

Additional positive Phase II COVID-19 results presented for the ABNCoV2 vaccine

Hørsholm, Denmark, February 28, 2022 – ExpreS²ion Biotech Holding AB's affiliate ExpreS²ion Biotechnologies ApS ("ExpreS²ion") announces that additional positive results for the ABNCoV2 vaccine, that is being developed as a universal booster vaccine, has been presented from the Phase II clinical trial conducted by Bavarian Nordic. The full study data confirms that existing levels of SARS-CoV-2 neutralizing antibodies increased by 2-40-fold, depending on the initial levels of antibodies, with no serious adverse events reported. Based on this excellent outcome, Bavarian Nordic plans to initiate a Phase III study in the first half of 2022.

As reported [previously](#) by ExpreS²ion, the data from the first study group of 103 subjects demonstrated that a single booster dose with the ABNCoV2 vaccine raised the neutralizing antibodies against the original (Wuhan) variant and peaked at two weeks with a 2-40-fold increase depending on the initial antibody levels. The same trend was observed for all other SARS-CoV2 variants tested, namely Alpha, Beta and Delta. All subjects were boosted to absolute antibody levels reported to be associated with a very high efficacy (>90%) against SARS-CoV2.

The additional results reported today from a group of 66 seropositive subjects who received one lower dose (50 µg) of ABNCoV2 confirm similar high neutralizing antibody levels against the same SARS-CoV-2 variants of concern as observed with the higher dose. Taking the pre-booster levels and/or time since the last vaccination into account, the higher booster dose of ABNCoV2 trended towards inducing stronger levels of neutralizing levels against SARS-CoV-2. Furthermore, a group of 28 seronegative subjects, who had not been previously vaccinated or infected with SARS-CoV-2, received 2 doses of the 100 µg formulation of ABNCoV2 4 weeks apart. The neutralizing antibody levels against the Wuhan variant were elevated to levels reported to be highly efficacious (>90%) against SARS-CoV-2 also for this group.

The vaccine was generally well-tolerated, with no related serious adverse events reported and no relevant difference in the safety profile between subjects receiving either the low (50 µg) or high dose (100 µg) of ABNCoV2. While the 50 µg dose has shown positive results, it has been decided to use the 100 µg dose in the Phase III trial to maximize the likelihood of success.

The Phase III trial is planned to be initiated in the first half of 2022. It will include approximately 4,000 seropositive study participants who will receive a booster vaccination with 100 µg ABNCoV2 or an mRNA-based vaccine, aiming to demonstrate non-inferiority of ABNCoV2 to the licensed mRNA vaccine. An overall agreement has been made with regulatory authorities on the trial design, and manufacturing of vaccine bulk for the trial has been completed, pending filling at Bavarian Nordic's manufacturing line in the near future.

CEO Bent Frandsen comments:

"It is encouraging to see that the full Phase II data confirms the strong and broad immune response induced by ABNCoV2 against COVID-19, and that Bavarian Nordic will be able to initiate the Phase III study as planned in the first half of 2022. It is also important to note that the high antibody levels demonstrated from a booster dose with ABNCoV2, combined with the fact that mRNA-based vaccines have been shown to be effective as a booster vaccine against the Omicron variant, adds to the belief that ABNCoV2 has the potential to become a powerful universal booster vaccine without the need for future adaptation."

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=6480>.

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) 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. More importantly, the data confirms the potential of ABNCoV2 to induce neutralizing antibodies against circulating variants of SARS-CoV2, including the Delta variant. These strong positive results were further confirmed when the remaining data from the COUGH-1 study was announced in November 2021.

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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.