ExpreS2ion Updates ES2B-C001 Phase I Programme and Reports Additional Preliminary Immunogenicity and Safety Observations

Hørsholm, Denmark, 19 May 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 an update to the Phase I program for ES2B-C001 (HER2-VLP), its first-in-class active immunotherapy targeting HER2-expressing cancers. The updated design is intended to deliver a more informative translational data package, adds a maintenance treatment component, and is supported by a revised Phase II plan. ExpreS2ion also reports additional preliminary Phase I observations, including anti-HER2 antibody responses in 9 of 9 evaluable patients and no safety signals of concern identified to date, including in the first patient dosed in the 450 µg cohort. The Phase I primary readout target of end-2026 and Phase II initiation target of mid-2027 remain unchanged.

Phase I Programme Update
The ES2B-C001-S01 trial is a First-in-Human, open-label Phase I study enrolling patients with advanced HER2+ or HER2-low breast cancer. The study combines dose-escalation and expansion elements across three planned dose levels. Two dose cohorts (50 µg and 150 µg) have been evaluated, and the third and highest dose cohort (450 µg) was initiated in May 2026, following approval by the Data Safety Monitoring Board.

Preliminary immunogenicity data are encouraging. Anti-HER2 antibody responses have been observed in 9 of 9 evaluable patients,[1] consistent with the immunotherapy's intended mechanism of action. Antibody titres increased over successive dosing visits and elevated levels have been maintained at later follow-up, consistent with a durable immune response. No safety signals of concern have been identified to date, including in the first patient dosed in the 450 µg cohort.

The updated programme incorporates an enriched translational analysis programme, developed in response to feedback from potential development partners and investors, designed to generate deeper insights into immune response quality and durability, mechanism of action, and preliminary efficacy signals. The resulting data package is designed to provide a comprehensive translational evidence base ahead of Phase II as well to meet informational needs of potential licensing and co-development partners.

Following the primary induction phase, enrolled patients will enter a maintenance phase of up to 18 months, subject to regulatory approval, to assess booster dosing potential and longer-term immune durability. The maintenance data will directly inform the optimal treatment schedule and duration for Phase II, allowing the design to be refined as real-world durability data accumulate. This maintenance component runs concurrently with Phase II initiation and does not affect the mid-2027 start target.

Updated Phase II Plan
ExpreS2ion has updated its Phase II development plan informed by clinical oncology expert input, evolving industry norms, and data generated to date in the Phase I trial. The plan will be refined further as additional Phase I data become available, with ExpreS2ion expecting 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.

The revised Phase II design is more targeted and focused than previously planned, and is expected to be more capital-efficient. This is expected to support ExpreS2ion's ability to advance the programme independently and may strengthen the commercial proposition for potential licensing or co-development partners. Any Phase II initiation remains subject to Phase I data, regulatory interactions, financing considerations and final protocol development.

Key Milestones — Unchanged

- Phase I primary readout: End-2026
- Phase II initiation: Mid-2027

Bent U. Frandsen, CEO, commented:
"This update reflects the natural maturation of our ES2B-C001 programme and is a positive development for ExpreS2ion. The integrated Phase I design, combined with an enriched translational analysis programme developed in response to investor and partner feedback, aims to deliver a substantially deeper understanding of how ES2B-C001 works — covering immune response quality, durability, and preliminary efficacy signals — within our existing timeline and within the planned budget. Our updated Phase II design is more targeted and focused, improving our ability to advance the programme independently and enhancing its attractiveness to potential partners. We look forward to sharing further updates as the programme advances."

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.

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