12-month durability data announced for ABNCoV2 Phase II clinical trial

Hørsholm, Denmark, 16 June 2023 – ExpreS²ion Biotech Holding AB’s affiliate ExpreS²ion Biotechnologies ApS (“ExpreS²ion”) today provides an update on Bavarian Nordic’s Phase II clinical trial for ABNCoV2, a capsid virus-like particle (cVLP) based non-adjuvanted COVID-19 booster vaccine. Today Bavarian Nordic announced that the results of a 12-month follow-up analysis from a subset of subjects enrolled in a Phase II clinical trial of ABNCoV2 shows high protection levels (>90%) against the original Wuhan strain and previous variants of concern (Beta, Delta, and Omicron BA.4/5). Furthermore, neutralizing antibodies against variant XBB.1.1 were induced in 43% of the subjects at a lower level of efficacy (78%), compared with the original Wuhan strain.

CEO Bent Frandsen comments:
“At ExpreS²ion, we are thrilled about the 12-month durability data which documents the long-term protection envisioned with the VLP technology. 12-month protection levels exceeding 90% against Wuhan, Beta, Delta and Omicron BA.4/5 are to our knowledge unprecedented, even by the leading marketed COVID-19 vaccines. Furthermore, we see the favourable 12-month durability data as positive proof-of-concept for the combination of the ExpreS²™ antigen and cVLP, which bodes well for our other pipeline asset, ES2B-C001. ES2B-C001 is a unique HER2-cVLP breast cancer vaccine candidate on path towards Phase I clinical trial in 2024, using the similar technology platform to that of ABNCoV2.”

CSO Dr. Farshad Guirakhoo comments:
“We are not surprised that the separate analysis against XBB.1.1 resulted in lower levels of protection – this likely reflects that the virus has mutated enough that a new antigen might be required for the upcoming fall season. At ExpreS²ion, we have made multiple antigens with our proprietary ExpreS²™ platform that may be incorporated into the VLP system, potentially adapting ABNCoV2 to each season’s prevalent strain. We look forward to the Phase III data and learning more about Bavarian Nordic’s plans regarding the future of the vaccine.”

Bavarian Nordic expects results from the Phase III clinical trial in July 2023. Additional information can be found in the press release published today by Bavarian Nordic, see link below:

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, ExpreS²™, 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 favourable 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. Furthermore, six months post vaccination, neutralization titers were six times higher than pre-boost titers against Wuhan and nearly ten times higher than the pre-boost titers for Omicron BA.1. Compared to the data published for mRNA vaccines, the antibody decay appears less sharp, indicating a potentially longer duration of protection across variants of concern.

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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.