ExpreS²ion announces submission of the COUGH-1 clinical trial application by the Prevent-nCoV consortium and Bavarian Nordic to review ABNCoV2

Hørsholm, Denmark, January 8, 2021 – ExpreS²ion Biotech Holding AB's affiliate ExpreS²ion Biotechnologies ApS ("ExpreS²ion") 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 submitted to the Central Committee on Research Involving Human Subjects (CCMO) in the Netherlands. The CTA is expected to be approved under a COVID-19 fast-track review procedure. The CTA submission is in line with the plans to present initial clinical Phase I/IIa results in Q1 2021.

With the submission of the CTA, ExpreS²ion, its joint venture partner AdaptVac, and their development collaborators in the PREVENT-nCoV consortium and Bavarian Nordic have reached another significant milestone in the EU Horizon 2020-funded COVID-19 vaccine project. This follows the November 2020 announcement of the successful GMP manufacturing of the vaccine. The CTA document contains all achieved aspects of the vaccine development project so far, including the exciting rodent and non-human primate data, which document the fast, strong, and long-lasting vaccine efficacy, even after one dose. Furthermore, preliminary stability data on the vaccine potentially allows it to be stored at fridge temperatures for long time periods, and at room temperature for shorter time periods.

The CTA for the designated COUGH-1 study of ABNCoV2 (the cVLP COVID-19 vaccine) is expected to be approved under an accelerated review (fast-track procedure) by the Dutch authorities, which allows for an approval procedure with a maximum duration of 25 days.

CEO Bent Frandsen comments:
"It is quite an achievement to file a CTA for the first clinical trial in less than one year after the initiation of the vaccine design. This timeline shows that even when working with a novel vaccine platform based on a unique method for coupling S2 cell-produced subunit antigens to VLPs, that has not been subject to prior cGMP manufacturing, we can be competitive in reaching a clinical-stage development project. I am thrilled that we remain on track to present initial clinical Phase I/IIa results in Q1 2021."

Comment vis-à-vis other currently approved COVID-19 vaccine approaches
ABNCoV2 has the potential to be a best-in-class COVID-19 vaccine. Readouts from preclinical animal data show a more than 100-fold higher level of neutralizing antibodies after two dosages compared with published preclinical animal data from currently approved COVID-19 vaccines, such as Pfizer-BioNTech's, Moderna's, and AstraZeneca-Oxford's vaccines. Capsid based antigen display induces long-lived plasma cells potentially conferring immunity for decades, as seen with the Human Papilloma Virus vaccine. Furthermore, preliminary stability data of ExpreS²ion's and AdaptVac's cVLP COVID-19 vaccine show product handling requirements at more than freezing point, and even at room temperature levels, ie. 20-25C.

Bavarian Nordic continues to seek further financing and partners
Bavarian Nordic is responsible for the further clinical development, manufacturing and commercialization of ABNCoV2. These plans are dependent on external funding, which Bavarian is in the process of seeking from various initiatives established to rapidly advance COVID-19 vaccines. Its recent promising pre-clinical non-human primates data help to strengthen the vaccine from a regulatory and market perspective.

About the cVLP COVID-19 vaccine product
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 cVLP COVID-19 vaccine and variants hereof.

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, 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 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.

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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.