

ExpreS²ion provides update on anticipated development of the breast cancer vaccine candidate AV001, including a probable change in its ownership stake in AdaptVac

Hørsholm, Denmark, August 18, 2020 – ExpreS²ion Biotech Holding AB (“ExpreS²ion” or the “Company”) hereby announces that ExpreS²ion wishes to exercise the option to inlicense AV001 before it expires on February 26, 2021. The exercise of the option is subject to the Company obtaining the necessary financing to fund the exercise of the option and the further preclinical development of AV001. If so, the Company expects to be able to submit an application to start clinical trials in the first half of 2022. The Company furthermore announces that it will transfer 16 percent of its joint venture ownership in AdaptVac to joint venture partner NextGen vaccines, following which ExpreS²ion will hold 34 percent and NextGen Vaccines 66 percent of AdaptVac when the option to in-license AV001 is exercised. The transfer of ownership provides AdaptVac with the autonomy needed as an independent commercial entity, further strengthen its ties to leading scientists at the University of Copenhagen and facilitates future capitalisations of AdaptVac independent of ExpreS²ion. These strategic measures will enable AdaptVac to continue developing valuable assets for our joint venture, without drawing on ExpreS²ion core resources.

In February 2020, ExpreS²ion took out an exclusive option, at the Company’s sole discretion, to in-license AV001, AdaptVac’s HER2 cVLP therapeutic breast cancer vaccine. The agreement was based on the very promising preclinical results coming out of the program and runs until February 26, 2021. According to the Company’s updated development plans and subject to financing, the GMP process as well as the formulation and analytical methods for the vaccine should be developed by H1 2021. Preclinical tox studies will be concluded by H2 2021, with the application to start human clinical trials (CTA) then submitted to the regulatory authorities in H1 2022. The first clinical trial of AV001 will be a phase I/IIa trial with safety as the primary endpoint and various surrogate markers of efficacy as secondary endpoints. ExpreS²ion plans to initiate out-licensing discussions following this trial.

ExpreS²ion’s CEO Bent Frandsen comments:

"We are looking forward to fulfil our ambition to take over the AV001 project. As was the case with the results recently published from the COVID-19 vaccine showing extremely impressive immune responses in recognised animal models, we believe the Proof-of-Concept data from AV001 in breast cancer models are similarly unmatched. This is all the more important because HER2 is a validated target in breast cancer: We know we will have an effect if we can effectively raise antibodies against it. We will retain our close ties to AdaptVac and keep our current board representation but AdaptVac must now forge its own path forward. By shifting the ownership structure we believe we will enable AdaptVac to become an independent and strong company that will continue to develop promising new projects and excellent research. We think this is the best way to support them. This potential ownership change has no effect on the already agreed distribution of royalties and milestones in the Bavarian Nordic agreement concerning the COVID-19 vaccine."

About the option agreement

ExpreS²ion and AdaptVac entered into an option agreement on the therapeutic HER2 breast cancer vaccine candidate AV001 on [26 February 2020](#). The agreement provides ExpreS²ion an option to enter an exclusively global license to the program. The terms of the License Agreement, that ExpreS²ion may execute any time before February 26, 2021, contain financial consideration to AdaptVac in the form of an upfront payment at signature of DKK 2.5M (SEK 3.5M), a payment upon the release of clinical-ready production material of DKK 2.5M (SEK 3.5M) (estimated to be in 2021), a payment upon initiation of a clinical Phase I safety trial of DKK 2.5M (SEK 3.5M) (estimated to be in 2022), a payment upon initiation of a clinical Phase II efficacy trial of DKK 10M (SEK 14M) (estimated to be in 2023-24) and thereafter aggregated clinical Phase III development and regulatory milestone-based payments of DKK 200M (SEK 285M), and lower single-digit royalty rates of net sales. The License Agreement includes sublicensing rights allowing ExpreS²ion to partner with a larger

biopharmaceutical company on the further commercialisation of AV001, against a fixed percentage of partner payments to be paid to AdaptVac, in which case the remaining financial consideration towards AdaptVac falls away.

About AV001

The human epidermal growth factor receptor-2 (HER2), which mediates tumor growth, is overexpressed in many different cancer types, including bladder, pancreas, ovary, colon, kidney, prostate, breast and others. HER2 overexpression occurs in 20–30% of invasive breast cancers and is correlated with poor prognosis. Passive immunotherapy using monoclonal antibodies targeting epitopes in the extracellular domain of HER2, have resulted in significant improvement in progression-free and overall survival rate of HER2 positive metastatic breast cancer patients. Unfortunately, treatment of HER2-positive breast cancer with monoclonal antibodies (mAbs) is laborious, expensive and associated with severe side effects. Continuous administration of high doses of mAb often results in immune reactions against the therapeutic mAb leading to treatment requiring hypersensitivity reactions. The majority of patients with HER2-positive breast cancer acquire resistance to treatment with trastuzumab already within the first year. AV001 is based on AdaptVac's cVLP antigen display platform that unlike existing technologies, effectively facilitates directional covalent attachment of large vaccine antigens at high density on the surface of VLPs. The vaccine antigen (the extracellular domain of the HER2 molecule), was expressed using the ExpreS² technology. The repetitive surface structures on the VLPs facilitate a stronger immune response, including complement fixation and B cell receptor clustering, which activate the innate immune system and leads to greater B cell activation. AV001 is currently supported by an InnoBooster grant from Innovation Fund Denmark and a EUROSTARS grant from the EU.

About AdaptVac

[AdaptVac](#) is a joint venture between ExpreS²ion Biotechnologies and NextGen Vaccines, 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 entire pipeline of vaccines and immunotherapies in development.

Certified Adviser

Svensk Kapitalmarknadsgranskning AB
Telefon: +46 11 32 30 732
E-post: ca@skmg.se

For further information about ExpreS²ion, please contact:

Bent U. Frandsen, CEO
Telephone: +45 4256 6869
E-mail: buf@expres2ionbio.com

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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 300 proteins and 40 virus-like particles (VLPs) in collaboration with leading research institutions and companies. Since 2017, ExpreS²ion develops novel VLP based vaccines through its joint venture AdaptVac ApS. For additional information, please visit www.expres2ionbio.com and www.adaptvac.com.