ExpreS2ion Reports Positive DSMB Outcome and Expanded Preliminary Phase I Data for ES2B-C001

Hørsholm, Denmark, 12 August 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 announces the outcome of the third scheduled Data Safety Monitoring Board ("DSMB") meeting in the Phase I trial of ES2B-C001 (HER2-VLP), its first-in-class active immunotherapy targeting HER2-expressing cancers, together with updated preliminary immunogenicity and safety observations. The DSMB identified no dose-limiting toxicities across the three dose cohorts and recommended expanding the highest-dose cohort (450 µg) by three additional patients, strengthening the dataset at the top dose ahead of the primary readout. Preliminary data show anti-HER2 antibody responses in 12 of 13 evaluable patients, including all five patients who have completed the dosing schedule, with a median 16-fold peak increase in antibody levels among completers. The Phase I primary readout target of end-2026 is unchanged. Phase II initiation is now targeted for the second half of 2027 to allow the Phase II plan to be reviewed with regulatory authorities in both Europe and the United States ahead of trial start.

DSMB Outcome
On 10 August 2026, the DSMB held its third scheduled meeting in the ES2B-C001-S01 trial, a First-in-Human, open-label Phase I study enrolling patients with advanced HER2+ or HER2-low breast cancer across three dose cohorts (50 µg, 150 µg and 450 µg). The DSMB reviewed accumulated safety data and available immunogenicity data across all three cohorts and concluded that no adverse events meeting dose-limiting toxicity criteria have been observed, and that no changes to the protocol, eligibility criteria, concomitant medication or safety precautions are required. No suspected unexpected serious adverse reactions (SUSARs) have been reported in the study.

The DSMB recommended expanding the third and highest dose cohort (450 µg) by three additional patients. ExpreS2ion has accepted the recommendation. The expansion strengthens the safety and immunogenicity dataset at the highest dose ahead of the primary readout, which remains targeted for end-2026.

Preliminary Immunogenicity and Safety Observations
As of the 4 August 2026 data cut, 16 patients have been enrolled across the three dose cohorts. Five patients have completed the five-dose schedule, with the remaining patients ongoing or in follow-up. Following the DSMB recommendation, recruitment has been re-opened at the 450 µg dose level to enrol three additional patients.

Anti-HER2 antibody responses have been observed in 12 of 13 evaluable patients[1] across the three dose levels, consistent with the immunotherapy's intended mechanism of action. All five patients who have completed dosing responded, with a median 16-fold peak increase in anti-HER2 antibody levels relative to baseline. Antibody titres increased over successive dosing visits, indicating boosting following repeated administration, and elevated antibody levels have been maintained at later follow-up visits in patients with available longitudinal data, consistent with a sustained immune response. No serious adverse events assessed as related to ES2B-C001 have been reported, and no safety signals of concern have been identified in the data reviewed to date.

Phase II Update
ExpreS2ion continues to advance the more targeted and capital-efficient Phase II design outlined in May 2026. To ensure the strongest possible Phase II, the Company intends to review the plan with regulatory authorities in both Europe and the United States before trial initiation. To accommodate these interactions, Phase II initiation is now targeted for the second half of 2027. The adjustment reflects the planned regulatory interactions and is not related to safety or efficacy observations in Phase I. The Phase I primary readout target of end-2026 is unaffected by this change.

The Company expects to provide a more detailed preliminary Phase II design around the time of the targeted end-2026 Phase I readout, subject to data maturity and further clinical and regulatory input. Any Phase II initiation remains subject to Phase I data, regulatory interactions, financing considerations and final protocol development.

Key Milestones

- Phase I primary readout: End-2026 (unchanged)
- Phase II initiation: Second half of 2027 (previously mid-2027)

Bent U. Frandsen, CEO, commented:
"The DSMB's conclusions and the consistency of the antibody responses across all three dose levels strengthen our confidence in ES2B-C001. Twelve of thirteen evaluable patients have mounted anti-HER2 antibody responses, every patient who has completed dosing has responded, and expanding the highest-dose cohort will give us a deeper dataset at the top dose ahead of the end-2026 readout. Aligning the Phase II plan with regulatory input in both Europe and the United States is a deliberate choice; it is the best way to design a Phase II that serves patients and shareholders We look forward to sharing the Phase I results at the end of the year."

Certified Adviser
Redeye Nordic Growth AB

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.

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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 biotechnology company focused on the development of innovative active immunotherapies and vaccines for cancer and infectious diseases. 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.

[1] Preliminary, exploratory data. Evaluable patients are those who have received at least two immunisations and have both baseline and follow-up samples available. Response is defined as a ≥ 2-fold increase in anti-HER2 antibody titre versus baseline.

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