

ExpreS2ion Provides ES2B-C001 Phase I Update: All Patients Enrolled and Updated Readout Timing

Hørsholm, Denmark, 23 October 2026 – ExpreS2ion Biotech Holding AB's affiliate ExpreS2ion Biotechnologies ApS ("ExpreS2ion"), a clinical-stage biotechnology company with a pipeline of novel immunotherapies targeting oncology and infectious diseases, today provides an update on the Phase I trial of ES2B-C001 in patients with advanced HER2-positive or HER2-low breast cancer. All 19 patients that the study planned to enrol have started the treatment and the last patient's last visit is expected at the end of December 2026, instead of end-2026 as previously communicated. Updated preliminary data show anti-HER2 antibody responses in 12 of 13 evaluable patients, with no dose-limiting toxicities observed and no serious adverse events assessed as related to ES2B-C001. The Phase II initiation target of the second half of 2027 is unchanged.

Bent U. Frandsen, CEO of ExpreS2ion, comments:

"All patients in the trial have now started treatment, and we continue to see antibody responses to ES2B-C001 in the large majority of evaluable patients, with no safety signals of concern identified so far. These data will underpin our partner discussions. The Scientific Advisory Board's review has sharpened our Phase II design planning as we work towards the primary readout in the first quarter of 2027."

Study status

All 19 patients have been enrolled and have started treatment: seven at 50 µg, six at 150 µg and six at 450 µg. The last patient's last visit in the five-dose priming phase is expected at the end of December 2026, provided visits stay on schedule and no further dropouts require an additional patient. Consequently, the primary readout data are expected to be published in Q1 2027 instead of end-2026 as previously announced.

Patients who complete the priming phase, and who fulfil the eligibility criteria, may continue in the maintenance phase which comprises 3 booster doses administered at 6 month intervals. The first maintenance (booster) dose was given in September 2026.

Safety

No dose-limiting toxicities have been observed, and no suspected unexpected serious adverse reactions (SUSARs) have been reported across the 75 doses given by the data cut-off. No serious adverse events assessed as related to ES2B-C001 have been reported.

Updated immunogenicity data (data cut-off 5 October 2026)

At the 5 October 2026 data cut-off, 13 patients were evaluable for immunogenicity[1], of whom 12 (92%) had an anti-HER2 antibody response[2], with responses seen at all three dose levels. Of the other six patients dosed, five, the most recently enrolled, were not yet evaluable, and one was not evaluable since only one dose was administered. Across the evaluable patients, the median peak increase in anti-HER2 antibody titre[3] was eight-fold, ranging up to 81-fold relative to baseline.

Nine patients had completed the five-dose priming course at the data cut-off. Eight of them had a response, with a median peak increase of eight-fold.

Titres generally rose with successive doses during the priming phase. Later samples, taken at weeks 29–35, are so far available for three patients; all three had titres above baseline.

Next steps

- **Phase I:** the remaining priming-phase visits, ending with the last patient's last visit at the end of December 2026, followed by database lock in February 2027 and publication of the primary readout data in Q1 2027. Eligible patients will be offered to continue into the maintenance phase, which runs until 2028.
- **Translational programme:** all planned translational studies have been initiated, with results expected at the end of 2026.
- **Phase II planning:** ExpreS2ion's Scientific Advisory Board met recently to review the Phase I data and the Phase II plans. Taking into account the safety profile observed to date, it suggested evaluating ES2B-C001 together with standard of care in a first-line of therapy patient population. The review and the updated Phase II plan give a clearer basis for partner discussions. The Phase II design remains subject to partner input, regulatory interactions and financing.

[1] Evaluable: at least two doses, with samples at baseline and after the two doses.

[2] Response: a two-fold or greater increase in anti-HER2 antibody titre from baseline at any visit after dosing. The data are preliminary and exploratory, and no conclusions on clinical benefit can be drawn at this stage.

[3] Measured as anti-HER2 antibodies with lambda light chains. This separates the patient's own response from anti-HER2 antibody drugs, such as trastuzumab, that many patients receive alongside the trial treatment.

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This press release constitutes inside information that ExpreS2ion Biotech Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation 596/2014. The information was sent for publication, through the agency of the contact persons set out above, at the time stated by the Company's news distributor, MFN, at the publication of this press release.

For further information about ExpreS2ion, please contact:

Bent U. Frandsen, CEO

Keith Alexander, CFO

Email: investor@expres2ionbio.com

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.

About Expres2ion

Expres2ion is a clinical-stage biotechnology company developing active immunotherapies and vaccines for cancer and infectious diseases. Its lead asset, ES2B-C001, is a first-in-class active immunotherapy for HER2-expressing cancers, currently in Phase I clinical development. ES2B-C001 is built on Expres2ion's proprietary, Phase III-validated Expres2™ protein expression platform, which also underpins a portfolio of partnered development programmes and a contract services (CRO) business. Expres2ion develops novel VLP-based vaccines in association with AdaptVac ApS, of which Expres2ion owns 34%. Expres2ion Biotech Holding AB is listed on Nasdaq First North Growth Market. For additional information, please visit www.expres2ionbio.com.

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