

ABNCoV2 phase I/II shows high-level and broad *in vitro* efficacy with low reactogenicity

Hørsholm, Denmark, Aug 9, 2021 – AdaptVac, a PREVENT-nCoV consortium member, announces that the analysis for all dose groups in the ABNCoV2 phase I/II study demonstrated an excellent safety and reactogenicity profile and high-level SARS-CoV-2 *in vitro* live virus neutralization levels (up to 12 fold vs. convalescent sera) compared to reported levels for leading mRNA COVID-19 vaccines (up to 4.1 fold convalescent sera). High *in vitro* efficacy was achieved in all groups receiving ABNCoV2, including non-adjuvanted formulations. Importantly, high levels of cross-variant live viral *in vitro* neutralization were shown for variants of concern, including the dominant Delta and the escape Beta variant.

This achievement was made possible through close collaboration between Radboud University Medical Center, Bavarian Nordic, AdaptVac, Copenhagen University, Aarhus University, ExpreS²ion Biotechnologies, AGC Biologics, BioConnection, and all the PREVENT-nCoV partners.

Low reactogenicity

All dosages were well tolerated and no serious adverse events has occurred in the study. In contrast to licensed SARS-CoV-2 vaccines, the reactogenicity profile of ABNCoV2 is comparable to licensed protein-based vaccine such as hepatitis B vaccines and well tolerated even at doses beyond those that induce maximal immune-responses.

“We were positively surprised that such a well tolerated vaccine induces such high levels of neutralizing antibodies“, said Prof. Dr. Benjamin Mordmüller, Radboud University Medical Centre.

Very strong antibody responses and *in vitro* efficacy without the need for adjuvant

High titred antibody responses were achieved even at the lowest dose ranges. This was further improved for participants receiving 25 ug or higher doses of ABNCoV2 with or without adjuvant. Furthermore, very strong *in vitro* efficacy was achieved in SARS-CoV-2 live virus neutralization assays 14 days post second vaccination, achieving levels up to 12 fold vs. human convalescent serum and up to 3.5 fold vs the high titred WHO verified standard reagent. Of note, reported neutralization levels vs convalescent sera of leading mRNA vaccines are up to 4.1 fold. Importantly, high levels of cross-variant live viral *in vitro* neutralization were shown for variants of concern, including the dominant Delta and escape variant Beta.

“The ABNCoV-2 vaccine is now well positioned for further development having demonstrated an excellent safety profile and best-in-class virus neutralization levels in the PhI/IIa trial at Radboud University Medical Center“, said Wian de Jongh, AdaptVac’s CEO. “It is particularly impressive that our cVLP platform technology can achieve superior *in vitro* efficacy without the need for an immune stimulating adjuvant.”

Ease of production

The modular nature of AdaptVac’s capsid Virus-Like Particle (cVLP) display platform is perfectly suited to the potential future need for variant matched vaccines. This allows for ABNCoV2 to be produced using standard, cost-efficient production systems used in already established large-scale production facilities throughout Europe, including Denmark.

Next steps: Initiation of PhII booster study in Germany

Bavarian Nordic has decided to further advance the development of ABNCoV2 by investing in a Phase II clinical trial and to scale up manufacturing in preparation for further clinical development towards licensure. The Phase II study will investigate the ability of ABNCoV2 to boost existing immunity through prior vaccination, to create a more durable immune response that could protect against the current circulating variants of COVID-19. The trial will be conducted at two centers in Germany and is expected to be initiated later in August, pending final approval from the Ethics Committee.

“Until now we have seen mutations that increase transmission, what we are starting to see now are mutations that increase escape from immunity. The induction of high-level cross-variant neutralizing antibodies in humans combined with vaccine stability even at ambient temperatures, makes ABNCOV2 a promising candidate for effective worldwide pandemic and future epidemic control.” Said Associate Prof. Morten Nielsen, AdaptVac’s Chairman of the board. *“These advantages also makes ABNCoV2 particularly well suited for countries with current low-vaccine coverage.”*

Validation of AdaptVac’s proprietary cVLP platform

In preclinical studies, the versatile cVLP platform technology has consistently been shown to significantly improve antibody responses to a range of vaccine targets. The PhI/IIa study has now confirmed the platform advantages in humans for SARS-CoV-2. Importantly, the platform may be combined with any antigen expression system to address a wide array of diseases.

“Demonstration of strong antibody and in vitro virus neutralization responses in humans serves as a significant proof-of-concept for cVLP antigen display, especially as this can be achieved without adjuvant. Thus, it validates it as a broadly applicable infectious disease vaccine technology platform” said Adam F. Sander Bertelsen, AdaptVac’s CSO.

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About Radboud University Medical Center

Until January 1st 2021 Radboud University Medical Center was part of the Radboud University Nijmegen established in 1923 under the name Stichting Katholieke Universiteit (SKU). Since then, Radboudumc is an independent organization. It’s role in the consortium is to design, setup and conduct the investigator-initiated first-in-human clinical trial of ABNCoV2 (COUGH-1, EudraCT 2020-004621-22). On 15 May 2021, the first volunteer of the trial received his first vaccination with ABNCoV2 at Radboud University Medical Center in Nijmegen, the Netherlands.

About the clinical Phase I/II study for the ABNCoV2 vaccine (COUGH-1)

The investigator-initiated clinical Phase I/II study, also known as COUGH-1, has as main trial objectives to assess the safety and tolerability of two doses (dose ranges from 6-70 µg) of ABNCoV2, formulated with and without adjuvant, in healthy adult volunteers and to identify the dosage and formulation that optimizes the immunogenicity-tolerability ratio following first vaccination with ABNCoV2. COUGH-1 is a single centre, open labelled trial in 45 SARS-CoV-2-naïve volunteers and is performed at [Radboud University Medical Center in Nijmegen, the Netherlands](#). Final results from the study are expected later in the second half of 2021.

About the PREVENT-nCoV consortium

The consortium (<https://cmp.ku.dk/research/var2csa-team/prevent-ncov/>) is funded by an EU Horizon 2020 grant to develop a COVID-19 vaccine (Grant agreement 101003608 <https://cordis.europa.eu/project/id/101003608>). Further the vaccine development at University of Copenhagen is supported by the Carlsberg Foundation, the Danish research councils and Gudbjørg og Ejnar Honorés Fond. The consortium members are world-leading experts in their respective fields, covering all relevant areas of viral research and vaccine development required for rapid clinical development of a COVID-19 vaccine. This includes pre-clinical and clinically validated experience from working with similar Coronaviruses such as MERS and SARS, ExpreS²ion's *Drosophila* S2 insect cell expression system, and AdaptVac's capsid virus-like particle (cVLP) technology. In addition to [ExpreS²ion](#) and [AdaptVac](#), the consortium members are Leiden University Medical Center ([LUMC](#)), Institute for Tropical Medicine ([ITM](#)) at University of Tübingen, The Department of Immunology and Microbiology ([ISIM](#)) at University of Copenhagen, the Laboratory of Virology at [Wageningen University](#), and Radboud University Medical Center. Through the Carlsberg foundation grant the Prevent-nCoV consortium works closely together with Department of Biomedicine at Aarhus University.

About AdaptVac

AdaptVac is a joint venture between ExpreS²ion Biotechnologies and NextGen Vaccines, owned by the inventors of the novel proprietary and ground-breaking viral capsid-like virus particle (cVLP) platform technology spun out from the University of Copenhagen. The Company aims to accelerate the development of highly efficient therapeutic and prophylactic vaccines within high value segments of oncology, infectious diseases and immunological disorders. Granting of the core patent in the U.S. has expanded AdaptVac's patent protection to include our entire pipeline of vaccines and immunotherapies in development. Please visit: www.adaptvac.com.

This press release was submitted for publication through the agency of the contact person set out above on August 9, 2021.