



BAVARIAN NORDIC

Press Release

Bavarian Nordic Reports Additional Positive Phase 2 Results for its COVID-19 Vaccine Candidate Ahead of Phase 3 Trial

- Data from the remaining two groups are now available, confirming the ability of ABNCoV2 to boost neutralizing antibodies to levels reported to be highly efficacious (>90%) against SARS-CoV-2¹
- Plan to initiate Phase 3 during the first half of 2022

COPENHAGEN, Denmark, February 28, 2022 - Bavarian Nordic A/S (OMX: BAVA), a fully integrated vaccines company, announced today additional positive results from a Phase 2 clinical trial of its non-adjuvanted COVID-19 vaccine candidate, ABNCoV2, which is being developed as a universal booster vaccine.

Bavarian Nordic has [previously reported](#) results from a group of 103 seropositive subjects who had been initially vaccinated with either mRNA or Adenovirus-based vaccines showing that vaccination with ABNCoV2 (100 µg) was able to demonstrate a strong boosting effect, increasing the existing levels of SARS-CoV-2 neutralizing antibodies against the Wuhan variant to levels reported to be highly efficacious (>90%) against SARS-CoV-2¹. A similar fold increase was observed for all SARS-CoV-2 variants of concern tested (Wuhan, Alpha, Beta and Delta) following the booster vaccination with ABNCoV2.

The results being reported today are from a group of 66 seropositive subjects who received one lower dose (50 µg) of ABNCoV2 that confirmed similar high neutralizing antibody levels against the same SARS-CoV-2 variants of concern as observed with the higher dose. Comparing the induced levels of neutralizing titres by also taking into account the starting titre (pre-booster) and/or the time since the last vaccination we could show that the higher booster dose of ABNCoV2 trended towards inducing stronger levels of neutralizing titres against SARS-CoV-2.

Secondly, a group of 28 seronegative subjects, who had not been previously vaccinated or infected with SARS-CoV-2 received 2 doses of the 100 µg formulation of ABNCoV2 4 weeks apart. These data confirm the high neutralizing levels reported from the Phase 1 clinical trial (COUGH-1 study), 2 weeks post second dose, with neutralizing antibody levels against the Wuhan variant elevated to levels reported to be highly efficacious (>90%) against SARS-CoV-2¹.

The vaccine was generally well-tolerated, with no related serious adverse events reported and no relevant difference in the safety profile between subjects receiving either the low (50 µg) or high dose (100 µg) of ABNCoV2. While the 50 µg dose has shown positive results, it has been decided to use the 100 µg dose in the Phase 3 trial to maximize the likelihood of success.

Based on these encouraging results, Bavarian Nordic continues its preparations to initiate a Phase 3 trial in the first half of 2022. The trial will include approximately 4,000 seropositive subjects who will receive a booster vaccination with 100 µg ABNCoV2 or an mRNA-based vaccine, aiming to demonstrate non-inferiority of ABNCoV2 to the licensed mRNA vaccine. An overall agreement has been made with regulatory authorities on the trial design, and manufacturing of vaccine bulk for the trial has been completed, pending filling at the Company's own manufacturing line in the near future.

Paul Chaplin, President and CEO of Bavarian Nordic, commented: "The full data from our Phase 2 study allows us to progress according to plans and initiate the Phase 3 trial in the first half of 2022, and we are pleased that the results have reaffirmed the strong and broad immune responses induced by ABNCoV2 against COVID-19. Real world data have shown that the currently approved mRNA vaccines are effective as a booster against the Omicron variant and as we have shown that ABNCoV2 is just as immunogenic we have made the decision to move into

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Phase 3, as planned. While we will continue to evaluate the immune responses against Omicron and other variants of concern that may emerge, the regulatory approval will be based on our ability to demonstrate non-inferiority of ABNCoV2 to current approved mRNA vaccines based on the original Wuhan strain. We continue to believe ABNCoV2 has the potential to offer broad efficacy without need for future adaptation and thus could help fulfil the future need for a universal booster vaccine against COVID-19.”

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-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 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)