Further efficacy data from the COVID-19 clinical Phase I/II study with ABNCoV2 confirms strong positive results

Hørsholm, Denmark, November 12, 2021 – ExpreS2ion Biotech Holding AB’s affiliate ExpreS2ion Biotechnologies ApS ("ExpreS2ion") announces that the remaining virus neutralization data, for the two highest dose ranges of 50 μg and 70 μg, have now been published from the COUGH-1 COVID-19 Phase I/II clinical trial to evaluate the ABNCoV2 vaccine. The headline results met its safety and efficacy endpoints also for these dose ranges, and thus for the study in its entirety.

COUGH-1 headline results
Positive initial data from the first-in-human study of ABNCoV2, the capsid virus like particle (cVLP) COVID-19 vaccine candidate licensed from ExpreS2ion’s joint venture partner AdaptVac, was announced on August 9, 2021, and the remaining data for the high dose groups have now become available. The results demonstrate that the vaccine was well tolerated across all dose groups, with no observed difference in the adverse event profile after first and second vaccinations. No serious adverse events were reported, and the safety profile was comparable to other vaccines based on recombinant protein-technology.

In all dose groups, antibody titers were boosted after the second vaccination to levels significantly higher than those reported for current approved COVID-19 vaccines. Titers were up to 12-fold higher than those measured in convalescent human samples with similar strong responses seen across the groups receiving 25, 50 and 70 μg, indicating a plateau within this range. This could potentially provide rationale for reducing the dose of the vaccine while maintaining optimal effect.

Importantly, ABNCoV2 demonstrated high neutralization titers against all SARS-CoV-2 variants of concern, including the dominant Delta and escape variant Beta.

Current status on the clinical development
Bavarian Nordic continues its Phase II trial to evaluate ABNCoV2 as a booster vaccine for individuals with previous COVID-19 disease or vaccination, expecting headline data before end of the year. In parallel, Bavarian Nordic is preparing for ABNCoV2 to be investigated during 2022 in a Phase III trial, which as previously announced has obtained funding from the Danish State.

CEO Bent Frandsen comment
"I am delighted that the strong initial headline results from the COUGH-1 COVID-19 Phase I/II clinical trial to evaluate the ABNCoV2 vaccine is further strengthened now that data from all the dose groups have been published. The strong positive results achieved in this trial reaffirms the potential of the ABNCoV2 vaccine to become an important tool in the global fight to end the COVID-19 pandemic."

About the cVLP COVID-19 vaccine product, ABNCoV2
Under the PREVENT-NCoV consortium, ExpreS2ion and its joint venture 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 study was announced in November 2021.

Bavarian Nordic is sponsor of the Phase II trial, which is being conducted at two centers in Germany. The trial will enroll a total of up to 210 healthy adult volunteers into two groups: one group of 150 seropositive (prior disease or vaccinated) subjects will receive one 100 \( \mu \)g dose of ABNCoV2. Enrollment into this group will be stratified by seropositivity, i.e., previous COVID-19 disease or type of previous vaccination received, with at least 40 subjects enrolled in each stratification group. A second group of up to 60 seronegative subjects will receive two 100 \( \mu \)g doses of ABNCoV2, 28 days apart. The primary endpoint of the study is SARS-CoV-2 neutralizing antibody titers at 2 weeks after the last vaccination, i.e., after the second vaccination in initially seronegative subjects and after the single boost vaccination in seropositive subjects. Additional endpoints will, among others, focus on the safety of the vaccine and neutralizing antibody titers against variant strains circulating at the time of analysis at 2 weeks after last vaccination.

**About AdaptVac**

AdaptVac is a joint venture between ExpreS\textsuperscript{2}ion Biotechnologies (34% ownership) and NextGen Vaccines (66%), 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.

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**About ExpreS\textsuperscript{2}ion**

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