Company Announcement

Bavarian Nordic's COVID-19 Booster Vaccine Candidate Demonstrates Durable Antibody Response Six Months After Vaccination in Phase 2 Clinical Trial

- Six months post the booster vaccination with ABNCoV2, the neutralization antibody titers against Wuhan and the Omicron variant remained high and at levels associated with a greater than 90% efficacy.

COPENHAGEN, Denmark, October 17, 2022 – Bavarian Nordic A/S (OMX: BAVA) announced today the results of a six-month follow-up analysis from a Phase 2 clinical trial of ABNCoV2, a VLP-based, non-adjuvanted COVID-19 booster vaccine candidate.

Previously reported results from the trial showed, that vaccination with 100ug ABNCoV2 in 103 seropositive subjects was able to demonstrate a strong boosting effect, increasing the existing levels of SARS-CoV-2 neutralizing antibodies against both the Wuhan variant and variants of concern (Alpha, Beta, Delta and Omicron) to levels reported to be highly efficacious (>90%) against SARS-CoV-2[1].

A cohort of 41 subjects were followed for six months post vaccination. From this cohort, two subjects with confirmed COVID-19 disease were excluded from the immune analysis. Six months post vaccination, neutralization titers were six times higher than pre-boost titers against Wuhan and nearly 10 times higher than the pre-boost titers for Omicron BA.1. This represented less than a 50% decline in the peak neutralizing titers after six months and compared to the data published for mRNA vaccines[2,3,4], the antibody decay appears less sharp, indicating a potentially longer duration of protection across variants of concern.

Paul Chaplin, President and CEO of Bavarian Nordic said: "It is highly encouraging that the strong booster responses we have reported for ABNCoV2 against all variants of concern are maintained after six months post vaccination at levels associated with a high degree of efficacy. These latest data further support the concept that ABNCoV2 could be a universal booster vaccine inducing strong and durable immune responses against all major variants of concern, including Omicron, without the need to modify the vaccine. We look forward to generating further data in the ongoing Phase 3 trial that will shortly open sites in Denmark."

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 in previously vaccinated subjects has confirmed the ability of ABNCoV2 to significantly boost antibody titers to levels reported to be highly efficacious (>90%) against SARS-CoV-2, including variants of concern.

A global Phase 3 trial assessing the non-inferiority of ABNCoV2 compared to Comirnaty® in terms of neutralizing antibodies against the SARS-CoV-2 index virus was initiated in September 2022. The double-blind, controlled trial will enroll two groups of a total of 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 first group, which is currently enrolling in the U.S., will evaluate the safety and tolerability of the vaccine in 3,000 subjects receiving a single 100 µg dose of ABNCoV2. The second group will start enrollment of 1,000 subjects in Denmark and Belgium later in October. Subjects in this group will be randomized to receive either a single 100 µg dose of ABNCoV2, or a single 30 µg adult booster dose of Comirnaty.

About Bavarian Nordic

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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 in Europe and Canada. 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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[1] P. B. Gilbert et al., Science 10.1126/science.abm3425 (2021)
[2] Bellusci et al. Antibody affinity and cross-variant neutralization of SARS-CoV-2 Omicron BA.1, BA.2 and BA.3 following third mRNA vaccination
[3] Forgacs et al. The Effect of Waning on Antibody Levels and Memory B Cell Recall following SARS-CoV-2 Infection or Vaccination
[4] Qu et al. Durability of Booster mRNA Vaccine against SARS-CoV-2 BA.2.12.1, BA.4, and BA.5 Subvariants (letter)