

Interim safety update on COUGH-1, the COVID-19 clinical phase I/II study for the ABNCoV2 vaccine

Hørsholm, Denmark, April 12, 2021 – ExpreS²ion Biotech Holding AB’s affiliate ExpreS²ion Biotechnologies ApS (“ExpreS²ion”) announces that the first group of volunteers in the clinical Phase I/II study, COUGH-1, have been satisfactorily administered with the ABNCoV2 capsid virus-like particle (cVLP) based COVID-19 vaccine. The clinical study runs as planned with no untoward safety signal in now 18 healthy volunteers.

The clinical Phase I/II study, COUGH-1, is designed to assess the power of the cVLP technology in combination with ExpreS²-made SARS-CoV2 antigens to safely induce a strong immune response. The first group of 18 healthy volunteers have now been administered with the three doses 6 mcg, 12 mcg, and 25 mcg, with and without adjuvant. So far, the vaccine has been very well tolerated and first immunological investigations are ongoing.

The COUGH-1 study will continue to proceed as planned. Doses of up to 70 mcg are expected to be administered in additional 24 healthy volunteers in May and June. The headline results of the complete study are expected to be released in July 2021.

CEO Bent Frandsen comments:

“I am excited to see that the COVID-19 clinical phase I/II study for the ABNCoV2 vaccine is progressing according to plan, and that no untoward safety signals were observed in the first group of volunteers. We look forward to being able to present the headline results of the study in July.”

About the cVLP COVID-19 vaccine product, ABNCoV2

ExpreS²ion and its joint venture partner AdaptVac are engaged in the development of a unique capsid virus-like particle (VLP) COVID-19 vaccine, partly sponsored through a [Horizon 2020 EU grant award](#) to the PREVENT-nCoV consortium to rapidly advance the vaccine candidate against COVID-19 into the clinic. This vaccine technology has the potential to mimic a virus to the body’s immune system, giving the optimal stimulus to generate a fast, long-lasting immune response that offers a highly-efficacious protection. Importantly, the production of the vaccine technology can be readily scaled to commercial quantities and ExpreS²ion and AdaptVac are working with [AGC Biologics for the manufacture and scale-up of the vaccine](#). [Bavarian Nordic has licensed the commercialization rights](#) to the ABNCoV2 cVLP COVID-19 vaccine and variants hereof.

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 of ABNCoV2, formulated with and without the adjuvant MF59, 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 phase 1, single centre, open labelled trial in healthy, adult, SARS-CoV-2-naïve volunteers and is performed at [Radboud University Medical Center in Nijmegen, the Netherlands](#). The trial involves first-in-human administration, pre-defined, sequential dose escalation of ABNCoV2, and adjuvant selection. It intends to inform dosage and formulation for subsequent clinical development.

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 research councils and Guldberg 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 (ExpreS²), 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 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 AdaptVac

[AdaptVac](#) is a joint venture between ExpreS²ion Biotechnologies (34% ownership) and NextGen Vaccines (66%), owned by the inventors of the novel proprietary and ground-breaking capsid virus-like particle (cVLP) platform technology spun out from the University of Copenhagen. AdaptVac 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 the full pipeline of vaccines and immunotherapies in development.

Certified Adviser

Svensk Kapitalmarknadsgranskning AB
Telefon: +46 11 32 30 732
E-post: ca@skmq.se

For further information about ExpreS²ion Biotech Holding AB, please contact:

Bent U. Frandsen, CEO
Telephone: +45 4256 6869
E-mail: buf@expres2ionbio.com

This press release constitutes inside information that ExpreS²ion Biotech Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation 596/2014. The information was sent for publication, through the agency of the contact persons set out above, at the time stated by the Company's news distributor, Cision, at the publication of this press release.

About ExpreS²ion

ExpreS²ion Biotechnologies ApS is a fully owned Danish subsidiary of ExpreS²ion Biotech Holding AB with company register number 559033-3729. ExpreS²ion has developed a unique technology platform, ExpreS², for fast and efficient non-clinical development and production of complex proteins for new vaccines and diagnostics. ExpreS² is regulatorily validated for clinical supply. The platform includes functionally modified glycosylation variants for enhanced immunogenicity and pharmacokinetics. Since 2010, the Company has produced more than 300 proteins and 40 virus-like particles (VLPs) in collaboration with leading research institutions and companies. Since 2017, ExpreS²ion develops novel capsid VLP based vaccines through its joint venture AdaptVac ApS. For additional information, please visit www.expres2ionbio.com and www.adaptvac.com.