Phase III COVID-19 clinical trial initiated to compare ABNCoV2 to Comirnaty®

Copenhagen, Denmark, September 2nd, 2022 – AdaptVac, a PREVENT-nCoV consortium member, announces that a phase III clinical trial to evaluate ABNCoV2 capsid virus-like particle (cVLP) based COVID-19 vaccine has been initiated by Bavarian Nordic. The double-blind, controlled, non-inferiority trial will compare the neutralizing antibodies induced by non-adjuvanted ABNCoV2 and market leader Pfizer/BioNtech Comirnaty®, the licensed mRNA vaccine. Initial trial results are expected end-2022.

The double-blind, controlled Phase 3 clinical trial will enroll approximately 4,000 adult subjects who either previously completed primary vaccination or have already received one booster dose of a licensed COVID-19 vaccine. The trial consists of two groups, A and B. The active, controlled group (A) will be conducted in Denmark and Belgium and will start enrollment later this fall. Subjects in the group will be randomized to receive either a single 100 µg dose of ABNCoV2 or a single 30 µg adult booster dose of Comirnaty. The other group (B), which has now started enrollment in the U.S., will evaluate the safety and tolerability of the vaccine in subjects receiving a single 100 µg dose of ABNCoV2. Initial trial results are expected towards the end of 2022, which will allow for a rolling submission to the regulatory authorities, aiming to obtain approval of the vaccine in 2023. The Phase 3 development of ABNCoV2 is funded through an agreement between Bavarian Nordic and the Danish State.

"We are delighted by the rapid progression of ABNCoV2 towards the goal of delivering a safe and efficacious vaccine to help end the COVID-19 pandemic world-wide. The successful PhII study, and now initiation of PhIII, demonstrates the unique strengths of our universal cVLP vaccine platform. ABNCoV2 remains the only protein based COVID-19 vaccine generating high-level neutralizing antibody responses without the need for adjuvant. This strongly supports our on-going discussions towards out-licensing with large-Biotech and Pharma.", said Wian de Jongh, AdaptVac's CEO.

Proven technology: capsid Virus-Like Particle (cVLP) vaccine technology successful in PhI & PhII clinical studies
The cVLP technology was developed to be a highly efficacious, cost-effective, heat stable and versatile to enable production and distribution also in under-developed regions globally. In addition to the COVID-19 vaccine, AdaptVac has recently initiated a cVLP displayed malaria vaccine development program as part of a €10M EU funded consortium. Furthermore, after impressive preclinical data in transgenic mouse models of breast cancer, ExpreS^{2}ion Biotechnologies is expected to enter PhI in 2024 with a HER2-cVLP cancer vaccine, licensed from AdaptVac.

Our COVID-19 PhI study demonstrated exceptionally high neutralizing antibody levels without the need for adjuvant in a primary vaccine setting. The only protein-based vaccine to achieve protective levels without the need for an adjuvant. It was also demonstrated that these levels could be further increased by addition of an adjuvant. This demonstrates the strength of the platform and our ability to additionally boost the immune response if ever required for protection against a future disease outbreak.

The overall COVID-19 Phase 2 results confirmed the ability of non-adjuvanted ABNCoV2 to boost neutralizing antibodies to levels reported to be highly efficacious against SARS-CoV-2, both when used for primary vaccination and when used as a booster in subjects previously vaccinated with mRNA- or Adeno-based vaccines. A similar fold increase was observed for all SARS-CoV-2 variants of concern tested (Wuhan, Alpha, Beta, Delta and Omicron) following the booster vaccination with ABNCoV2. While the neutralizing antibody titers against Omicron were the lowest when compared to all other variants of concern tested, they were boosted to levels reported to be associated with a high level of protection (>90%). 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.

"The many ongoing preclinical and clinical COVID19 vaccine developments have laid the foundation for a historical head-to-head comparison of both traditional and next-generation vaccine technologies incl. virus-like particle-based platforms, which may be superior to other tehcnologies in their ability to generate durable protective immune responses. In this context, it is exciting that our cVLP platform is the only one that does not require the addition of an adjuvant.", said Adam Bertelsen, AdaptVac's CSO.

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About the PREVENT-nCoV consortium

The consortium 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, ExpreS^{2}ion Biotechnologies' *Drosophila* S2 insect cell expression system, and AdaptVac's capsid virus-like particle (cVLP) technology. In addition to ExpreS^{2}ion 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 ExpreS^{2}ion 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. Please visit: www.AdaptVac.com

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