

Approval and initiation of the COVID-19 clinical phase I/II study for the ABNCoV2 vaccine

Hørsholm, Denmark, March 08, 2021 – AdaptVac, a PREVENT-nCoV consortium member, announces that the clinical trial application (CTA) for a clinical phase I/II study for the ABNCoV2 capsid virus-like particle (cVLP) based COVID-19 vaccine has been approved by the Central Committee on Research Involving Human Subjects (CCMO) in the Netherlands. The clinical study is now planned to start March 12th with the enrolment of 42 study participants to investigate safety and secondary efficacy parameters.

Critical milestone reached

Approval of the clinical trial application is the final critical step on the path to the clinic. This was made possible through close collaboration between Expres²ion Biotechnologies, Bavarian Nordic, AdaptVac, Copenhagen University, AGC, BioConnection and Radboud University Medical Center.

“Reaching this critical milestone is a big step forward for our SARS-CoV-2 vaccine, AdaptVac’s cVLP vaccine platform, and the Prevent-nCoV consortium. We now look forward to demonstrating safety and strong virus neutralization levels in the PhI/IIa trial to be initiated at Radboud University Medical Center.” said Wian de Jongh, AdaptVac’s CEO

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 will now provide data in humans for SARS-CoV-2.

“Demonstration of strong and durable antibody responses in humans will serve as a significant proof-of-concept for cVLP antigen display and validate the platform technology” said Adam F. Sander Bertelsen, AdaptVac’s CSO.

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About Radboud University Medical Center

Radboud University Medical Centre is part of the Radboud University Nijmegen established in 1923 under the name Stichting Katholieke Universiteit. RUMC’s role in the consortium is to sponsor the trial, obtain the needed ethical and regulatory approvals, and perform the PhI/PhIIa clinical study. Specifically, First-in-man-testing of the SARS-CoV-2 vaccine will be performed at Radboud University Medical Centre in Nijmegen, the Netherlands as described in WP5. RUMC will be the clinical study site for the Phase I/IIa trial, where the study execution, data capture, project-, quality- and safety management as well as sample- and data –analysis will be performed.

About the PREVENT-nCoV consortium

The consortium is funded by an EU Horizon 2020 grant to develop a COVID-19 vaccine. 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.

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 (CLP) 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

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