



BAVARIAN NORDIC

Company Announcement

Bavarian Nordic Announces Topline Results from Phase 1 Clinical Trial of Equine Encephalitis Virus Vaccine

COPENHAGEN, Denmark, June 8, 2020 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today topline results from the the first-in-human trial of MVA-BN® WEV, a prophylactic vaccine candidate against three equine encephalitis viruses (western, eastern and Venezuelan), for which there are currently no preventative vaccines available.

The Phase 1 trial, funded by the United States Department of Defense's (DOD) Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense's (JPEO-CBRND) Joint Project Manager for Chemical, Biological, Radiological, and Nuclear Medical (JPM CBRN Medical) was designed to evaluate the safety, tolerability and immunogenicity of MVA-BN WEV in 45 healthy adults in three treatment groups receiving different doses of the vaccine. All subjects were revaccinated after four weeks.

Data from the study showed that the vaccine was well tolerated and immunogenic across all dose groups. Neutralizing antibody responses were observed in all dose groups, with peak levels reached after the second vaccination. Responses were detected as early as 2 weeks after the first vaccination in the highest dose group, in which also complete seroconversion was observed after the second vaccination. The most common vaccine-related adverse event was injection site pain.

These clinically meaningful Phase 1 data warrant further clinical investigation, and Bavarian Nordic is currently in the process of obtaining additional funding from the U.S. authorities for the further clinical advancement of the vaccine candidate.

"We are pleased to report positive topline results from the first-in-human trial with our vaccine candidate against equine encephalitis viruses. A safe and effective vaccine against this fatal disease is a high priority for the U.S. government and we believe that our vaccine candidate is well positioned to meet these requirements. Our public-private partnership with the U.S. has previously shown the way for the successful development of vaccines against smallpox and Ebola, and we hope to continue the fruitful collaboration in this important disease area as well," said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic.

About Equine Encephalitis Viruses

Eastern, Venezuelan and western equine encephalitis viruses 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 for human use against any of the equine encephalitis viruses.

Last year, the U.S. experienced the worst outbreak of Eastern equine encephalitis since monitoring of the disease began. According to the U.S Centers for Disease Control and Prevention (CDC), 38 cases, including 15 deaths were reported in 2019, compared to an annual average of 7 cases over the past decade. The majority of cases occurred in northeastern parts of the U.S., where mosquitoes have been found to carry the virus.

Federal funding acknowledgment

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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.

About Bavarian Nordic

Bavarian Nordic is a fully integrated biotechnology 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 market-leading vaccines 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 investigational Ebola vaccine, licensed to Janssen. 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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