

Expres2ion reports consistent, durable anti-HER2 responses; advances ES2B-C001 Phase I after independent DSMB review

Hørsholm, Denmark, 25 March 2026 – Expres2ion Biotech Holding AB's affiliate Expres2ion Biotechnologies ApS ("Expres2ion"), a clinical-stage biotechnology company with a focused pipeline of active immunotherapy candidates targeting cancer and infectious diseases, today reports updated immunogenicity data from its ongoing Phase I clinical trial of ES2B-C001, an active immunotherapy targeting HER2. The updated dataset shows anti-HER2-specific antibody responses in eight of nine evaluable patients, with antibody titres increasing over time following repeated dosing. Following review of the available safety and tolerability data, the independent Data Safety Monitoring Board (DSMB) supports further progression of the study, including expansion of the ongoing cohort and escalation to the next dose level. The trial remains active, with additional patient follow-up and sample analyses pending.

Updated immunogenicity data

The updated analysis includes patients treated across the 50- μ g and 150- μ g dose levels. A response is defined as a ≥ 2 -fold increase in anti-HER2-specific antibody titres versus baseline.

Eight of nine evaluable patients met the predefined responder criterion, confirming induction of anti-HER2-specific antibody responses. These findings support the ability of ES2B-C001 to stimulate a HER2-targeted immune response in patients with advanced breast cancer, a key objective of the ongoing Phase I study. Antibody titres increased over successive dosing visits, indicating boosting following repeated administration. Antibody titres increased during treatment and remained elevated at later visits in patients with follow-up data. In the first patient, for whom Expres2ion reported initial immunogenicity data ([PR 4 September 2025](#)), antibody titres remained elevated approximately five months after the final dose, indicating a sustained immune response within the observation period.

DSMB assessment

Based on its review of accumulated safety and tolerability data, the independent DSMB reviewed the available safety and tolerability data and recommended continuation of the trial with escalation to the next dose level (450 μ g) and expansion of the 150- μ g cohort. No safety signals of concern have been identified to date. This assessment supports that the safety profile observed to date is acceptable for further clinical exploration. No conclusions regarding clinical benefit can be drawn at this stage.

Next steps

The company plans to progress to the next dose level in line with study conduct and regulatory processes, while continuing enrolment in the expanded cohort. Ongoing activities include further patient follow-up, completion of pending immunogenicity analyses, and continued evaluation of the consistency and persistence of antibody responses.

Bent U. Frandsen, CEO of ExpreS2ion, commented:

“These early results strengthen our confidence in ES2B-C001 as a first-in-class active immunotherapy targeting HER2. The consistent immune responses, indications of durability, and favourable safety profile seen to date support continued clinical evaluation. In addition, with the DSMB recommending progression of the study, we remain excited about potential further validation from the coming data readouts in 2026 from this on-going clinical trial.”

Technical summary (interim)

The Phase I study is an open-label, dose-escalation and expansion trial evaluating ES2B-C001 in patients with advanced HER2-positive or HER2-low breast cancer. Doses of 50 µg and 150 µg have been evaluated to date, with escalation to the next planned dose level (450 µg) supported by the DSMB.

The patient population is heterogeneous with respect to disease stage and concomitant treatments, which may influence individual immune responses. These findings are preliminary and based on a limited number of patients in an ongoing Phase I study. The patient population includes a mix of completed, ongoing, and discontinued participants, with some samples pending analysis.

About ES2B-C001 (HER2-VLP)

ES2B-C001 is a first-in-class active immunotherapy designed to treat HER2-expressing cancers by stimulating the patient’s immune system to generate a polyclonal antibody response against HER2. This novel approach combines ExpreS2ion’s ExpreS2 production platform with AdaptVac’s virus-like particle (VLP) technology, both of which have been validated in late-stage clinical development in other programmes, including a Phase III study that met its primary endpoint. The HER2-VLP active immunotherapy is designed to induce a durable immune response and may offer a complementary approach to existing HER2-targeted therapies, including monoclonal antibodies and antibody-drug conjugates. Preclinical studies ([Ruzzi et al., 2022](#)), have shown anti-tumour activity across multiple models, including inhibition of tumour growth and improved survival.

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About ExpreS2ion

ExpreS2ion is a biotechnology company focused on the development of innovative active immunotherapies and vaccines for infectious diseases and cancer. The company has developed the ExpreS2™ platform, a proprietary protein expression technology used across more than 500 recombinant protein and virus-like particle (VLP) projects spanning research, diagnostics, and therapeutic development. Proteins produced using the ExpreS2 platform are being evaluated in multiple clinical programmes worldwide. The platform has also been applied in partnered development programmes that have progressed into late-stage clinical evaluation, including Phase III studies that have met their primary endpoints. The platform, marketed as GlycoX-S2™, includes

functionally modified glycosylation variants designed to enhance immunogenicity and pharmacokinetics. ExpreS2ion develops novel VLP-based vaccines in association with AdaptVac ApS, of which ExpreS2ion owns 34%. ExpreS2ion Biotech AB is listed on Nasdaq First North Growth Market. For additional information, please visit www.expres2ionbio.com.

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