

ExpreS2ion announces dosing of first patient in Phase I clinical trial of ES2B-C001, its novel therapeutic breast cancer immunotherapy

Hørsholm, Denmark, 23 June 2025 – Today ExpreS2ion Biotech Holding AB ("ExpreS2ion" or the "Company"), a clinical-stage biotechnology company with a focused portfolio of immunotherapy candidates targeting infectious diseases and cancer, is pleased to announce that the first patient has been dosed in the Phase I clinical trial of ES2B-C001 (HER2-VLP), the company's novel therapeutic breast cancer immunotherapy candidate. The first patient was dosed with ES2B-C001, and it was well tolerated. The trial is being conducted in collaboration with the clinical staff at the Medical University of Vienna and investigates the safety and tolerability of ES2B-C001 in patients with metastatic HER2-expressing breast cancer.

The Phase I study is designed as a First-in-Human trial to evaluate the safety and tolerability of ES2B-C001 with or without an adjuvant. Secondary objectives include the assessment of immunogenicity and the potential antitumour activity of the vaccine. The study will enrol patients with HER2-expressing metastatic breast cancer who have progressed on or are refractory to standard HER2-targeted therapies.

On 13 May 2025, ExpreS2ion filed a protocol amendment to optionally include concurrent administration of a HER2-targeted antibody-drug conjugate (such as trastuzumab deruxtecan) in select patients. The amendment also proposes an increase in the number of clinical trial sites in Austria. A response to this amendment is expected in Q3 2025. To further support patient enrolment, referral pathways have been established through agreements with five clinics in Vienna, enabling referral of eligible patients to the active study site at the Medical University of Vienna.

Bent U. Frandsen, CEO, comments:

"The dosing of the first patient in this Phase I clinical trial is a significant milestone for ExpreS2ion and our development of ES2B-C001. This first-in-human study represents a critical step forward in our mission to develop innovative therapies for patients with HER2-expressing breast cancer who have limited treatment options. Moreover, the potential of ES2B-C001 to address multiple cancer indications, including gastro-oesophageal cancer, highlights the broader impact this immunotherapy could have in oncology."

Dr. Rupert Bartsch, MD, PhD, Clinical Division of Oncology, Medical University of Vienna, Austria, comments:

"We are very pleased to be working with ExpreS2ion to develop ES2B-C001 for the metastatic breast cancer population. While this is still an early phase of development, a therapeutic breast cancer vaccine has the potential to overcome resistance to conventional treatment strategies and may have durable effects, making this innovative form of immunotherapy a beacon of hope."

About ES2B-C001 (HER2-VLP)

ES2B-C001 is a first-in-class therapeutic vaccine candidate targeting HER2-expressing cancers. It combines ExpreS2ion's ExpreS2 protein expression platform with virus-like particle (VLP) technology developed by AdaptVac ApS. The vaccine is designed to elicit a broad polyclonal antibody response against multiple domains of the HER2 receptor, with the goal of overcoming resistance seen with current HER2-targeted monoclonal antibodies.

Preclinical studies, including those published by [Ruzzi et al. \(2022\)](#), have shown that ES2B-C001 significantly reduces tumour burden and improves survival in animal models. In addition to

metastatic breast cancer, the immunotherapy may also have potential in other HER2-expressing cancers, such as gastro-oesophageal cancer.

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 improve 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.

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