Økonomisk Ugebrev presentation

Innovative vaccines for a healthier world

STO: EXPRS2

ExpreS2ion Biotech Holding AB
Org. Nr. 559033-3729

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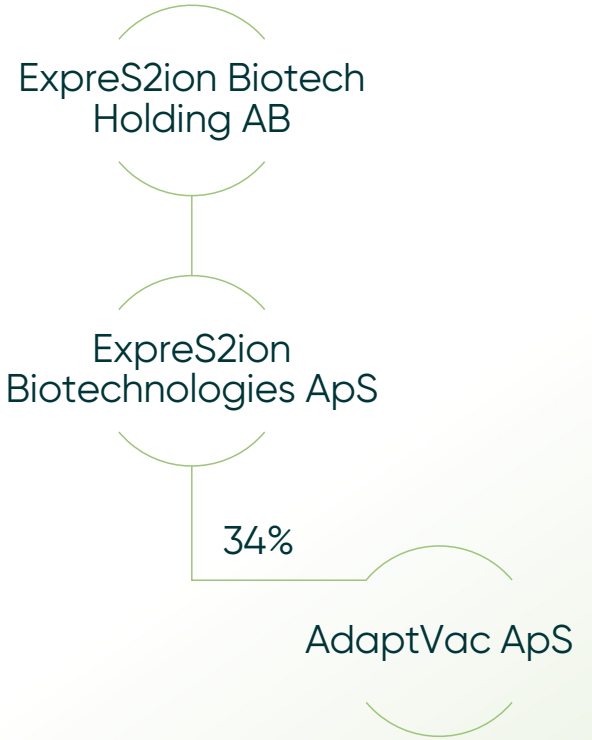
Company overview

About ExpreS2ion



ExpreS2ion Biotech Holding AB

- Listed on the Nasdaq First North Growth Market since 2016
- Holding company for ExpreS2ion Biotechnologies ApS, which it owns 100%

ExpreS2ion Biotechnologies ApS

- Established in 2010
- Protein expression platform technology, vaccine pipeline and CRO business
- Located on the DTU Science Park
- Approximately 20 FTEs
- Owns 34% of AdaptVac ApS

AdaptVac ApS

- Co-founded in 2017 by ExpreS2ion and researchers from Copenhagen University (NextGen Vaccines ApS)
- Virus-like particle (VLP) platform – AdaptVac's VLP is a delivery vehicle in two ExpreS2ion vaccines

Management team

Over 100 years of experience relevant to advancing drug development

Bent Frandsen
CEO

>25 years industry, finance, business development and management experience

MSc in Finance/Strategic Management
Copenhagen Business School

Keith Alexander
CFO

>20 years asset management, strategy, equity research & consulting experience

MBA in Finance
The Wharton School of the University of Pennsylvania

Dr. Farshad Guirakhoo
CSO

>35 years of broad translational research experience in vaccine development

PhD in Virology
Medical University of Vienna

MSc in Genetics
Institute of Biochemistry & Biophysics, University of Tehran

Dr. Max Søgaard
SVP of R&D & Technology

>20 years academic and industrial research experience

PhD in Biochemistry
University College London

MSc in Molecular Biology
Aarhus University

ExpreS2™ platform technology

1) Enables development of novel vaccines

ExpreS2-produced proteins can be combined with, e.g., a virus-like particle to produce vaccines

Advantages to other vaccine types

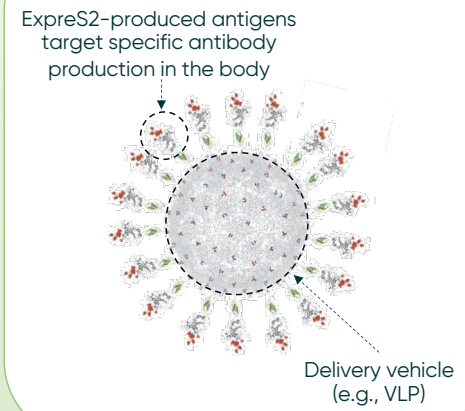
1. Safety – Inherently safe, as they cannot replicate and cause infection
2. Immunogenicity – Induce a strong immune response due to their similarity to real viruses
3. Versatility – ExpreS2 is the basis for vaccines against wide variety of diseases, with and without delivery vehicles

2) Enables production of hard-to-express proteins

Advantages to other protein-production methods

1. Speed in production
2. Higher yields
3. Homogeneous manufacturing batches
4. Thermal stability
5. Functional modification options

Illustrative ExpreS2 vaccine



ExpreS2 platform proofs-of-concept

Discovery	Lead optimization	CTA-enabling	Phase I	Phase II	Phase III - Validated
Influenza Through partnership with Copenhagen University	**Cytomegalovirus** ExpreS2ion has first right to license	**HER2+ breast cancer** Wholly-owned by ExpreS2ion	**6 x Malaria** Under development by Oxford University	**1 x Malaria** Under development by Oxford University	**COVID-19** Licensed to Bavarian Nordic; met Phase III primary endpoint
Nipah and filovirus Through participation in VICI consortium	**Influenza** Through participation in INDIGO consortium				
Two undisclosed projects					

+ numerous additional pharmaceutical and biotech protein production projects

The depicted projects are active except for the Bavarian Nordic COVID-19 project ABNCoV2.

Vaccine pipeline

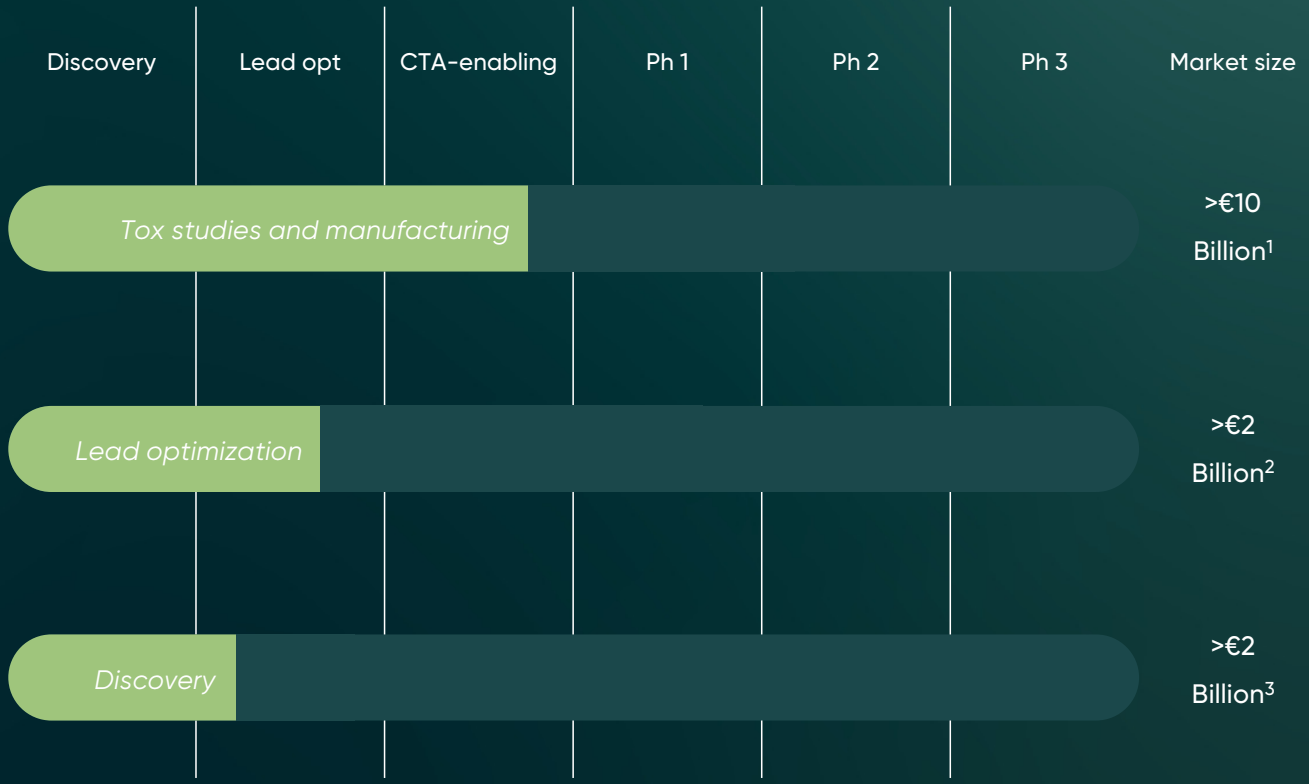
ES2B-C001
HER2+ breast cancer (therapeutic)

Oncology

ES2B-I002
Cytomegalovirus (prevention)

Infectious disease

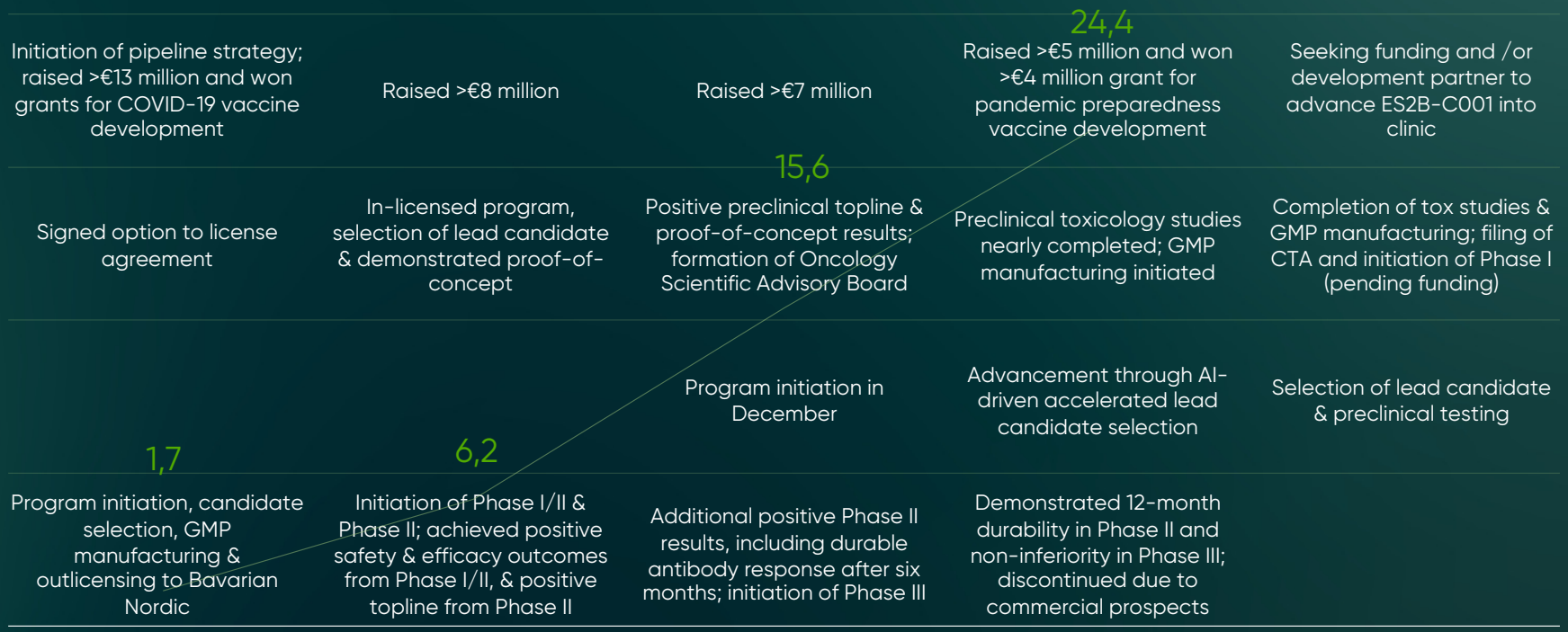
Exploratory
Undisclosed



1 Global Data, 2022, for HER2+ breast cancer
2 Market estimate from Moderna, 41st Annual J.P. Morgan Healthcare Conference (Presentation)
3 Based on data for global market for existing therapies from Future Market Insights

Spend against milestones achieved

Cumulative operating costs in € millions since initiation of pipeline strategy



	2020	2021	2022	2023	2024-2025
General / fundraising	Initiation of pipeline strategy; raised >€13 million and won grants for COVID-19 vaccine development	Raised >€8 million	Raised >€7 million	Raised >€5 million and won >€4 million grant for pandemic preparedness vaccine development	Seeking funding and /or development partner to advance ES2B-C001 into clinic
ES2B-COO1 HER2+ breast cancer (therapeutic)	Signed option to license agreement	In-licensed program, selection of lead candidate & demonstrated proof-of-concept	Positive preclinical topline & proof-of-concept results; formation of Oncology Scientific Advisory Board	Preclinical toxicology studies nearly completed; GMP manufacturing initiated	Completion of tox studies & GMP manufacturing; filing of CTA and initiation of Phase I (pending funding)
ES2B-I002 Cytomegalovirus (prevention)			Program initiation in December	Advancement through AI-driven accelerated lead candidate selection	Selection of lead candidate & preclinical testing
ABNCoV2 COVID-19 vaccine	Program initiation, candidate selection, GMP manufacturing & outlicensing to Bavarian Nordic	Initiation of Phase I/II & Phase II; achieved positive safety & efficacy outcomes from Phase I/II, & positive topline from Phase II	Additional positive Phase II results, including durable antibody response after six months; initiation of Phase III	Demonstrated 12-month durability in Phase II and non-inferiority in Phase III; discontinued due to commercial prospects	

ES2B-C001

HER2+ breast cancer vaccine

Breast Cancer is the most common cancer

- 1 in 8 women will be diagnosed with invasive breast cancer
- In approximately 25% of breast cancer tumours, HER2 is overexpressed, which is associated with a more aggressive disease, higher recurrence rate, and increased mortality[1]
- 685,000 deaths worldwide in 2020 due to breast cancer[2]

1 Mitri Z et al. The HER2 Receptor in Breast Cancer: Pathophysiology, Clinical Use, and New Advances in Therapy (Chemother Res Pract. 2012; 2012: 743193)
2 Breast Cancer Research Foundation (https://www.bcrf.org/breast-cancer-statistics-and-resources)

Competitive landscape leaves room for improvement

PERJETA® pertuzumab

Herceptin® trastuzumab

Monoclonal antibodies (mAbs) and chemotherapy

Standard of care for most stage II and III HER2+ breast cancers after surgery[1]

- mAbs target the HER2 receptor on tumour cells to reduce proliferation and induce tumour cell destruction

ENHERTU® trastuzumab deruxtecan

Kadcyla®

Antibody drug conjugates (ADC)

Novel treatments for HER2 positive and HER2 low breast cancer

- ADCs target delivery of a toxin agent payload guided by HER2 receptor on tumour cells

Serious drawbacks exist with these therapies

- Resistance to monoclonal antibodies often develops
- Repeated intravenous infusions required: time intensive for patients and resource intensive for hospitals
- Potential for a range of toxicities

1 https://www.breastcancer.org/research-news/perjeta-plus-herceptin-and-chemo-shows-benefits

ES2B-C001 could succeed where other HER2 vaccines are failing

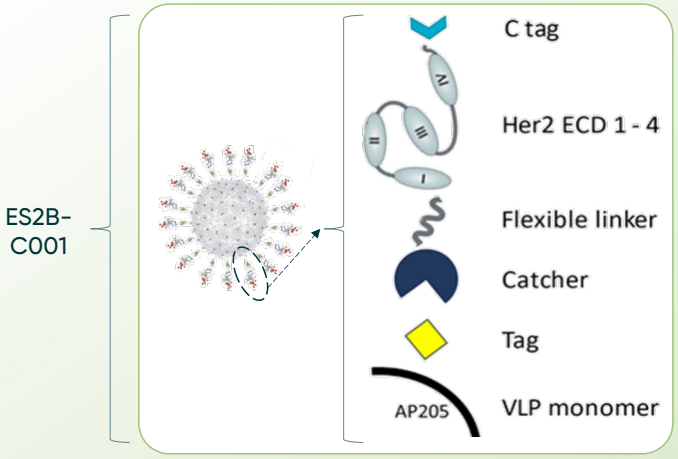
Solutions under development	Limitations	Overcome by ES2B-C001
Epitope-based vaccines No clinical validation in Phase III	• Limited to certain HLA subtypes • Limited capacity to overcome therapy resistance • Poor immunogenicity	✓ ✓ ✓
Protein-based vaccines Very few projects under clinical development	• Challenging antigen presentation • High-production cost	✓ ✓
DNA vaccines Very few projects under clinical development	• Low immunogenicity (Abs) • High-production cost • Complex/costly storage/transportation	✓ ✓ ✓
Dendritic cells vaccines Very few projects under clinical development	• Complex production • Questionable safety • High-production costs	✓ ✓ ✓

ES2B-C001 targets multiple epitopes of ECD

Indication	HER2-expressing cancers, in first instance HER2+ breast cancer (BC)
Delivery method	Intramuscular (i.m.)
Development stage	Preclinical (CTA-enabling)
Advantages	• Highly immunogenic • Safety profile • Longevity of response • Combination with SoC • Off-the-shelf, scalable, cost-effective

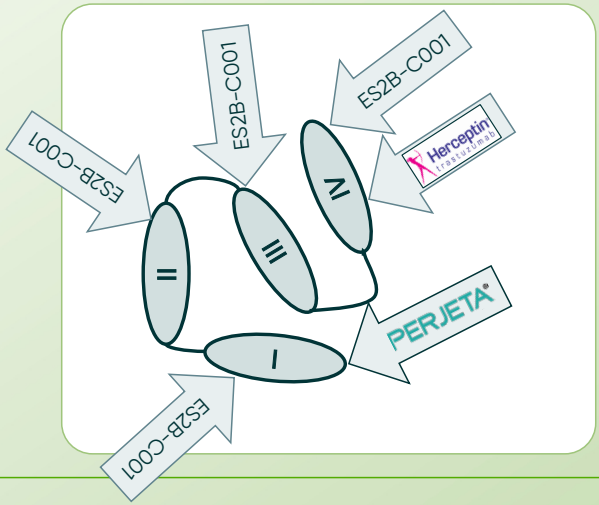
Description

- Extracellular domain (ECD) of HER2 protein coupled to the Acinetobacter Phage 205 (AP205) capsid virus-like particle (cVLP)



Benefits vs. commercial mAbs

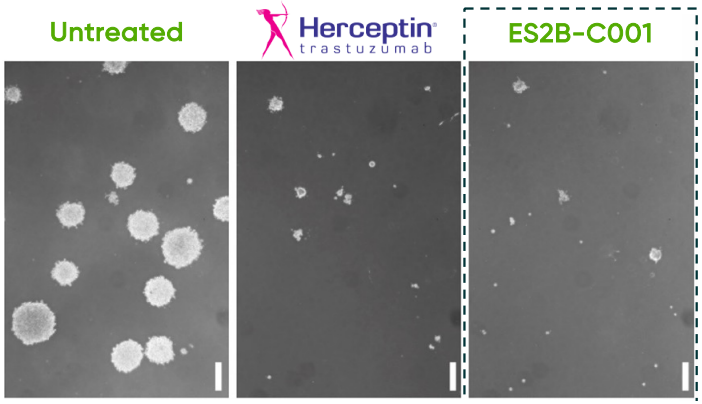
- Polyclonal antibodies generated by ES2B-C001 target numerous epitopes within the ECD of HER2 protein
- mAbs only target one epitope within one domain



Overcomes Herceptin resistance

The soft agar human cancer cell growth inhibition assay provides *in vitro* evidence

Trastuzumab-sensitive HER2+ human cancer cells[1]



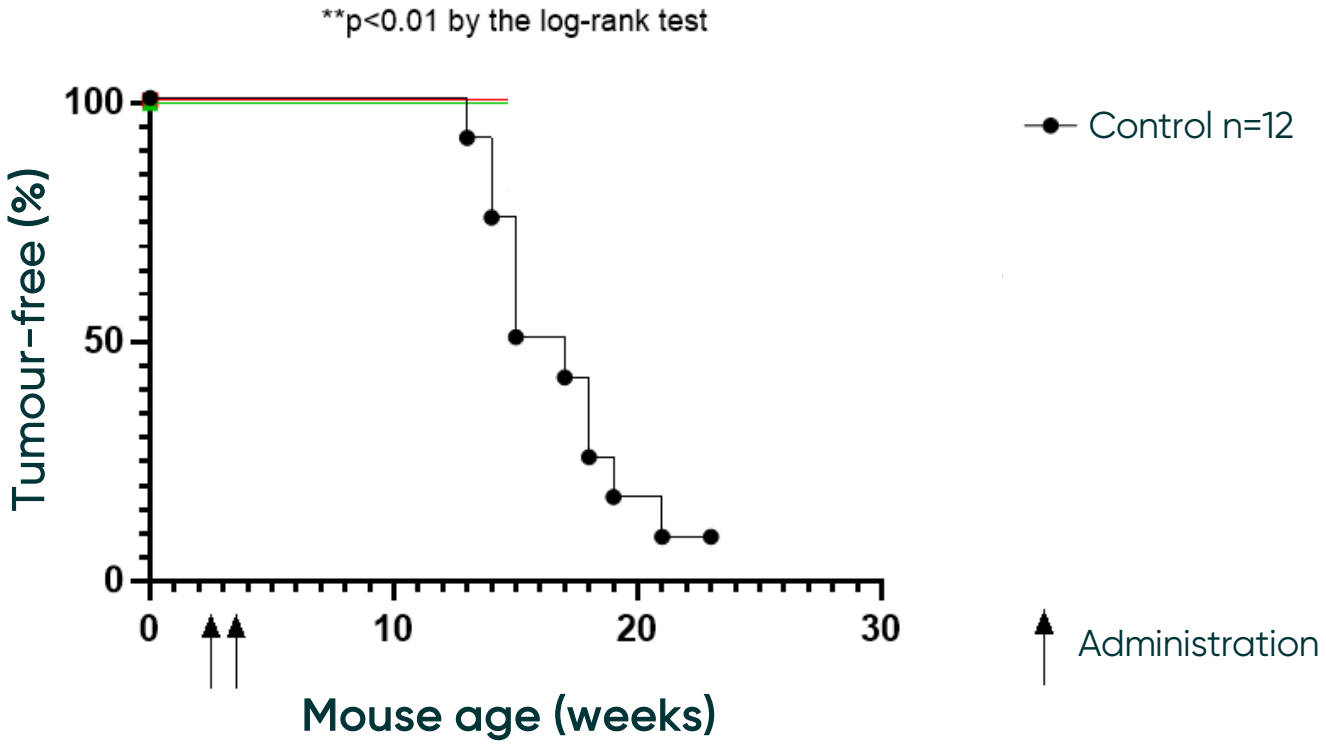
Both Herceptin (trastuzumab) and ES2B-C001 inhibited growth in the trastuzumab-sensitive cells

Note that this data was generated for AdaptVac's predecessor vaccine candidate (HER2-VLP very similar to ES2B-C001)
1) Palladini, A. et al. (2018), "Virus-like particle display of HER2 induces potent anti-cancer responses", OncoImmunology, pub. Vol 7, no 3

Prevention of mammary carcinoma

In HER2 transgenic Delta 16 mice with a human candidate ES2B-C001

Vaccination with only 2 doses of adjuvanted ES2B-0001 completely prevented the onset of mammary carcinoma

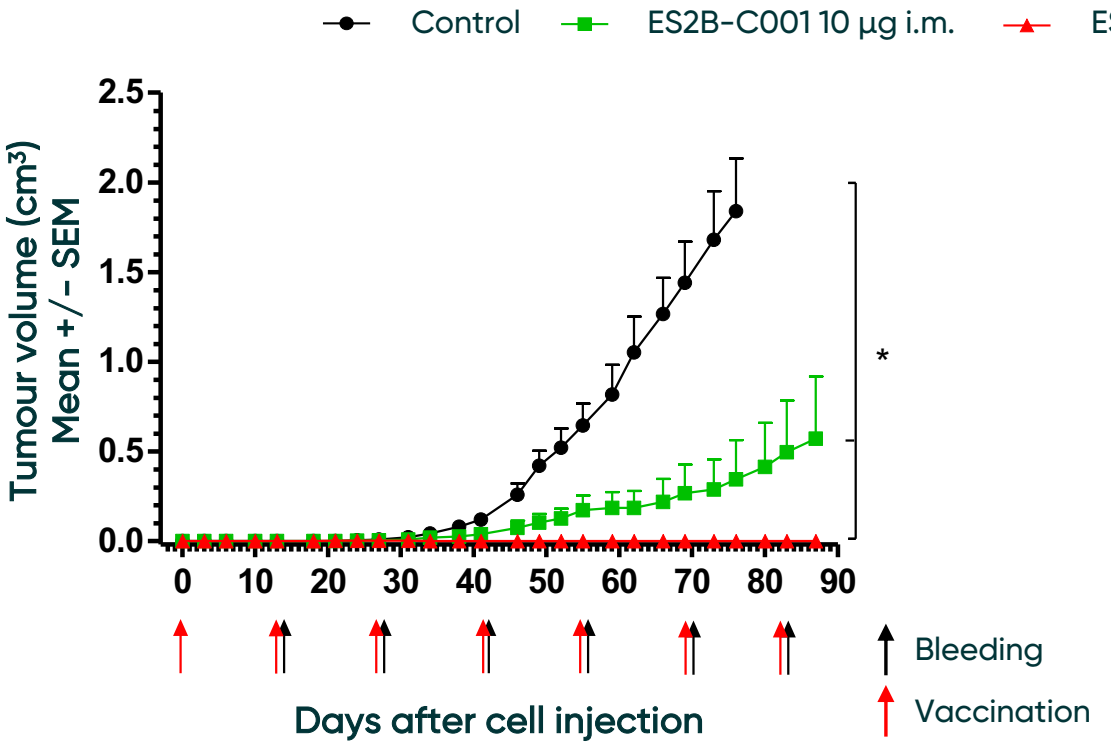


Studies conducted by Alma Mater Institute on Healthy Planet & DIMES, University of Bologna

Note: FVB mice are mice being challenged with tumours, while Delta16 mice spontaneously develop tumours and have been inoculated with tumour cells to accelerate tumour development
Ref. Ruzzi, et al., Biomedicines 2022, 10, 2654

Therapeutic vaccination in FVB mice

Completely inhibited QD cells tumour growth in FVB mice



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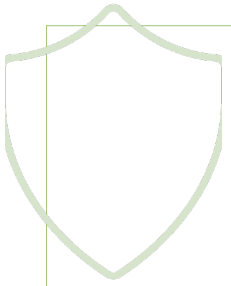
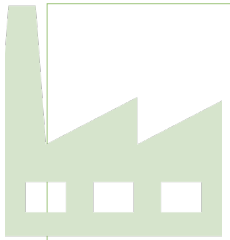
Status: rapidly approaching clinical readiness



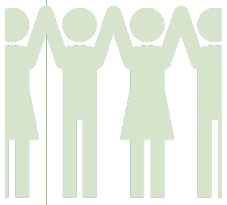
Preclinical safety

- Study is complete
- Draft report is near completion



Chemistry, manufacturing and controls

- GMP drug substance production initiated
- Stability studies underway



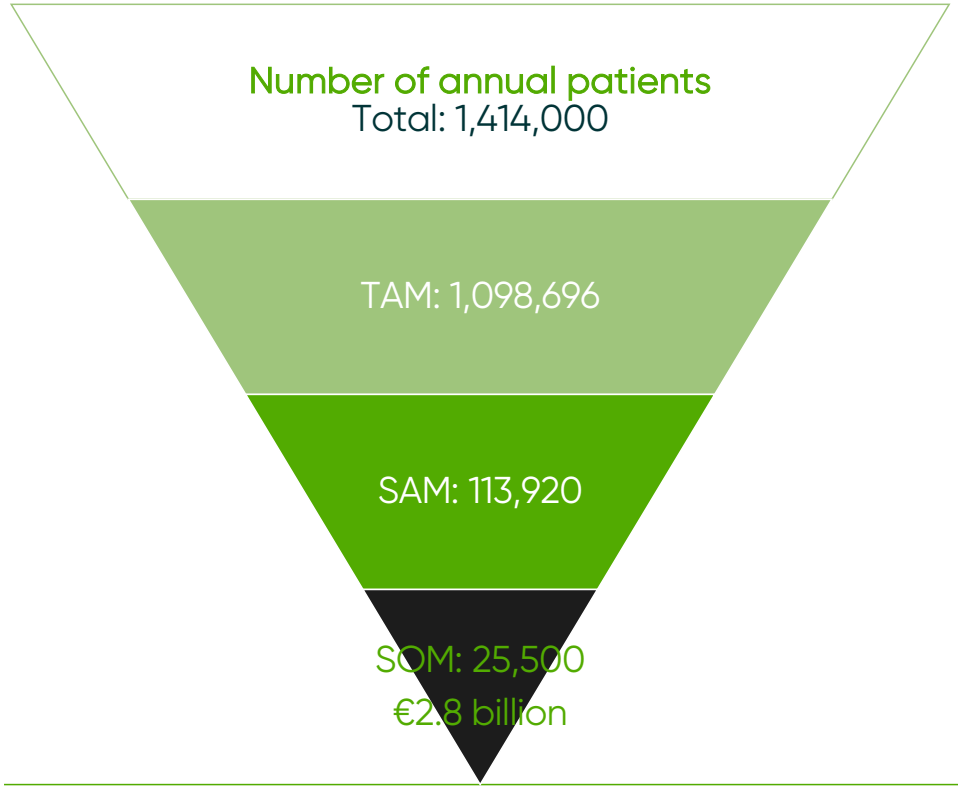
Clinical

- Design of Phase I clinical trial underway

Business development

- Life science business development consultancy engaged, and they are actively marketing ES2B-C001 to potential partners

Obtainable market estimated at €2.8 billion



Total market

Number of treated breast cancer patients per year
$32 billion global market size expected by 2026[3]

Total addressable market

In top 8 countries with early or advanced breast cancer

Serviceable addressable market (SAM)

Reduced to EU top 5 countries and US and estimated percent serviceable

Serviceable obtainable market (SOM)

Reduced by estimated penetration rate, based on first year at peak (20%)

Annual market value based on w.a. cost per patient in first year at peak penetration[2]

1 Mordor Intelligence, breast cancer therapeutics market, 2021.
2 Source: https://www.bizjournals.com/sanfrancisco/news/2020/06/29/cancer-genentech-fda-phesgo-herceptin-perjeta.html
Assuming no change in cost of treatment, i.e. general drug price inflation offset impact of increased competition

Oncology scientific advisory board

Advised by the leading specialists in oncology and specifically breast cancer

Dr. Giuseppe Curigliano, MD, PhD

Associate Professor of Medical Oncology at the University of Milano and the Head of the Division of Early Drug Development at the European Institute of Oncology, Italy (IRCCS). Dr. Curigliano is recognized among the leading experts in the world within the field of HER2 expressing breast cancer and has authored or co-authored more than 650 peer-reviewed scientific papers.

Dr. Javier Cortes, MD, PhD

Doctor in Medical Oncology, and Head of the International Breast Cancer Centre (IBCC) in Barcelona. Dr. Cortes He is an active member of the Spanish, European, and American Societies of Medical Oncology (SEOM, ESMO, ASCO), and is a member of expert panels that develop the treatment guidelines for metastatic breast cancer. He is the author of more than 380 publications.

Dr. Daniel Lenihan, MD, FACC, FESC, FIC-OS

Dr. Lenihan has been active in cardio-oncology, for over 25 years. He has previously held positions at MD Anderson Cancer Center in Houston, Texas, Vanderbilt University in Nashville, Tennessee, and Washington University in St Louis, Missouri. His current research projects include early phase clinical trials in cardio-oncology, heart failure and amyloidosis. Dr. Lenihan serves as editor on several scientific journals and has authored or co-authored more than 210 peer-reviewed scientific papers.

Dr. Ulrik Lassen, MD, PhD

Professor at University of Copenhagen, Department of Clinical Medicine. In 2017, he was appointed Head of the Department of Oncology at Copenhagen University Hospital, Rigshospitalet, Denmark. As a Clinical Oncologist he has been working with Phase 1 Oncology trials since 2005 and is ESMO board certified in Medical Oncology. Dr. Lassen has (co-)authored ~300 peer reviewed publications.

Dr. Michael Andersson, MD, DMSci

Dr. Andersson is a Clinical Oncologist working as consultant at the Breast Oncology Unit in the Copenhagen University Hospital, Rigshospitalet, Denmark since 1998. He has special interest in HER2-positive breast cancer and has published on and been Principal Investigator in several national and international studies of HER2-positive early and metastatic breast cancer. Dr. Andersson has authored or co-authored more than 140 peer reviewed publications.

Dr. Rupert Bartsch, MD

Associate Professor of medicine at the Medical University of Vienna in Austria and serves as the director of the Breast Cancer Programme at the Department of Oncology. Dr. Bartsch has a longstanding clinical and scientific focus on breast cancer and brain metastases. Together with his colleagues, he has published over 150 articles in peer-reviewed journals.

Investment highlights

Unmet medical need	• ExpreS2ion is developing a therapy for HER2+ breast cancer, the most common cancer
Market size	• Obtainable market conservatively estimated at €2.8 B
Technical validation	• Clinically validated platform technology in use by broad mix of proprietary and partner-driven vaccine candidates
Experienced team	• Proven leadership and experienced scientific team backed by knowledgeable Board & supportive SAB

Q&A

Investor Relations

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