



BAVARIAN NORDIC

*Company Announcement*

## **Bavarian Nordic Announces Initiation of Phase 1 Clinical Trial of Equine Encephalitis Virus Vaccine**

**COPENHAGEN, Denmark, October 8, 2019** - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today the initiation of the first-in-human trial of MVA-BN® WEV, a prophylactic vaccine candidate against the equine encephalitis virus - a rare, but potentially deadly illness.

The program, which is funded by the United States Department of Defense (DOD) Joint Project Manager for Chemical, Biological, Radiation, and Nuclear Medical (JPM CBRN Medical) is a multi-year agreement valued up to USD 36 million and aims to develop a vaccine against three separate strains of the equine encephalitis virus, Eastern (EEEV), Venezuelan (VEEV), and Western (WEEV), for which there are currently no preventative vaccines available

The Phase 1 trial will evaluate the safety, tolerability and immunogenicity of MVA-BN WEV in 45 healthy adults in three treatment groups receiving different doses of the vaccine. Topline results from the study are expected to become available in 2020.

A successful Phase 1, based on demonstrating a favorable safety and immunogenicity could lead to follow-on funding, beyond the initial contract award of USD 36 million, to support further preclinical, clinical development and manufacturing to support licensure in the U.S.

“After the recent FDA approval of our smallpox vaccine, which was developed in collaboration with various U.S. government agencies and has become an integral part of the national stockpile, we are excited to advance this new program, helping to fulfil the U.S. government’s goal to develop a broad range of medical countermeasures to protect U.S. citizens,” said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic. “The prevalence of Eastern equine encephalitis, which is currently on the rise in the U.S., highlights the importance of a vaccine to help fight these diseases. Again, we are leveraging the unique properties of our MVA-BN platform technology to address unmet medical needs, and we look forward to continuing our work with DOD on this important program.”

### **About Equine Encephalitis Viruses**

Eastern, Venezuelan and Western equine encephalitis virus belong to the family alphavirus, and are transmitted through mosquitos, as well as birds and some mammals. While the viruses vary in infection rates and severity of disease, all three pathogens are associated with risks of flu-like symptoms, potential central nervous disorders, and death. All three viruses are considered as potential biological threats, having been investigated as potential biological weapons at various times in the past century. The viruses belong to the U.S. list of prioritized pathogens amongst other agents, like smallpox, anthrax and other lethal diseases, which are covered by the current vaccination policy for U.S. military personnel being deployed around the globe. However, there are currently no approved vaccines against any of the equine encephalitis viruses.

Currently, the U.S. is experiencing the worst outbreak of Eastern equine encephalitis since monitoring of the disease began. In 2019 to-date, more than 30 cases, including nine deaths have been reported, mostly in northeastern parts of the U.S., where mosquitoes have been found to carry the virus.

### **Federal funding acknowledgment**

This project is funded in whole or in part with federal funds under an *Other Transaction Authority* agreement with U.S. Army Contracting Command-New Jersey through the Medical CBRN Defense Consortium, contract MCDC-17-04-001/2018-315

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**About Bavarian Nordic**

Bavarian Nordic is a fully integrated biotechnology company focused on the development of innovative therapies against infectious diseases and cancer. Using our live virus vaccine platform technology, MVA-BN<sup>®</sup>, we have created a diverse portfolio of proprietary and partnered product candidates intended to unlock the power of the immune system to improve public health with a focus on high unmet medical needs. In addition to our long-standing collaboration with the U.S. government on the development and supply of medical countermeasures, including the only FDA-approved, non-replicating smallpox vaccine, our infectious disease pipeline comprises a proprietary RSV program as well as vaccine candidates for Ebola, HPV, HBV and HIV, which are developed through a strategic partnership with Janssen. Additionally, we have developed a portfolio of active cancer immunotherapies, designed to alter the disease course by eliciting a robust and broad anti-cancer immune response while maintaining a favorable benefit-risk profile. For more information visit [www.bavarian-nordic.com](http://www.bavarian-nordic.com) or follow us on Twitter [@bavariannordic](https://twitter.com/bavariannordic).

**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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