



BAVARIAN NORDIC

Company Announcement

Bavarian Nordic Initiates Phase 2 Clinical Trial of COVID-19 Booster Vaccine

- Phase 2 trial will investigate vaccine's ability to boost existing immunity from prior COVID-19 vaccination or disease
- Immune responses against circulating SARS-CoV2 variants will also be assessed
- Preparations ongoing to support Phase 3 development

COPENHAGEN, Denmark, August 23, 2021 - Bavarian Nordic A/S (OMX: BAVA) announced today the initiation of a Phase 2 clinical trial of its COVID-19 vaccine candidate, ABNCoV2. The trial will investigate the potential of ABNCoV2 as a booster vaccine for individuals with previous COVID-19 disease or vaccination.

The trial will enroll 150 healthy adults with existing immunity against SARS-CoV-2, acquired through previous disease or from prior immunization with approved COVID-19 vaccines, and will investigate the ability of a single vaccination with ABNCoV2 to boost existing levels of SARS-CoV-2 neutralizing antibodies across all groups. A second arm in the trial will enroll up to 60 healthy adults with no prior vaccination or disease who will receive two vaccinations for evaluation of neutralizing antibody levels from ABNCoV2 when used as a prime-boost vaccine. In both groups, neutralizing immune responses against circulating variants of SARS-CoV2 will be evaluated, as high levels of neutralizing antibodies have been reported as highly predictive of protection against COVID-19¹.

Initial trial results are expected in the fourth quarter of 2021. Subjects in the group with existing immunity will remain on trial for up to two years to evaluate the durability of the immune response from the boost vaccination.

Paul Chaplin, President and CEO of Bavarian Nordic, commented: "We are pleased to advance our COVID-19 vaccine candidate into Phase 2 that we hope will confirm the high levels of neutralizing antibodies induced by ABNCoV2 that have already been shown in preclinical studies and a Phase 1 clinical trial. There is a growing expectation that booster vaccinations will be required to manage the pandemic and to broaden the protection against emerging variants and we remain committed to the development of ABNCoV2, as we believe it has the potential to fulfil these requirements."

In parallel with the Phase 2 trial, Bavarian Nordic is preparing for a Phase 3 trial of ABNCoV2 in 2022, pending external funding.

About ABNCoV2 and the Phase 2 trial

ABNCoV2 is a next-generation COVID-19 vaccine candidate, initially developed by AdaptVac 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 durable and highly protective response from a COVID-19 challenge. Initial data from the first-in-human trial of the vaccine have confirmed its ability to induce strong and broad antibody levels, superior to those of the current approved vaccines, while also providing a favorable safety profile. More importantly, the data confirms the potential of ABNCoV2 to induce neutralizing antibodies against circulating variants of SARS-CoV2, including the Delta variant.

Bavarian Nordic is sponsor of the Phase 2 trial, which is being conducted at two centers in Germany. The trial will enroll a total of up to 210 healthy adult volunteers into two groups: one group of 150 seropositive (prior disease or fully vaccinated) subjects will receive one 100 µg dose of ABNCoV2. Enrollment into this group will be

Page 1 of 2

stratified by seropositivity, i.e., previous COVID-19 disease or type of previous vaccination received, with at least 40 subjects enrolled in each stratification group. A second group of up to 60 seronegative subjects will receive two 100 µg doses of ABNCoV2, 28 days apart.

The primary endpoint of the study is SARS-CoV-2 neutralizing antibody titers at 2 weeks after the last vaccination, i.e., after the second vaccination in initially seronegative subjects and after the single boost vaccination in seropositive subjects. Additional endpoints will, among others, focus on the safety of the vaccine and neutralizing antibody titers against variant strains circulating at the time of analysis at 2 weeks after last vaccination.

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.

Contacts

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

US: Graham Morrell, Paddock Circle Advisors, graham@paddockcircle.com, Tel: +1 781 686 9600

Company Announcement no. 26 / 2021

ⁱ Khoury et al. doi.org/10.1101/2021.03.09.21252641