Positive safety and efficacy outcome of the COVID-19 clinical Phase I/II study for the ABNCoV2 vaccine

Hørsholm, Denmark, August 09, 2021 – ExpreS²ion Biotech Holding AB's affiliate ExpreS²ion Biotechnologies ApS ("ExpreS²ion") announces that COUGH-1, the COVID-19 Phase I/II clinical trial to evaluate the ABNCoV2 vaccine, as headline results has met its safety and efficacy endpoints with excellent virus neutralization levels of up to 12 times higher compared to the levels achieved after COVID-19 infection. This is significantly higher than the virus neutralization levels reported for leading mRNA COVID-19 vaccines reaching only up to 4.1 times higher than the levels achieved after COVID-19 infection. High efficacy was reported in all groups receiving ABNCoV2, including the lowest dose ranges and non-adjuvanted formulations. Importantly, high virus neutralization levels were shown also for relevant COVID-19 variants such as the dominant Delta and the escape Beta variant.

Headline results
All dosages were well tolerated, and no serious adverse events have occurred in the study. In contrast to licensed SARS-CoV-2 vaccines, ABNCoV2's safety profile 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.

High titred antibody responses were achieved even at the lowest dose ranges. This was further improved for participants receiving 25 µg 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 versus human convalescent serum and up to 3.5-fold vs the high titred WHO verified standard reagent. Of note, reported neutralization levels versus 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.

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

Next steps: Initiation of a Phase II booster clinical study in Germany
Bavarian Nordic will further advance the development of the vaccine candidate and has planned a Phase II trial, which will evaluate ABNCoV2 as a booster vaccine for individuals with previous COVID-19 disease or vaccination. 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. In parallel, Bavarian Nordic is preparing for a Phase III trial of ABNCoV2 in 2022, pending external funding.

CEO Bent Frandsen comments:
"The demonstration of an excellent safety profile and best-in-class virus neutralization levels in this Phase I/II clinical trial constitutes an important milestone for the development of the ABNCoV-2 vaccine. I am thrilled to see that ABNCoV-2 was able to achieve superior efficacy even without an immune stimulating adjuvant, and that high neutralization levels were shown also for the Delta and Beta variants. These results position ABNCoV-2 as a strong candidate for world-wide use, either on its own or as a booster vaccine."

The excellent trial results were made possible through close collaboration between ExpreS²ion, AdaptVac, Radboud University Medical Center, University of Copenhagen and all the PREVENT-nCoV-partners, as well as Aarhus University, AGC Biologics, BioConnection B.V. and Bavarian Nordic.

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 is based on a recombinant protein part manufactured using ExpreS²ion technology and AdaptVac´s vaccine delivery technology that has the potential to mimic a virus to the body's immune system, - together 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 (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 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 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 (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@skmg.se

For further information about ExpreS²ion Biotech Holding AB, please contact:
Bent U. Frandsen, CEO
Telephone: +45 4256 6869
E-mail: buf@expres2ionbio.com

Keith Alexander, CFO
Telephone: +45 5131 8147
E-mail: ka@expres2ionbio.com

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 34%-owned joint venture AdaptVac ApS. For additional information, please visit www.expres2ionbio.com and www.adaptvac.com.