

## First subject vaccinated in COVID-19 Phase III clinical trial for ABNCoV2 as a booster vaccine

**Hørsholm, Denmark, September 2, 2022 – ExpreS<sup>2</sup>ion Biotech Holding AB's affiliate ExpreS<sup>2</sup>ion Biotechnologies ApS ("ExpreS<sup>2</sup>ion") announces that a Phase III clinical trial to evaluate the ABNCoV2 capsid virus-like particle (cVLP) based COVID-19 vaccine has been initiated by Bavarian Nordic, including the vaccination of the first subject. The trial aims to demonstrate non-inferiority of ABNCoV2 as a booster vaccine for individuals with previous COVID-19 disease or vaccination compared to the licensed mRNA vaccine Comirnaty®. Initial trial results are expected towards the end of 2022.**

The double-blind, controlled Phase III clinical trial will enrol approximately 4,000 adult subjects who either previously completed primary vaccination or have already received one booster dose of a licensed COVID-19 vaccine. The trial consists of two groups. The active, controlled group will be conducted in Denmark and Belgium, with enrolment starting later this autumn. Subjects in this group will be randomized to receive either a single 100 µg dose of ABNCoV2 or a single 30 µg adult booster dose of Comirnaty®. The other group, which has now started enrolment in the U.S., will evaluate the safety and tolerability of the vaccine in subjects receiving a single 100 µg dose of ABNCoV2. The trial will assess non-inferiority of ABNCoV2 compared to Comirnaty® in terms of neutralizing antibodies against the SARS-CoV-2 (Wuhan wild type) as the primary endpoint, and other variants of concern as secondary endpoint. As previously announced, the trial is supported by funding from the Danish State.

### **CEO Bent Frandsen comments:**

"We are excited to report that Bavarian Nordic has initiated the Phase III clinical trial for ABNCoV2 as a COVID-19 booster vaccine. This vaccine has great potential to become a powerful universal booster vaccine and thus a valuable tool in the continued global fight against COVID-19. At the same time, I am very proud that our ExpreS<sup>2</sup> technology platform, as well as AdaptVac's VLP technology platform, has now reached the important milestone of being used in a Phase III clinical trial for the first time. This is a historical achievement and an important seal of approval, for ExpreS<sup>2</sup>ion as a company and for our platform, which further strengthens the credibility of all our portfolio projects."

Bavarian Nordic expects the initial Phase III data readout towards end-2022, which will allow for a rolling submission to the regulatory authorities, aiming to obtain approval of the vaccine in 2023.

Additional information can be found in the press release published today by Bavarian Nordic, see link <https://www.bavarian-nordic.com/investor/news/news.aspx?news=6621>

### **About the cVLP COVID-19 vaccine product, ABNCoV2**

Under the PREVENT-NCoV consortium, ExpreS<sup>2</sup>ion and its 34%-owned associate company AdaptVac have applied their unique *Drosophila S2* insect cell protein production technology, ExpreS<sup>2</sup>™, and capsid virus-like particle (VLP) COVID-19 technology, respectively, to develop a novel next-generation COVID-19 vaccine, known as ABNCoV2. [Bavarian Nordic has licensed the global commercialization rights](#) to the ABNCoV2 COVID-19 vaccine and variants hereof.

ABNCoV2 has shown to be [highly immunogenic in relevant preclinical models](#) inducing durable and highly protective response from a COVID-19 challenge. [Initial Phase I/II clinical study data from COUGH-1](#), the first-in-human trial of the vaccine, have confirmed its ability to induce strong and broad antibody levels, superior to those of the current approved vaccines, while also providing a favorable safety profile. In the Phase II trial, ABNCoV2 was demonstrated to induce a significant boost to the neutralizing antibodies against all tested variants, [including the Omicron variant](#).

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**Certified Adviser**

Svensk Kapitalmarknadsgranskning AB  
Telefon: +46 11 32 30 732  
E-post: [ca@skmq.se](mailto:ca@skmq.se)

**For further information about ExpreS<sup>2</sup>ion Biotech Holding AB, please contact:**

Bent U. Frandsen, CEO  
Telephone: +45 4256 6869  
E-mail: [buf@expres2ionbio.com](mailto:buf@expres2ionbio.com)

Keith Alexander, CFO  
Telephone: +45 5131 8147  
E-mail: [ka@expres2ionbio.com](mailto:ka@expres2ionbio.com)

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**About ExpreS<sup>2</sup>ion**

ExpreS<sup>2</sup>ion Biotechnologies ApS is a fully owned Danish subsidiary of ExpreS<sup>2</sup>ion Biotech Holding AB with company register number 559033-3729. ExpreS<sup>2</sup>ion has developed a unique technology platform, ExpreS<sup>2</sup>, for fast and efficient development and production of complex proteins for new vaccines and diagnostics. ExpreS<sup>2</sup> is regulatorily validated for clinical supply through the clinical development value chain from Phase I to Phase III. The platform includes functionally modified glycosylation variants for enhanced immunogenicity and pharmacokinetics. Since 2010, the Company has produced more than 500 proteins and virus-like particles (VLPs) in collaboration with leading research institutions and companies. ExpreS<sup>2</sup>ion develops novel VLP based vaccines in association with AdaptVac ApS, of which ExpreS<sup>2</sup>ion owns 34%. Since 2020, the Company is focusing on its development pipeline of high-value assets within infectious diseases and oncology. For additional information, please visit [www.expres2ionbio.com](http://www.expres2ionbio.com).