

Updated Phase III trial for the ABNCoV2 COVID-19 vaccine to include a licensed mRNA vaccine

Hørsholm, Denmark, June 16, 2022 – ExpreS²ion Biotech Holding AB's affiliate ExpreS²ion Biotechnologies ApS ("ExpreS²ion") announces that Bavarian Nordic's upcoming Phase III clinical trial to evaluate the ABNCoV2 capsid virus-like particle (cVLP) based COVID-19 vaccine has been redesigned due to a licensed mRNA vaccine now being available as a comparator vaccine. This enables the design of a more robust double-blind, controlled study to demonstrate non-inferiority of ABNCoV2 to a licensed mRNA vaccine. The trial will be initiated in August, with data readout still expected in late 2022 followed by a possible approval in 2023.

Bavarian Nordic, the exclusive licensee of the ABNCoV2 vaccine, has redesigned the upcoming Phase III trial to include a licensed mRNA-based vaccine (Comirnaty®) in the comparator arm of the study, to potentially support the primary objective of the study and demonstrate that the neutralizing antibodies induced by ABNCoV2 are non-inferior to the levels stimulated by the licensed mRNA-based vaccine.

The Phase III trial will enroll 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, which will run in parallel. The active, controlled group will enroll 1,000 subjects who 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 will evaluate the safety and tolerability of the vaccine in 3,000 subjects who will receive a single 100 µg dose of ABNCoV2.

CEO Bent Frandsen comments:

"This update of the Phase III study design, allowing for a double-blind, controlled study with a licensed mRNA-based vaccine, is really exciting. It will enable even more robust data and a direct comparison to a licensed mRNA-based vaccine, and thus hopefully demonstrate the strong advantages of ABNCoV2 as a universal COVID-19 booster vaccine shown in earlier trials."

Bavarian Nordic is still expecting the initial data readout before the end of 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, which can be found at the following link: <https://www.bavarian-nordic.com/investor/news/news.aspx?news=6587>

About the cVLP COVID-19 vaccine product, ABNCoV2

Under the PREVENT-NCoV consortium, ExpreS²ion and its 34%-owned associate company AdaptVac have applied their unique *Drosophila* S2 insect cell protein production technology and capsid virus-like particle (VLP) 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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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 500 proteins and virus-like particles (VLPs) in collaboration with leading research institutions and companies. ExpreS²ion develops novel VLP based vaccines in association with AdaptVac ApS, of which ExpreS²ion owns 34%. For additional information, please visit www.expres2ionbio.com.