



BAVARIAN NORDIC

Company Announcement

Bavarian Nordic Announces Initiation of a Global Phase 3 Clinical Trial of its COVID-19 Booster Vaccine Candidate

- First subject vaccinated in Phase 3 clinical trial evaluating potential of the VLP-based candidate, ABNCoV2 as a booster COVID-19 vaccine
- Trial will assess non-inferiority of ABNCoV2 compared to Comirnaty® in terms of neutralizing antibodies against the SARS-CoV-2 (Wuhan wild type) as the primary endpoint, and other variants of concern as secondary endpoints

COPENHAGEN, Denmark, September 2, 2022 - Bavarian Nordic A/S (OMX: BAVA) announced today the dosing of the first subject in the Phase 3 clinical trial of ABNCoV2, a VLP-based, non-adjuvanted COVID-19 booster vaccine candidate.

The double-blind, controlled Phase 3 clinical 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. An active controlled group will be conducted in Denmark and Belgium and will start enrollment later this fall. 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. The second group, which has now started enrollment in the U.S., will evaluate the safety and tolerability of the vaccine in subjects receiving a single 100 µg dose of ABNCoV2.

Initial trial results are expected towards 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 Chief Executive Officer of Bavarian Nordic, said: “Advancing ABNCoV2 into Phase 3 trials represents another significant step in the progression of our pipeline this year, and not least an important contribution to the development of a universal COVID-19 booster vaccine. In clinical trials to-date, ABNCoV2 has shown potential to boost neutralizing antibodies against SARS-CoV-2, including variants of concern, to levels associated with a high degree of protection. We hope that the Phase 3 trial will confirm these strong results, thus unleashing the potential of ABNCoV2 as a differentiated approach without the need for adaptation”.

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

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.

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-

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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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