ExpreS2ion Reports Updated Immunogenicity Data from First Three Patients and DSMB Recommendation to Progress ES2B-C001 Phase I Trial to Next Dose Cohort

Hørsholm, Denmark, 19 December 2025 – ExpreS2ion Biotech Holding AB's affiliate ExpreS2ion Biotechnologies ApS ("ExpreS2ion"), a clinical-stage biotechnology company with a focused pipeline of vaccine candidates targeting infectious diseases and cancer, today reports (i) updated immunogenicity results from the first three patients enrolled in its ongoing Phase I clinical trial of ES2B-C001, a novel HER2-targeted therapeutic breast cancer vaccine, and (ii) that the independent Data Safety Monitoring Board (DSMB) has reviewed safety data from the first cohort and recommended progression to the next dose cohort.

High-level immunogenicity observations

The Phase I trial is designed to evaluate the safety, tolerability, and immunogenicity of ES2B-C001 in patients with advanced HER2-expressing breast cancer who have received prior standard therapies. Blood samples are collected at baseline and at predefined timepoints following vaccination and analysed for HER2-specific antibody responses.

Based on analyses from the first cohort, ExpreS2ion has observed induction of HER2-specific immune responses following vaccination in multiple patients, with antibody levels increasing to levels significantly above pre-dose baseline.

In addition, early follow-up data provide an indication that vaccine-induced HER2-specific antibody responses may be maintained during the monitoring period without an apparent decline. This observation is preliminary and is based on limited data from early trial participants.

Taken together, these early findings suggest the potential for a robust immune response with indications of durability. However, interpretation is limited by the small number of patients, the exploratory nature of the analyses, and the early stage of the study. The Phase I safety trial remains ongoing, and additional data are required to further characterize the consistency, magnitude, and persistence of immune responses across patients and dose levels.

DSMB review supports escalation to mid dose cohort

Following review of the available safety data from the first cohort of three patients vaccinated with the low dose **50 µg ES2B-C001 + adjuvant**, the DSMB recommended that the trial proceeds to the next cohort of three patients to receive the mid dose **150 µg ES2B-C001 + adjuvant**, in accordance with the study protocol.

ExpreS2ion will now proceed with enrolment and vaccination of the mid dose cohort, while continuing ongoing safety monitoring and immunogenicity assessments as the trial advances.

Commenting on the update

Dr. Rupert Bartsch, MD, PhD, Clinical Division of Oncology, Medical University of Vienna, Austria, commented: "The updated immunogenicity observations across the first patients are encouraging and support continued clinical investigation of ES2B-C001. Importantly, the DSMB's recommendation to progress reflects the safety profile observed to date in the first cohort, and we will continue to carefully monitor safety and immune responses as the study advances."

Bent U. Frandsen, CEO of ExpreS2ion, commented: "Following our September patient read-out, this combined update marks another step forward for ES2B-C001. Early immunogenicity data across the first three patients are supportive, and the DSMB recommendation to proceed to the next dose cohort keeps us on track to build the clinical dataset for this novel therapeutic vaccine approach."

About ES2B-C001 (HER2-VLP)
ES2B-C001 is an innovative immunotherapy developed to treat HER2-expressing cancers by stimulating a patient's own immune system, offering a novel alternative to existing antibody-based approaches. This approach combines ExpreS2ion's ExpreS2 production platform with AdaptVac's VLP technology, both of which have been proven in clinical Phase III. The HER2-VLP vaccine is designed to stimulate a robust and durable polyclonal immune response against HER2-expressing tumours, offering a complementary strategy to current treatment regimens such as monoclonal antibodies (mAb) or antibody-drug conjugate (ADC) therapies. Preclinical studies (Ruzzi et al. (2022)), have demonstrated the safety and efficacy across multiple animal models, significantly inhibiting tumour growth and improving survival rates.

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About ExpreS2ion
ExpreS2ion is a biotechnology company that develops innovative vaccines for a healthier world. We want to transform healthcare by developing novel vaccines, that are life-saving and improving quality of life across the world. ExpreS2ion has developed the unique human clinical Phase III-validated technology platform, ExpreS2™, for fast and efficient development and production of the active material in vaccines. The platform, under the brand GlycoX-S2™, includes functionally modified glycosylation variants for enhanced immunogenicity and pharmacokinetics. Since 2010, ExpreS2ion 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.