ExpreS²ion announces successful manufacturing of the cVLP COVID-19 vaccine and further positive updates

Hørsholm, Denmark, November 16, 2020 – ExpreS²ion Biotech Holding AB's affiliate ExpreS²ion Biotechnologies ApS ("ExpreS²ion") announces that the capsid virus like particle (cVLP) based COVID-19 vaccine, which is licensed to Bavarian Nordic, has been successfully manufactured with a full batch release to follow after final quality analysis. The project remains on track for presenting initial clinical Phase I/IIa results in Q1 2021, depending on the speed of the clinical trial application (CTA) approval procedure. Furthermore, the cVLP technology and manufacturing processes used are perfectly suited for rapidly manufacturing new vaccines in response to potential COVID-19 mutations.

With the completion of the GMP manufacturing of the cVLP-based COVID-19 vaccine by AGC Biologics, a critical milestone towards initiating clinical trials has been reached. This was made possible through the collaborative efforts of the PREVENT-nCoV consortium, and a close collaboration between ExpreS²ion Biotechnologies, Bavarian Nordic, AdaptVac, Copenhagen University and AGC Biologics throughout process development. Bavarian Nordic is now seeking external funding for the further clinical development, manufacturing and commercialization of the COVID-19 vaccine, with the manufacturing process well-positioned to be scaled up to the billion-dose level once the required funding has been secured.

Exciting new pre-clinical data in non-human primates supporting potential one dose vaccine
This news follows close on the heels of Bavarian Nordic 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.

CEO Bent Frandsen comments:
"We are excited that the cVLP-based COVID-19 vaccine has been successfully manufactured and that the project, pending the regulatory CTA approval, is on track to present initial clinical Phase I/IIa results in Q1 2021. This accelerated development timeline demonstrates the scalability of the cVLP vaccine approach, which also has been shown to have other important advantages such as excellent immune response after just one dose, and single-digit Celsius temperature handling. Furthermore, I want to highlight that our ExpreS² platform and AdaptVac's cVLP platform are perfectly suited for rapid response to future COVID-19 variants that may emerge due to mutations such as we have seen in Denmark recently."

Pfizer/BioNtech positive vaccine results supports the cVLP COVID-19 vaccine approach
Successful results of the Pfizer Phase III study demonstrate high likelihood of success for the cVLP COVID-19 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 ExpreS²ion's and AdaptVac's cVLP vaccine. One of the main logistical issues with the Pfizer vaccine is the requirement for -80C storage, while preliminary data suggests that the cVLP COVID-19 vaccine may be stable even at ambient temperatures. As billions of vaccine doses will be required to satisfy the demand of the global population, ExpreS²ion acknowledges the 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 risk groups, will be the main areas where the cVLP vaccine is expected to 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 for simply exchanging the surface protein, while keeping the cVLP constant. This platform approach is further supported by the company's SARS-CoV-2 spike production process being specifically designed to accommodate future mutation variants.

Bavarian Nordic continues to seek further financing and partners
Bavarian Nordic is responsible for the further clinical development, manufacturing and commercialization of the cVLP COVID-19 vaccine. 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 NHP 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.

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

For further information about ExpreS^{2}ion 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 ExpreS^{2}ion
ExpreS^{2}ion Biotechnologies ApS is a fully owned Danish subsidiary of ExpreS^{2}ion Biotech Holding AB with company register number 559033-3729. ExpreS^{2}ion has developed a unique technology platform, ExpreS^2, for fast and efficient non-clinical development and production of complex proteins for new vaccines and diagnostics. ExpreS^2 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, ExpreS^{2}ion develops novel capsid VLP based vaccines through its joint venture AdaptVac ApS. For additional information, please visit www.expres2ionbio.com and www.adaptvac.com.