



BAVARIAN NORDIC

Company Announcement

Bavarian Nordic Reports Encouraging Preclinical Data for COVID-19 Vaccine Candidate Ahead of First-in-Human Trial

COPENHAGEN, Denmark, March 8, 2021 - Bavarian Nordic A/S (OMX: BAVA, OTC: BVNRY) announced today preclinical data for the capsid virus like particle (cVLP) COVID-19 vaccine candidate, ABNCoV2, licensed from AdaptVac. The latest data confirm the previous strong immunogenicity results already published, and further demonstrate a protective efficacy from vaccination post-challenge with SARS-CoV-2.

The planned first-in-human trial of the vaccine is projected to start shortly at Radboud University Medical Centre in the Netherlands.

“We are pleased to report strong preclinical results for ABNCoV2, supporting the further development”, said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic. “While several vaccines have now been approved and widely distributed to help fight the global pandemic, the durability and breadth of protection against emerging variants currently remains unknown and highlights the need to still prioritize the development of the next generation of COVID-19 vaccines. COVID-19 will likely remain with us as another infectious disease that needs to be managed and booster vaccinations will likely be necessary to maintain or broaden the protection against this disease. We are confident that ABNCoV2 has the potential to address many of these challenges, and we look forward to the imminent initiation of the first-in-human trial.”

Preclinical study demonstrated immunogenicity and protection from SARS-CoV-2 challenge

As announced in November 2020, Bavarian Nordic has conducted a preclinical study of ABNCoV2. Follow-up data from the study, which investigated different dosing regimens of the vaccine with and without adjuvant, confirm the initial findings.

A single administration of low and high dose with adjuvant, but also the high dose without adjuvant induced SARS-CoV-2 neutralizing antibodies at comparable levels to those measured in convalescent human samples, while a second administration of non-adjuvanted ABNCoV2 led to >50-fold higher titers. Additionally, following a challenge with SARS-CoV-2, virus load was significantly reduced in all vaccinated groups, compared to non-vaccinated controls, and no virus could be detected at any timepoint in the majority of the subjects vaccinated with two high doses of ABNCoV2.

Vaccine ready for first-in-human testing

The first clinical trial of ABNCoV2 is planned for initiation shortly and will be a phase 1/2 open label, dose-escalation trial assessing the safety and tolerability of two doses of ABNCoV2, formulated with and without adjuvant, in up to 42 healthy, adult, SARS-CoV-2-naïve volunteers.

Sponsor of the study is Radboud University Medical Centre, one of the members of the PREVENT-nCoV consortium which is funded by a Horizon 2020 EU grant to rapidly advance ABNCoV2 into the clinic.

About the PREVENT-nCoV consortium

The PREVENT-nCoV consortium members are AdaptVac, ExpreS2ion Biotechnologies, Leiden University Medical Center (LUMC), Institute for Tropical Medicine (ITM) at University of Tübingen, the Radboud University Medical Center (RUMC), the Department of Immunology and Microbiology (ISIM) at University of Copenhagen, and the Laboratory of Virology at Wageningen University.

About Bavarian Nordic

Page 1 of 2

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. Strategic National Stockpile 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 Janssen. 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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