

Company Announcement

# Bavarian Nordic Reports Positive Topline Phase 2 Results for its COVID-19 Vaccine Candidate

- Bavarian Nordic's non-adjuvanted COVID-19 vaccine candidate, ABNCoV2 (100μg), demonstrated a strong boosting effect, increasing the existing levels of SARS-CoV-2 neutralizing antibodies against the Wuhan variant by 2-40-fold depending on the initial levels of antibodies
- The large boosting effect of ABNCoV2 elevated the neutralizing antibodies to levels reported to be highly efficacious (>90%) against SARS-CoV-21
- A similar fold increase was observed for all SARS-CoV-2 variants tested (Wuhan, Alpha, Beta and Delta) following the booster vaccination with ABNCoV2
- The vaccine was well-tolerated, with no serious adverse events reported
- These initial results confirm the potential of ABNCoV2 to function as a universal COVID-19 booster vaccine
- The Company's management will host a conference call tomorrow at 2 pm CET (8 am EST) to discuss the results

**COPENHAGEN, Denmark, December 5, 2021** - Bavarian Nordic A/S (OMX: BAVA), a fully integrated vaccines company, announced today positive topline results from a Phase 2 clinical trial of its COVID-19 vaccine candidate, ABNCoV2.

## ABNCoV2 Phase 2 trial results

One hundred and three (103) subjects 18 years and older (23% above 65 years) that had been previously vaccinated with mRNA (67%) or adenoviral (32%) COVID-19 vaccines were enrolled and received a single booster vaccination with ABNCOV2 (100µg). At enrolment, the majority (≥57%) of all subjects either had no detectable neutralizing antibodies and/or were below the levels that could be quantified and the average neutralizing antibody titers against all SARS-CoV-2 variants tested were at levels reported to provide decreased levels of protection from COVID-19¹. One (1) week post vaccination with ABNCoV2, a 2-34-fold increase in the levels of neutralizing antibodies against the Wuhan SARS-CoV2 variant was observed and peaked at two (2) weeks with a 2-40-fold increase depending on the initial antibody levels. However, all subjects, irrespective of whether they initially had very low, or high neutralizing titers were boosted to absolute antibody levels reported to be associated with a very high efficacy (>90%) against SARS-CoV2¹.

The same trend in terms of the fold-increases post the booster with ABNCoV2 was also observed for all other SARS-CoV2 variants tested, namely Alpha, Beta and Delta.

ABNCoV2 was well tolerated with no serious adverse events reported. The most frequent observations were local injection site reactions that resolved shorty after vaccination.

Enrolment continues in the second seropositive group, receiving a single  $50\mu g$  dose of ABNCoV2 and a seronegative group receiving two  $100\mu g$  doses of ABNCoV2.

Paul Chaplin, President and CEO of Bavarian Nordic, commented: "We are very pleased to report positive topline results for our COVID-19 vaccine candidate, confirming the perfect profile as a non-adjuvanted universal booster vaccine. I am encouraged to see that ABNCoV2 boosted the levels of immunity to those associated with a high efficacy against COVID-19 and this was the case whether there was a low or high initial neutralizing antibody level. These results highlight the urgent need for an improved vaccine providing a more robust and long-lived level of protection".

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#### About the ABNCoV2 Phase 2 trial

The Phase 2 trial is planned to enroll a total of 210 healthy adult volunteers divided into three groups, of which results from the first group are being reported today:

- Individuals (n=90, actual=103) with existing immunity against SARS-CoV-2 (seropositive), from prior vaccination (mRNA and Adeno) or SARS-CoV-2 infection, receiving a single 100µg dose of ABNCoV2.
- Individuals (n=90) with existing immunity against SARS-CoV-2 (seropositive), from prior vaccination (mRNA and Adeno) or SARS-CoV-2 infection, receiving a single 50µg dose of ABNCoV2.
- Individuals (n=30) with no prior vaccination or SARS-CoV-2 infection (seronegative), receiving two 100µg doses of ABNCoV2.

Topline results for the first group confirmed ABNCoV2's ability to significantly boost antibody titers to levels associated with a very high degree of efficacy. High neutralizing antibody titers were demonstrated against all SARS-CoV-2 variants tested, including Delta.

Results from the two other study groups are expected during the first quarter of 2022. In parallel, Bavarian Nordic is also preparing for a Phase 3 trial of ABNCoV2, expected to be initiated in the first half of 2022 pending final feedback from the regulatory authorities.

#### Conference call and webcast

The management of Bavarian Nordic will host a conference call tomorrow, Monday, December 6, 2021, at 2 pm CET (8 am EST) to discuss the Phase 2 results, which will be followed by a Q&A session. A listen-only version of the call can be accessed via <a href="https://www.bavarian-nordic.com/investor/events.aspx?event=6437">https://www.bavarian-nordic.com/investor/events.aspx?event=6437</a>. To join the Q&A session, use one of the following dial-in numbers: Denmark: +45 32 72 04 17, UK: +44 (0) 844 481 9752, USA: +1 646-741-3167. Participant code is 4569358.

### About ABNCoV2

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 a durable and highly protective response from a COVID-19 challenge. Topline data from the Phase 2 trial has confirmed the ability to significantly boost antibody titers as previously demonstrated in preclinical and Phase 1 clinical trials. The data confirms the potential of ABNCoV2 to boost antibody titers against the Wuhan, Alpha, Beta and Delta SARS-CoV2 variants.

## **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 approved as a smallpox vaccine 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 <a href="https://www.bavarian-nordic.com">www.bavarian-nordic.com</a>.

## 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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<sup>&</sup>lt;sup>1</sup> P. B. Gilbert et al., Science 10.1126/science.abm3425 (2021)