

ExpreS2ion Reports First Immunogenicity Data from HER2 Breast Cancer Vaccine ES2B-C001 Phase I Trial

Hørsholm, Denmark, 4 September 2025 – 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 the first immunogenicity results from its ongoing Phase I clinical trial evaluating ES2B-C001, a novel HER2-targeted therapeutic breast cancer vaccine. The data, derived from the first patient enrolled in the trial, indicate that the vaccine is triggering a significant immune response.

Early Evidence of Immune Activation

The patient received two doses of the vaccine over six weeks. Blood samples taken before dosing (baseline) and three weeks after each dose and analysed for antibody levels against the HER2 protein.

Encouragingly, a significant increase in HER2-specific antibodies was observed three weeks after the second dose, compared to pre-dose baseline. The antibody measured is particularly relevant because it reflects a patient-generated, vaccine-induced immune response and is not affected by prior monoclonal antibody (mAb) or antibody-drug conjugate (ADC) therapies.

The results represent the first confirmation that the vaccine is able to activate the human immune system and break tolerance toward HER2, consistent with its intended mechanism of action.

"It is encouraging to observe early signs of immunogenicity in this first patient," said **Dr. Rupert Bartsch, MD, PhD, Clinical Division of Oncology, Medical University of Vienna, Austria**, Deputy Principal Investigator of the trial. "While we must remain cautious and await broader safety and efficacy data, the observed increase in HER2-specific antibodies is consistent with a vaccine-induced response. These initial findings support further evaluation of ES2B-C001 as a novel immunotherapeutic strategy for HER2-expressing breast cancer."

Lars Damstrup MD, PhD, Director of Clinical Development, commented: "It is important to underline that this observation about immunogenicity is based on one patient. That being said, the readout is significant, and I hope we will see the similar responses after the first cohort of three patients have been assessed in the Data Safety Monitoring Board towards the end of the year."

Bent U. Frandsen, CEO of ExpreS2ion, commented: "This first patient-level readout is an important milestone for ExpreS2ion and the ES2B-C001 program. It is our first observation of the immune system's reaction to our vaccine in humans. While these data are early, the results strengthen our belief in this vaccine and the platform's potential and validates the years of preclinical development that preceded it. We look forward to generating more data as the trial progresses."

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 novel 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's design aims to stimulate a robust and durable polyclonal immune response against HER2-expressing tumours, offering a complementary strategy to current treatments. Preclinical studies, as highlighted by [Ruzzi et al. \(2022\)](#), have demonstrated the safety and efficacy across multiple animal models, significantly inhibiting tumour growth and improving survival rates. By leveraging the patient's immune system, ES2B-C001 addresses the complexities of HER2-expressing breast cancers, potentially offering enhanced therapeutic options and filling critical gaps in the current treatment landscape. The ES2B-C001 Phase I clinical trial started as announced in [June 2025](#).

Certified Adviser

Svensk Kapitalmarknadsgranskning 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, Cision, 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 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.