ExpreS2ion Biotech reports encouraging immunogenicity observations from ongoing Phase I trial of ES2B-C001

Hørsholm, Denmark, 03 February 2026 – 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 updated immunogenicity observations from its ongoing Phase I clinical trial of ES2B-C001, a HER2-targeting cancer vaccine candidate. Based on data currently available, five out of six evaluable patients have demonstrated a drug-specific immune response, defined as an increase from baseline in anti-HER2 lambda light-chain antibody titers following treatment with ES2B-C001. The data remain early and under evaluation, and no formal conclusions can be drawn at this stage.

The updated assessment includes immunogenicity data available up to the end of January 2026 from patients treated in the first dose cohort (50 micrograms plus adjuvant) as well as initial observations from patients enrolled in the subsequent higher dose cohort (150 micrograms plus adjuvant). The data remain early and limited in scope, and additional patient follow-up and data are required before definitive conclusions can be drawn.

Based on the data currently available, five out of six evaluable patients have demonstrated a drug-specific immune response, defined as an increase from baseline in anti-HER2 lambda light-chain antibody titers following treatment with ES2B-C001. These lambda light-chain antibody responses are specific to the vaccine-induced immune response.

To date, two patients have completed all scheduled study visits and continue to show sustained elevated anti-HER2 lambda light-chain Ig titers over time, suggesting durability of the observed immune response. Additional patients remain on treatment, and follow-up is ongoing.

Commenting on the update

Bent U. Frandsen, CEO of ExpreS2ion, commented: "While the dataset remains limited and early, we are encouraged by the consistency of the immune responses observed in patients treated with ES2B-C001. Importantly, we continue to see vaccine-specific antibody responses without any new safety concerns, supporting continued progression of the clinical program."

Dr. Erik Heegard, Director, Clinical Development, commented: "From a clinical and immunological perspective, the timing and pattern of the observed responses are in line with what we would expect from an active cancer vaccine. At the same time, the small number of patients and the heterogeneity of prior and concurrent therapies mean that careful follow-up and further data are needed before drawing conclusions."

ExpreS2ion emphasizes that the current dataset remains limited, and the observations reported should be interpreted with caution. The company continues to work closely with investigators and the Data Safety Monitoring Board as the study progresses and additional data mature.

Patient enrolment and screening continue to progress as planned, and sites report that additional patients are available to proceed once dosing is permitted following the required safety reviews. Based on current visibility, ExpreS2ion remains on track to complete the dose-escalation portion of the study around mid-2026 and the expansion portion toward the end of 2026, subject to ongoing recruitment, safety reviews, and overall study conduct progressing as expected.

Further updates will be provided as appropriate.

About the ES2B-C001 Phase I trial
The ES2B-C001 Phase I trial is an open-label study evaluating the safety, tolerability, and immunogenicity of ES2B-C001 in patients with advanced HER2-positive or HER2-low breast cancer who have received prior standard-of-care therapy. The study is being conducted at multiple clinical centres in Austria and includes a dose-escalation phase followed by an expansion phase. ES2B-C001 is administered as an intramuscular vaccine with adjuvant across multiple dose levels. The primary objective of the study is to assess safety and tolerability, with immunogenicity as a secondary objective.

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.

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