, monkeypox and related *orthopoxvirus* infections and disease in adults 18 years of age and older determined to be at high risk for exposure.

The extended approval was granted following assessment of additional clinical and non-clinical data, generated since IMVAMUNE received approval as a smallpox vaccine by Health Canada in 2013. These data include among others a Phase 3 study which demonstrated that, in terms of efficacy, IMVAMUNE was non-inferior to replicating smallpox vaccines, while also confirming its favorable benefit/risk profile. IMVAMUNE is approved in Canada under the Extraordinary Use New Drugs (EUNDS) Pathway.

Paul Chaplin, President and CEO of Bavarian Nordic said. "The extended approval of IMVAMUNE in Canada confirms its potential to prevent infections from a wider range of *orthopoxviruses*, many of which are naturally occurring. While monkeypox is endemic to certain parts of Africa, *orthopoxvirus* infections may occur from animals to humans all over the world. Although cases are rare, no vaccine has previously been approved for these indications, and we are pleased to receive this extended approval of IMVAMUNE."

Bavarian Nordic has collaborated with the Canadian authorities since 2008 on supplying IMVAMUNE, initially for the Canadian Department of National Defence. Subsequent to the initial Canadian EUNDS approval in 2013, Bavarian Nordic has also collaborated with the Public Health Agency of Canada for stockpiling of the vaccine for the general population.

About Bavarian Nordic

Bavarian Nordic is a fully integrated vaccines company focused on the development, manufacture 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. Strategic National Stockpile of a non-replicating smallpox vaccine, which has been approved by the FDA under the trade name JYNNEOS®, also for the protection against monkeypox. The vaccine is approved as a smallpox vaccine in Europe under the trade name IMVANEX® and in Canada under the trade name IMVAMUNE®. Our commercial product portfolio furthermore contains the market-leading vaccine Rabipur®/RabAvert® against rabies and Encepur® against 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, MVABEA®, which is licensed to Janssen. For more information visit www.bavarian-nordic.com.

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