Bavarian Nordic Advances Development of Equine Encephalitis Virus Vaccine

COPENHAGEN, Denmark, January 24, 2019 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) reports further progress in the development of a prophylactic vaccine 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 Management Office for Medical Countermeasure Systems (JPM-MCS) through a multi-year agreement of up to USD 36 million, 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 vaccine is based on Bavarian Nordic’s proprietary, poxviral MVA-BN® platform, which due to its large genome is able to encode multiple antigens, thus providing the potential to protect against multiple diseases.

Since award of the contract in March 2018, Bavarian Nordic has received incremental funding to support the preclinical development, GMP manufacturing and most recently the funding to support a dose ranging Phase 1 clinical trial in 45 healthy volunteers. The study is planned to be initiated in the second half of 2019, with topline results 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 preclinical, clinical development and manufacturing to support licensure in the U.S.

“As a trusted partner and supplier of medical countermeasures for the U.S. government, we are pleased to see the rapid advance of another vaccine candidate in support of the preparedness against emerging and life-threatening diseases,” said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic. “We are happy to work with the DoD among many other government agencies to leverage our technology platform through research contracts like this, which have become an integral part of our business and revenue stream. Funding availability is crucial for the successful development of novel countermeasures, which could exceed USD 150 million in development costs towards licensure for a project of this type. As seen in the development of our MVA-BN smallpox vaccine, which was sparked by a small research contract with NIH more than 15 years ago, and currently under BLA review with the FDA, we have shown the way for public-private partnerships to improve the public health, now and in the future.”

About Equine Encephalitis Viruses
Eastern, Venezuelan and Western equine encephalitis virus belong to the family alphavirus, and are transmitted through mosquitoes, 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.

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About Bavarian Nordic
Bavarian Nordic is a fully integrated biotechnology company focused on the development of innovative and safer therapies against cancer and infectious diseases. Using our live virus vaccine platform technology, MVA-BN®, 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. We supply our MVA-BN® non-replicating smallpox vaccine to the U.S. Strategic National Stockpile and other government stockpiles. The vaccine is approved in the European Union and in Canada (under the trade names IMVANEX® and IMVAMUNE® respectively). In addition to our long-standing collaboration with the U.S. government on the development of medical countermeasures, 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, in collaboration with the National Cancer Institute, 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 risk-benefit profile. Through multiple industry collaborations, we seek to explore the potential synergies of combining our immunotherapies with other immune-modulating agents, e.g. checkpoint inhibitors. For more information visit www.bavarian-nordic.com or follow us on Twitter @bavariannordic.

About Medical Countermeasure Systems
JPM-MCS, a component of the U.S. Department of Defense’s Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, aims to provide U.S. military forces and the nation with safe, effective, and innovative medical solutions to counter chemical, biological, radiological, and nuclear threats. JPM-MCS facilitates the advanced development and acquisition of medical countermeasures and systems to enhance the nation’s biodefense response capability.

Contacts
Rolf Sass Sørensen
Vice President Investor Relations
Tel: +45 61 77 47 43

Press Release