Press Release

Bavarian Nordic Provides Update on the Phase 3 Program for its COVID-19 Booster Vaccine Candidate

- Phase 3 trial of ABNCoV2, a non-adjuvanted COVID-19 booster vaccine candidate, has been redesigned as comparator vaccine has now become available, enabling a double-blind, controlled study to demonstrate non-inferiority of ABNCoV2 to a licensed mRNA vaccine
- The fully sponsored trial will be initiated in August 2022, overall timelines remain unaffected with data read out still anticipated late in 2022 and subsequent approval in 2023

COPENHAGEN, Denmark, June 16, 2022 – Bavarian Nordic A/S (OMX: BAVA) today provided an update on the Phase 3 development of ABNCoV2, a VLP-based, non-adjuvanted COVID-19 booster vaccine candidate.

The upcoming Phase 3 trial has been redesigned to include a licensed mRNA-based vaccine (Comirnaty®) in the comparator arm of the study, to potentially support the primary objective of the study and demonstrate that the neutralizing antibodies induced by ABNCoV2 are non-inferior to the levels stimulated by the licensed mRNA-based vaccine. The addition of the comparator vaccine for clinical trial use has now been made possible in cooperation with regulatory authorities and vaccine manufacturers, and enables Bavarian Nordic to conduct a double-blind, controlled Phase 3 trial.

The Phase 3 trial will enroll approximately 4,000 adult subjects who either previously completed primary vaccination or have already received one booster dose of a licensed COVID-19 vaccine. The trial consists of two groups, which will run in parallel. The active, controlled group will enroll 1,000 subjects who will be randomized to receive either a single 100 µg dose of ABNCoV2 or a single 30 µg adult booster dose of Comirnaty. The other group will evaluate the safety and tolerability of the vaccine in 3,000 subjects who will receive a single 100 µg dose of ABNCoV2.

Based on the new design, the Phase 3 trial will now start enrolling in August 2022, but the overall timelines for trial remain unaffected. Thus, the Company still anticipates the initial data read-out before the end of 2022, which will allow for a rolling submission to the regulatory authorities, aiming to obtain approval of the vaccine in 2023.

Paul Chaplin, President and CEO of Bavarian Nordic, commented: "We are pleased to be able to run the Phase 3 trial of ABNCoV2 as a double-blind, controlled study, which provides us with a more robust foundation for the regulatory process towards approval. With its differentiated approach, we believe that ABNCoV2 could provide several advantages over the current licensed COVID-19 vaccines and look forward to initiating the study and presenting the first Phase 3 data for this universal booster vaccine candidate later this year."

About ABNCoV2
ABNCoV2 is a next-generation COVID-19 vaccine candidate, initially developed by AdaptVac, Denmark using their proprietary capsid virus like particle (cVLP) technology. Bavarian Nordic has licensed the global commercialization rights to the vaccine and has assumed the responsibility for further clinical development towards licensure.

ABNCoV2 has shown to be highly immunogenic in relevant preclinical models inducing a durable and highly protective response from a COVID-19 challenge. Results from a Phase 2 trial has confirmed the ability of ABNCoV2 to significantly boost antibody titers as previously demonstrated in preclinical and Phase 1 clinical trials, and also confirm the potential of ABNCoV2 to boost antibody titers against SARS-CoV2 variants of concern.

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The Phase 3 development of ABNCoV2 is being funded through an agreement with the Danish State.

About Bavarian Nordic
Bavarian Nordic is a fully integrated vaccines company focused on the development, manufacturing 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, also for the protection against monkeypox. The vaccine is also approved for protection against smallpox and monkeypox in Canada, and as a smallpox vaccine in Europe. Our commercial product portfolio furthermore contains market-leading vaccines against rabies and 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, 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. 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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