Company Announcement

Bavarian Nordic Reports Initial Results from First-in-Human Trial of COVID-19 Vaccine

- Vaccine was well tolerated across all dose groups with no observed difference in adverse event profile after first and second vaccination
- Strong booster effect demonstrated after second vaccination with antibody titers above levels detected in humans after COVID-19 disease and neutralization titers significantly above those reported for currently approved SARS-CoV-2 vaccines
- Strong cross neutralization of SARS-CoV2 variants, including the Delta variant

COPENHAGEN, Denmark, August 9, 2021 – Bavarian Nordic A/S (OMX: BAVA) today reported initial results from the first-in-human trial of ABNCoV2, led by the PREVENT-nCoV consortium.

The Phase 1/2 dose-escalation trial enrolled 45 healthy SARS-CoV-2-naïve adult volunteers at the Radboud University Medical Centre in the Netherlands, who received two doses (dose ranges from 6-70 µg) of ABNCoV2, formulated with and without adjuvant. The results demonstrate that the vaccine was well tolerated across all dose groups with no observed difference in the adverse event profile after first and second vaccination. No serious adverse events were reported and the safety profile was comparable to other vaccines based on recombinant protein-technology.

In all dose groups, antibody titers were significantly higher after the boost vaccination and were up to 12-fold higher than those measured in convalescent human samples and significantly higher than those reported for current approved COVID-19 vaccines. Importantly, high neutralization titers were demonstrated against all SARS-CoV-2 variants of concern, including the dominant Delta variant.

Final results from the study are expected later in the second half of 2021.

Paul Chaplin, President and CEO of Bavarian Nordic, commented: "We are very pleased to report positive results from this first-in-human trial of our COVID-19 vaccine, confirming its ability to induce strong and broad antibody levels, superior to those of the current approved vaccines, while also providing a favorable safety profile. These data are highly encouraging for our planned Phase 2 trial later this month, which is designed to evaluate the vaccine's potential as a universal booster vaccine."

Bavarian Nordic will further advance the development of the vaccine candidate and has planned a Phase 2 trial in up to 210 subjects. The aim of the trial, in addition to confirming the Phase 1 findings, is to evaluate ABNCoV2 as a booster vaccine for individuals with previous COVID-19 disease or vaccination. The trial will be conducted at two centers in Germany and is expected to be initiated later in August, pending final approval from the Ethics Committee. In parallel, Bavarian Nordic is preparing for a Phase 3 trial of ABNCoV2 in 2022, pending external funding.

About ABNCoV2
ABNCoV2 is a next-generation COVID-19 vaccine candidate, initially developed by AdaptVac using their proprietary capsid virus like particle (cVLP) technology. AdaptVac is member of the PREVENT-nCoV consortium which has received a Horizon 2020 EU grant to fund the first-in-human trial of the vaccine. Other members of the consortium are ExpreS2ion, Leiden University Medical Center (LUMC), Institute for Tropical Medicine (ITM) at University of Tübingen, The Department of Immunology and Microbiology (ISIM) at University of Copenhagen, and the Laboratory of Virology at Wageningen University.

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Bavarian Nordic has licensed the global commercialization rights to the vaccine and has assumed the responsibility for further clinical development towards licensure.

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. Government 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 the Janssen Pharmaceutical Companies of Johnson & Johnson. We are also committed to the development of a next generation COVID-19 vaccine based on an in-licensed capsid virus-like particle technology. The vaccine candidate, ABNCoV2, is currently being investigated in clinical trials. 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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