

Successful manufacture of COVID-19 cVLP vaccine

Hørsholm, Denmark, November 16, 2020 – AdaptVac, a PREVENT-nCoV consortium member, hereby announces that its capsid virus like particle (cVLP) based SARS-CoV-2 subunit vaccine has been successfully manufactured, full batch release to follow after final quality analysis. The project remains on track for delivery of initial PhI/IIa results in Q1 2021. Furthermore, the cVLP technology and the manufacturing processes were designed to enable rapid manufacture of new vaccines in response to potential COVID-19 mutations.

Critical manufacturing milestone reached

Completion of GMP manufacture of the vaccine by AGC Biologics is the next critical step forward on the path to the clinic. This was made possible through close collaboration between ExpreS²ion Biotechnologies, Bavarian Nordic, AdaptVac, Copenhagen University and AGC Biologics throughout process development. The consortium is now well positioned to scale this process with AGC Biologics to the billion-dose level once additional funding is secured.

“We are very happy for this successful collaboration with AGC Biologics, ExpreS²ion, Bavarian Nordic and all the PREVENT-nCoV consortium members, which enabled the production of the vaccine on such an accelerated timeline. This achievement demonstrates the scalability of our cVLP vaccine approach, and due to our platform production processes, enables a rapidly response to future COVID-19 variants which may emerge.” said Wian de Jongh, AdaptVac’s CEO

Exciting new pre-clinical data in non-human primates supporting potential one dose vaccine

This news follows close on the heels of Bavarian releasing preliminary positive and highly promising results regarding Non-Human Primate (NHP) studies, which showed similar data to those published for AdaptVac’s mouse studies. These preliminary results support the clinical development plan for the vaccine and again demonstrate excellent SARS-CoV-2 neutralization data, even after one dose.

On-track for initial clinical data in Q1 2021

Although COVID-19 has caused delays during development and manufacture, we are still on track for preliminary PhI/IIa results in Q1 2021 as planned.

Pfizer/BioNtech positive vaccine results supports AdaptVac’s COVID-19 vaccine approach

Successful results of the Pfizer PHIII study demonstrate high likelihood of success for our vaccine when comparing preclinical data from the two programs. Pfizer/BioNtech’s success will also demonstrate what level of antibodies are needed in humans to afford protection, information that will greatly accelerate and de-risk development of our cVLP vaccine. One of the main logistical issues with the Pfizer vaccine is the requirement for -80C storage, in fact our preliminary data suggests that the vaccine may even be stable at ambient temperatures. As billions of doses of vaccine will be required for the world population, AdaptVac believes there remains an urgent need to develop multiple vaccines to address the current pandemic, as well as the endemic season need that may follow. Specifically, longevity of protection, as well as efficacy in at risk groups, will be the main areas where we believe our vaccine can make a difference.

Potential for fast response to new COVID-19 variants

The emergence of SARS-CoV-2 mutations highlights the need for rapid response to any potential vaccine evading COVID-19 strain. The two-component approach of AdaptVac’s cVLP technology and ExpreS²ion’s SARS-CoV-2 spike protein production allows us to simply exchange the surface protein, while keeping the cVLP constant. This platform approach is further supported by our SARS-CoV-2 Spike production process being specifically designed to accommodate future mutation variants.

Bavarian Nordic actively supporting the project and continues to seek further funds and partners

Bavarian Nordic has responsibility for the further clinical development, manufacturing and commercialization. These plans are dependent on external funding, which the Company is in the process of seeking from various initiatives established to rapidly advance COVID-19 vaccines. Bavarian has actively supported AdaptVac's manufacture and clinical planning activities. Furthermore, Bavarian's recent promising pre-clinical NHP data helps to strengthen the vaccine from a regulatory and market perspective.

For further information about AdaptVac ApS, please contact:

Dr. Wian de Jongh, CEO

Telephone: +45 26394649

E-mail: wdj@adaptvac.com

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, and the Laboratory of Virology at [Wageningen 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 (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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