



inPROBE[®]
Smart Cancer Diagnostics

DIAGNOSTIC SYSTEM

CORPORATE PRESENTATION

Marcin Staniszewski
Chief Executive Officer



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LUBLIN, POLAND

PHILADELPHIA, USA

HEADQUARTERS AND R&D CENTER

- inPROBE® sensors production
- Optoelectronics and molecular R&D
- Monoclonal antibodies lab production
- Virus diagnostic device platform development



PHILADELPHIA LABORATORY

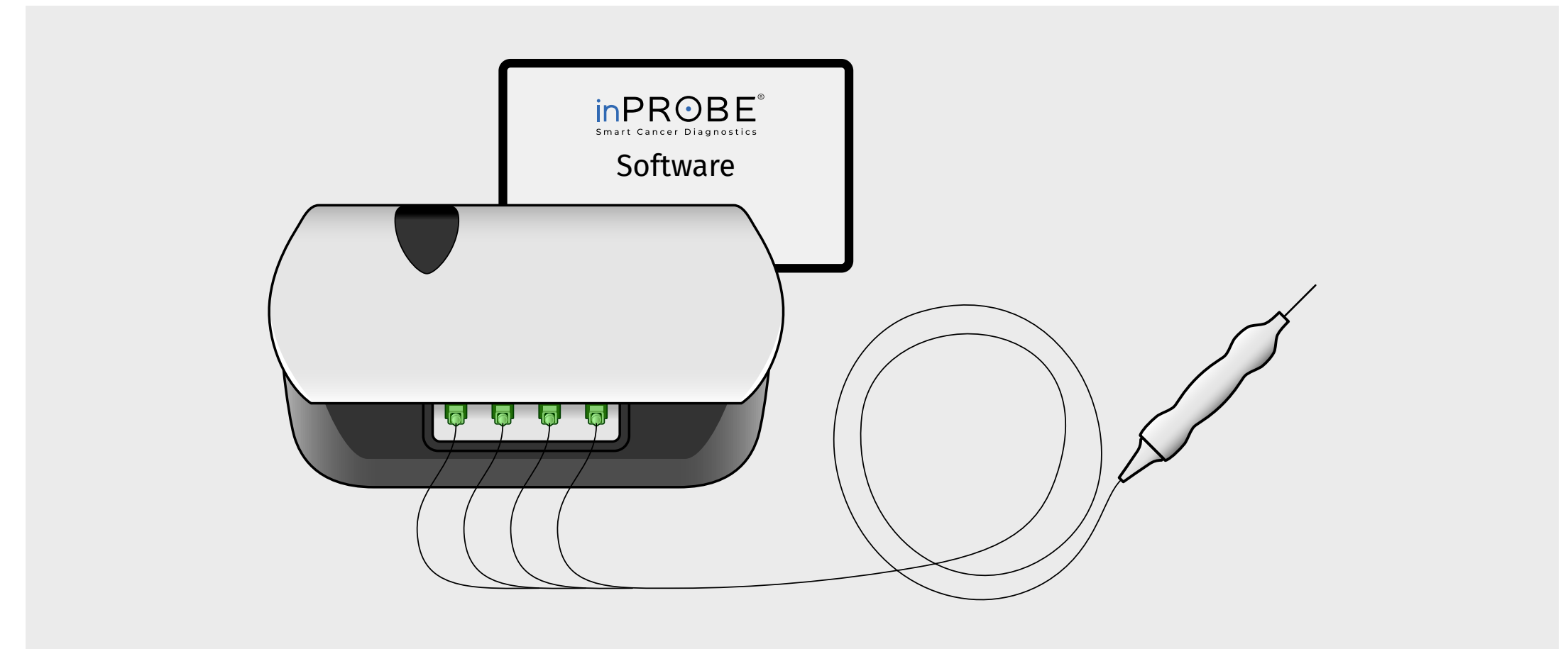
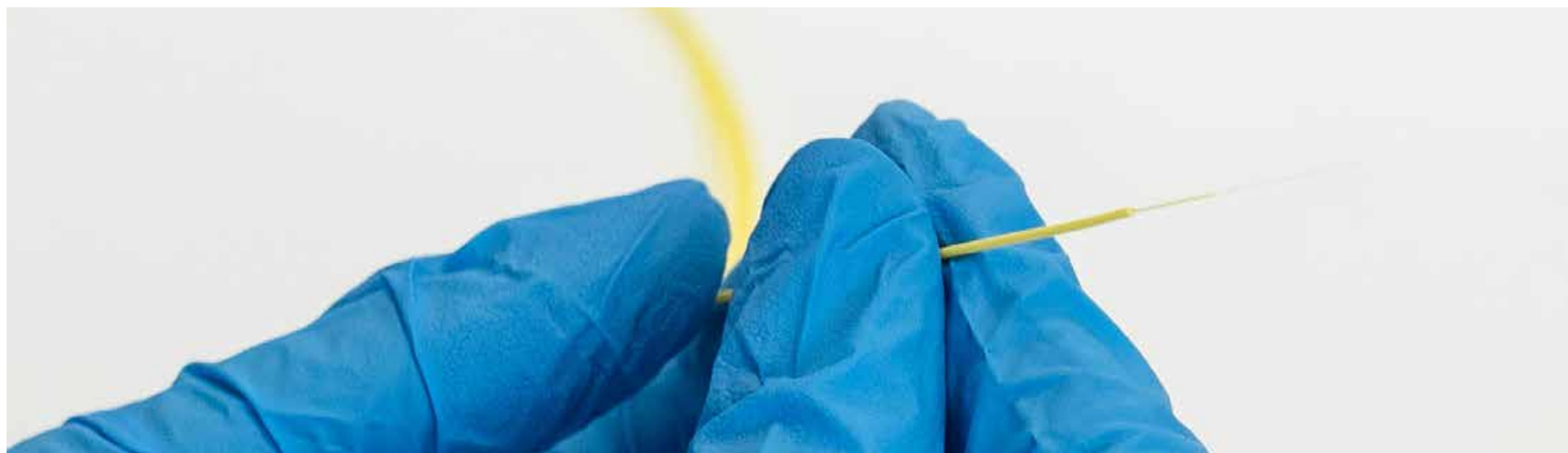
- Novel proteins and biomarkers development for cancer and eye research programs
- Protein cloning, expression and purification
- Protein characterization – properties and specificity



inPROBE® DIAGNOSTIC TECHNOLOGY

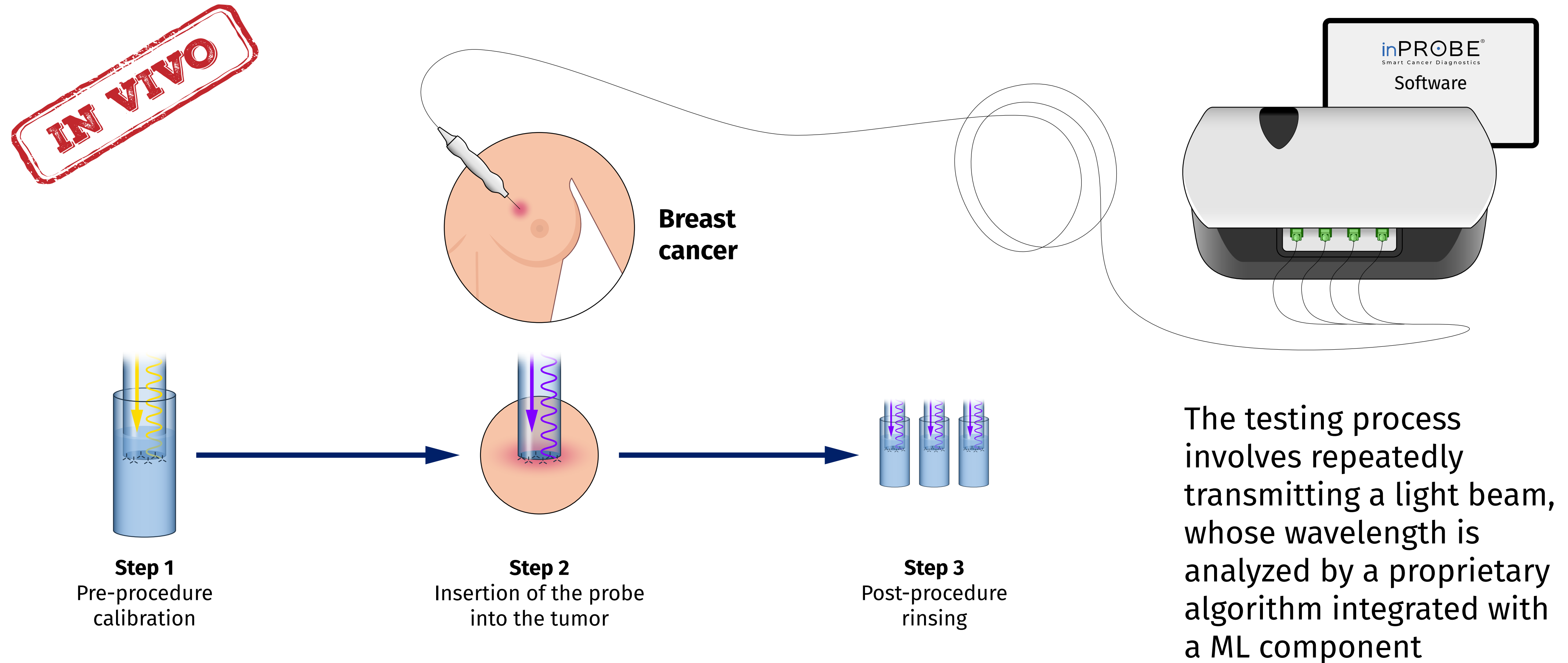
For both in-vivo and in-vitro applications

- **First photonic real-time immunoassay system**, utilizing molecular biology, chemistry, and biomedical engineering
- **Real-time detection of HER2 biomarker** and potentially also other proteins, antibodies and peptides, including other cancer biomarkers
- **Potential point-of-care diagnostic aid** to support and reduce the time to diagnosis



- **Novel analyzer with photonic sensor probe** consisting of 4 microprobes for biomarker detection in tissue and liquid samples
- **Each microprobe tip covered with monoclonal antibodies (mAbs)** for HER2 or other chosen target detection

inPROBE® Dx OVERVIEW – BREAST CANCER



inPROBE® CLINICAL STUDY (PoC)

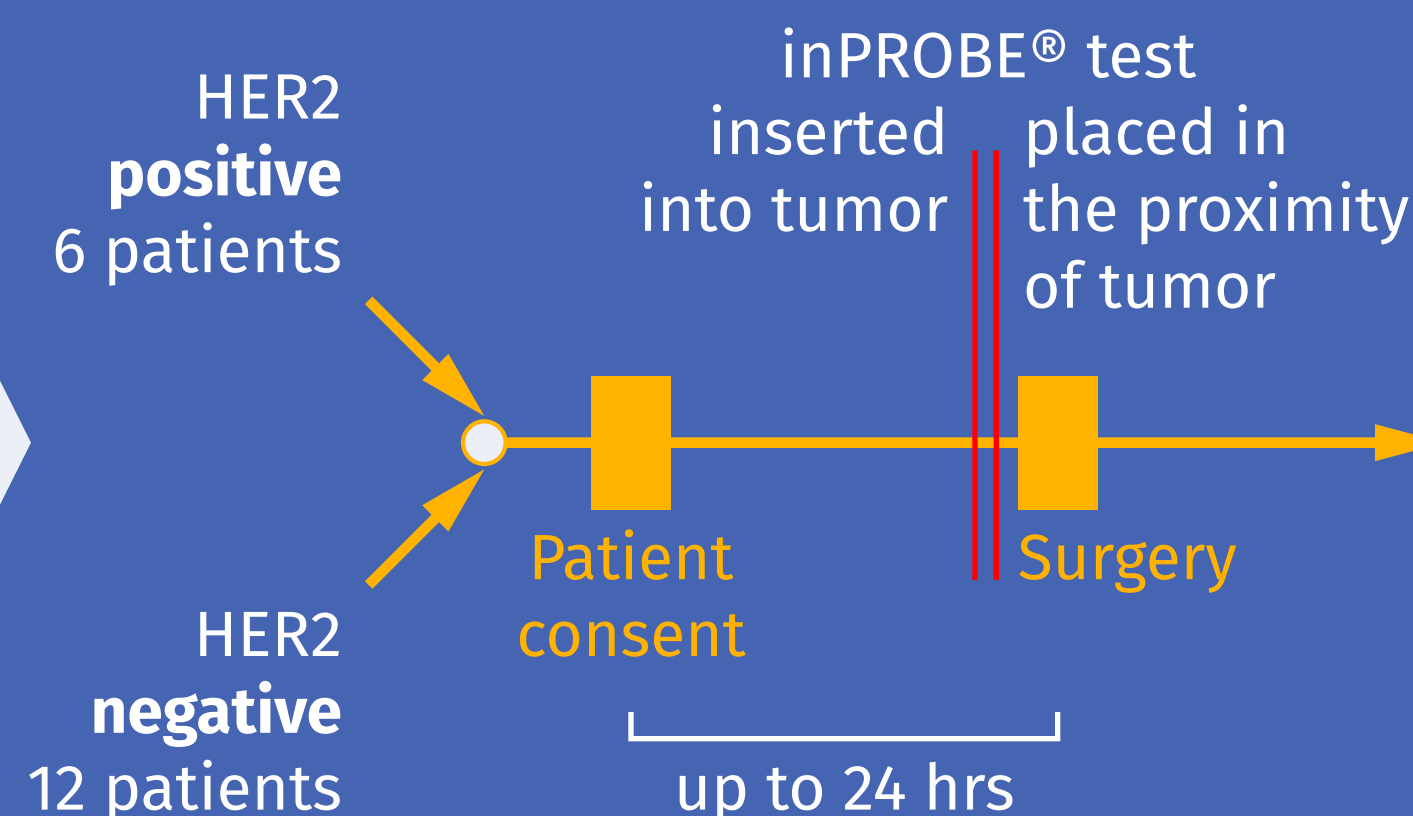
Open label, multicenter, single arm, Clinical Investigation of inPROBE® for the assessment of HER2 receptor expression in breast cancer completed March 2023



Study population

- 18 women with high risk breast cancer
- Age between 18 and 75 years old
- ECOG: 0 to 1
- Presence of breast cancer confirmed by core needle biopsy with a specified HER2 receptor status at the time of exam

Overall Study Design



Primary endpoint

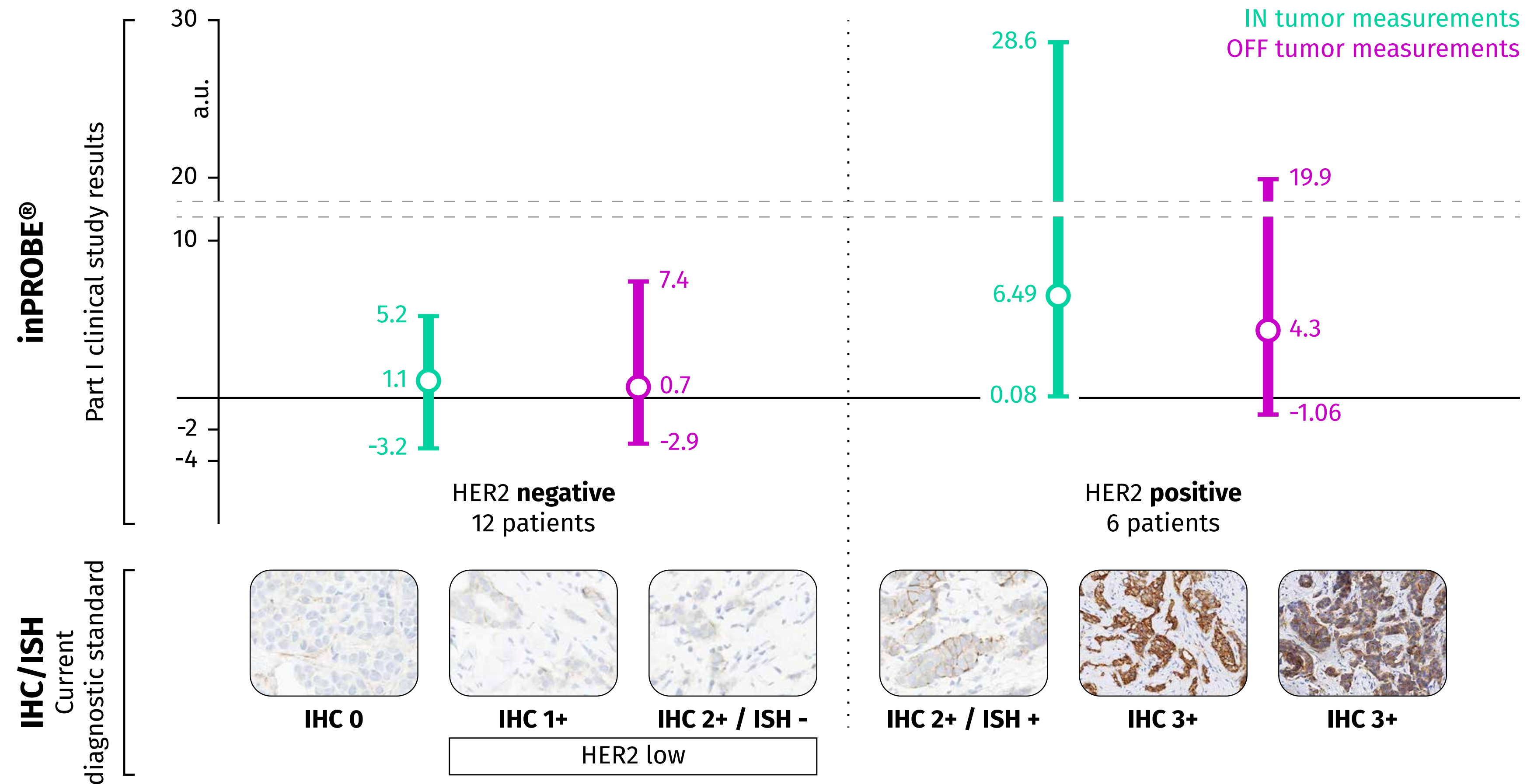
Determination of the range of HER2 receptor concentrations using inPROBE that correspond to the HER2 receptor status (positive/negative) determined by IHC/FISH (diagnostic standard).

Key secondary endpoints

Comparison of HER2 receptor concentrations detected using the inPROBE probe located in the tumor and its immediate surroundings (second probe) in HER2-positive patients.

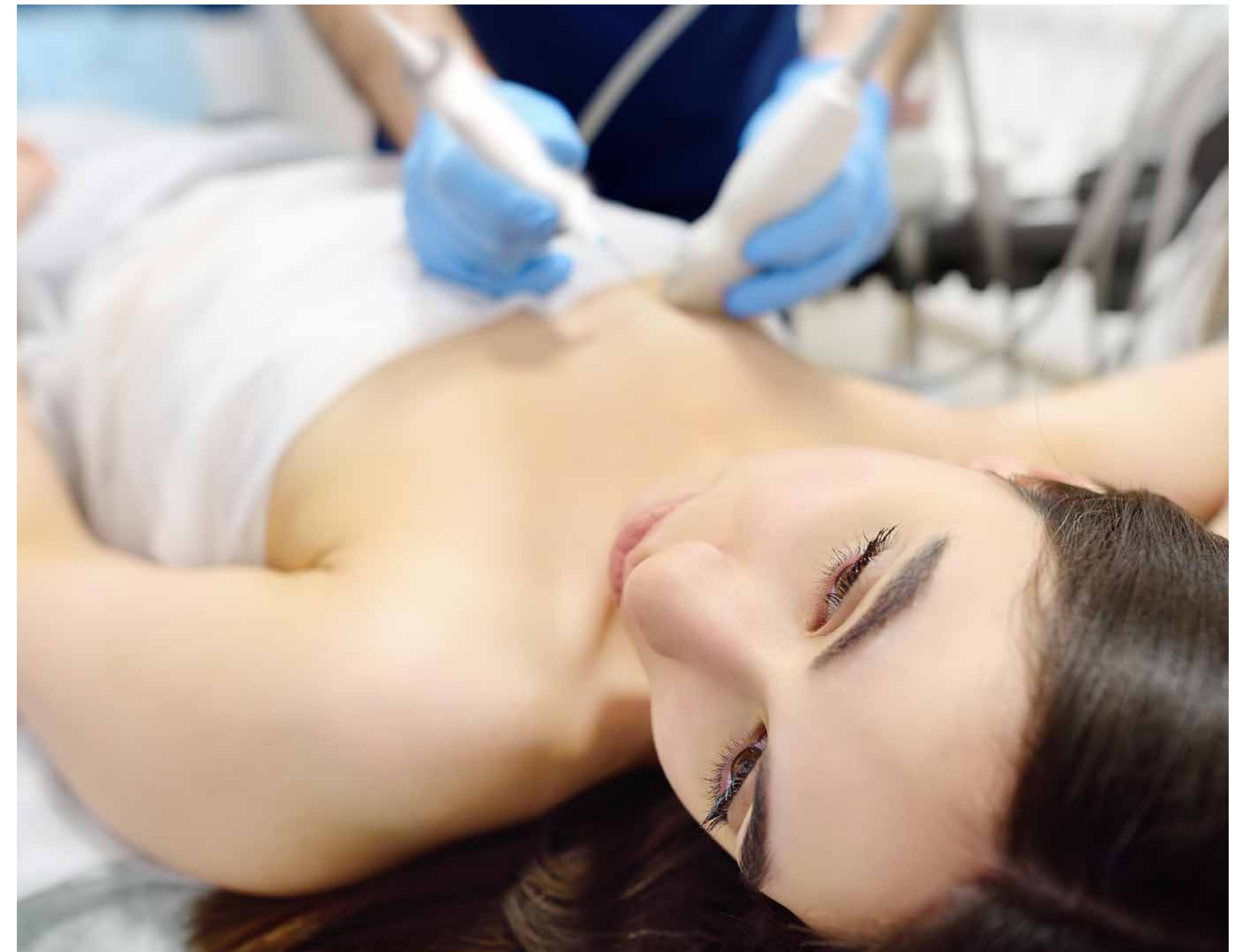
The occurrence of incidents involving damage, failure, or breakage of inPROBE during the diagnostic procedure, leading to AE/SAE.

inPROBE® CLINICAL STUDY (PoC)



inPROBE® CLINICAL STUDY (PoC) – PART II

- **Part II diagnostic efficacy study** previously planned to include 192 patients
- **We intend to adapt the Clinical Trial Protocol** to focus also on HER2-low patients
- **The final study design** to be consulted with US FDA
- **We are responding to the needs** of the current global trend in HER2-low and HER2-ultralow detection
- **Further inPROBE® calibration** vs. HER2 levels is planned to be performed



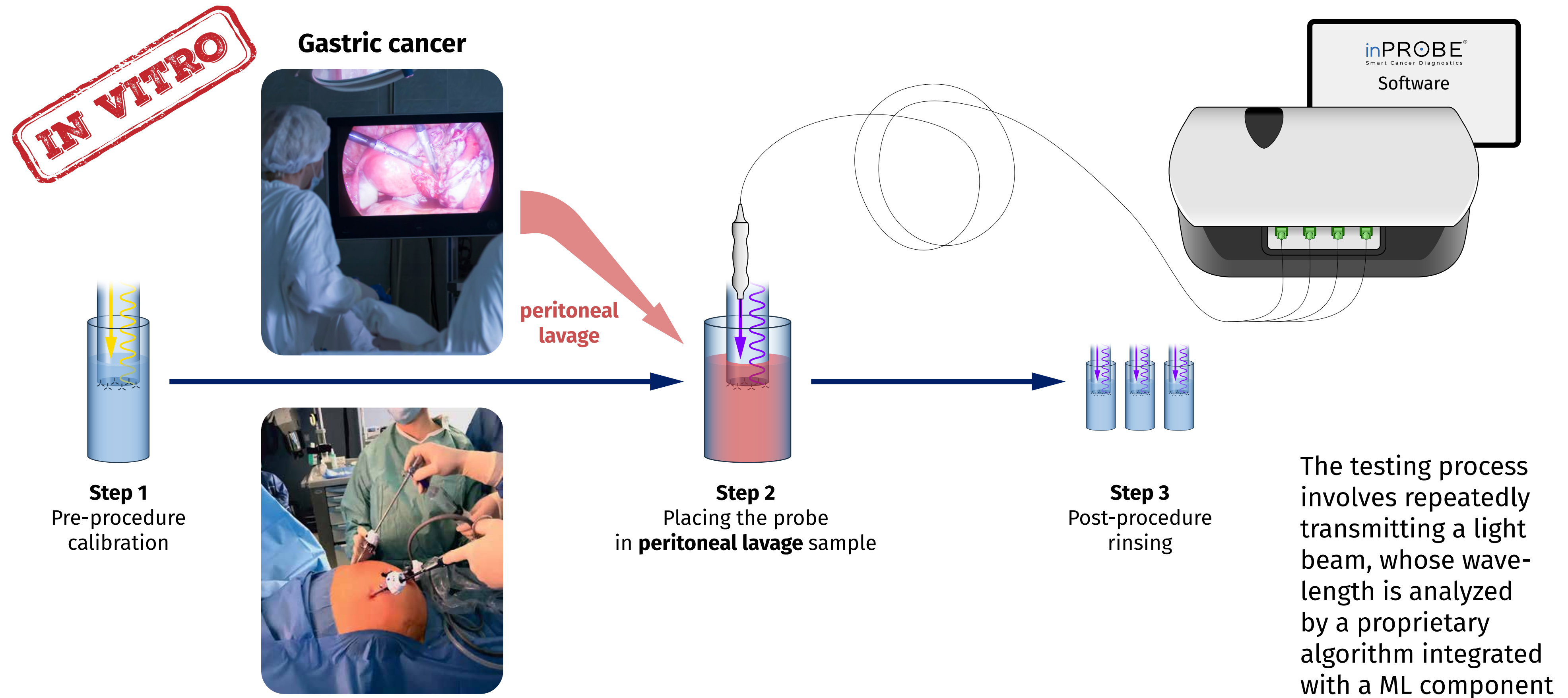
inPROBE® CASE REPORT GASTRIC CANCER

EORTC-NCI-AACR (2024)

- **inPROBE® recorded a positive signal for HER2 in tested peritoneal lavage samples**
- Assessment of HER2 expression in peritoneal lavage (PL) in gastric cancer (GC) patients is feasible and may be an effective method of increasing the identification rate for potential target therapy among selected patients
- inPROBE® technology presents an opportunity for HER2 determination in vitro during diagnostic laparoscopy in GC patients
- HER2 is an established predictive and prognostic biomarker in GC patients, assessed by immunohistochemistry (IHC) in tumor cells



inPROBE® Dx OVERVIEW – GASTRIC CANCER



HER2 OVEREXPRESSING CANCERS

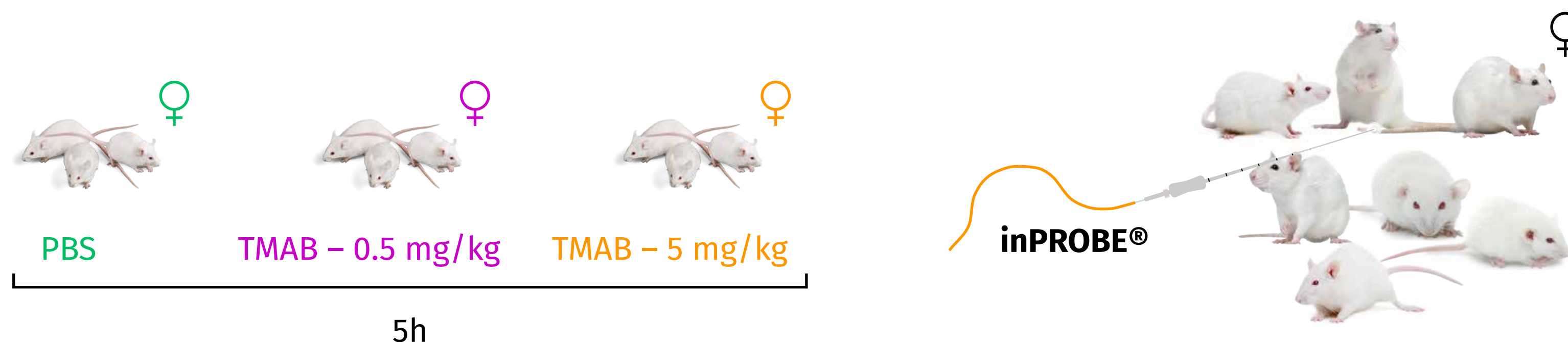
HER2-expressing cancers are a group of aggressive tumors often associated with faster progression and a poorer prognosis.

While HER2 positivity can accelerate tumor growth, targeted therapies have significantly improved patient outcomes. Accurate assessment of HER2 status is essential for selecting optimal treatments and advancing precision medicine research.



inPROBE® PRE-CLINICAL STUDY (PoC)

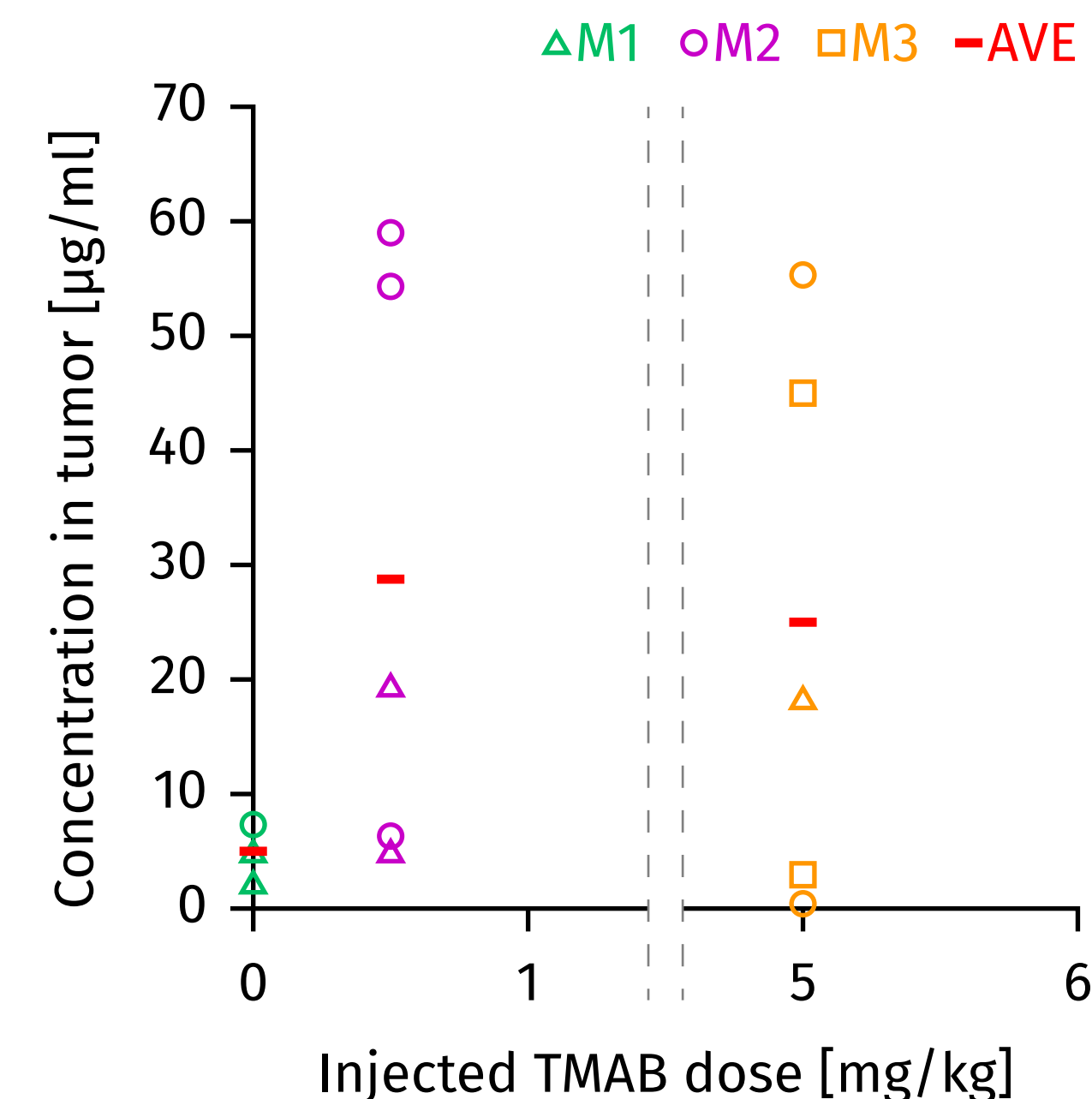
inPROBE® AS A PLATFORM FOR CANCER BIOMARKERS DETECTION IN SITU



Tissue accumulation of TMAB was assessed in vivo using sensor dedicated for TMAB and the mouse xenograft model (SCID mice) of a human HER2+ cancer (SK-OV-3).

The device safety was confirmed on rats by probe insertion into the mammary glands.

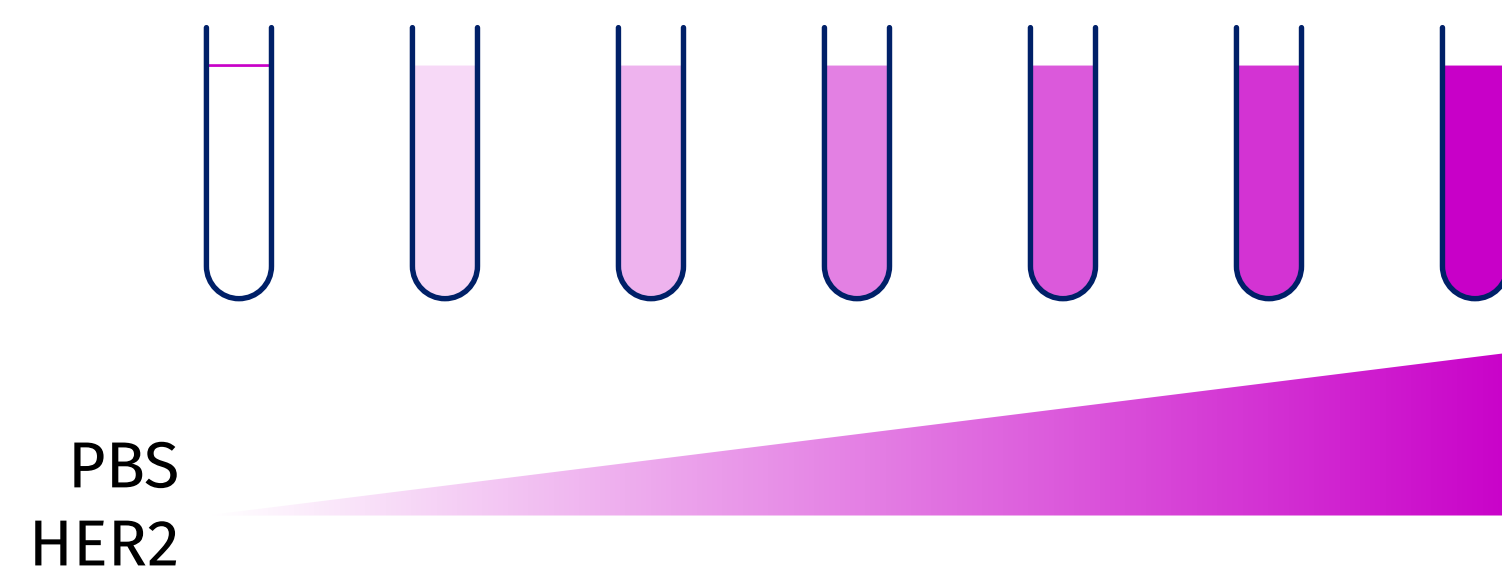
ESMO (2023), EORTC-NCI-AACR (2022)



After TMAB injection at 0.0, 0.5 or 5 mg/kg, measurements were performed inside tumor using inProbe sensor.

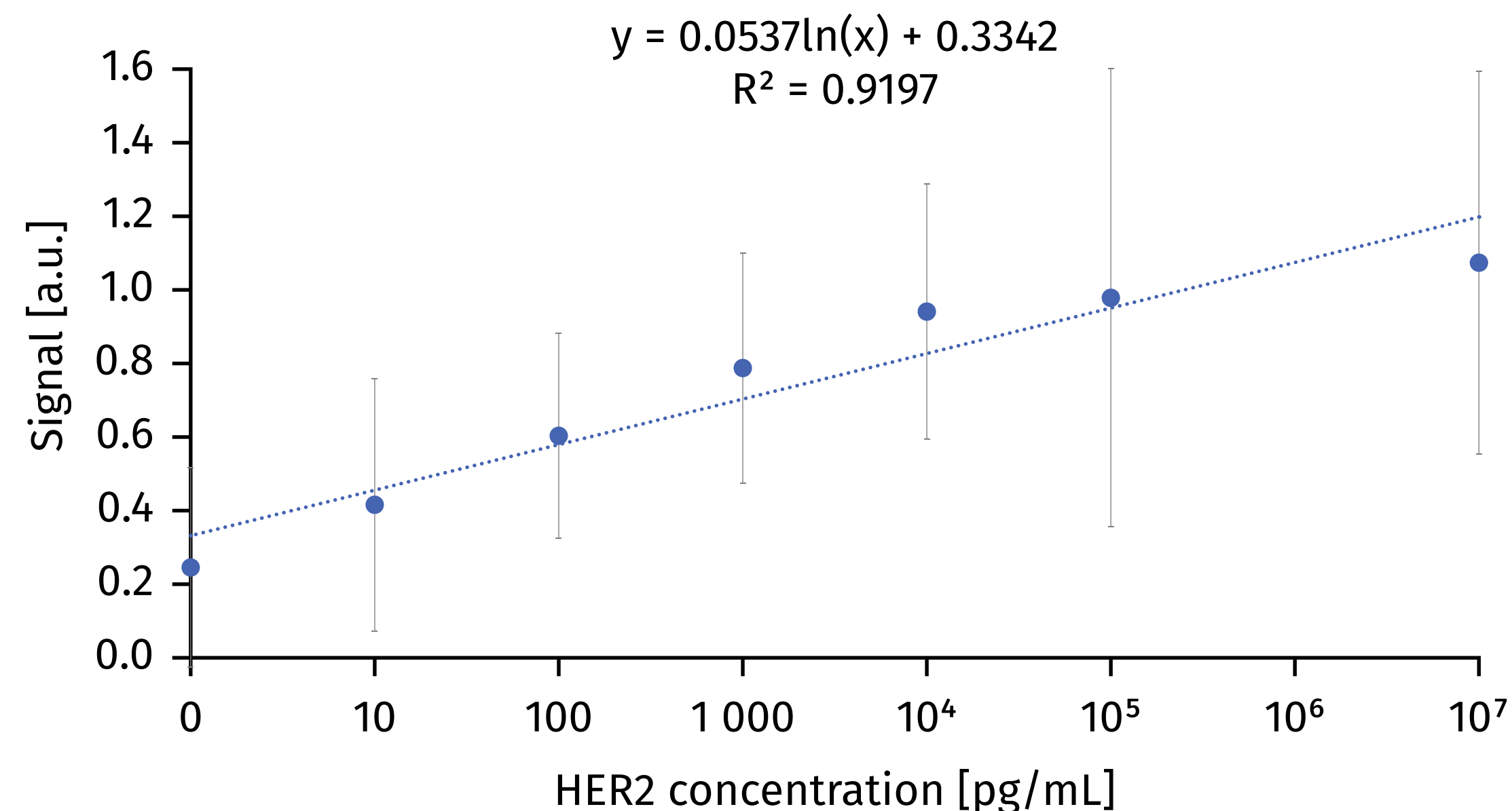
inPROBE® PRE-CLINICAL STUDY (PoC)

inPROBE® AS A PLATFORM FOR CANCER BIOMARKERS DETECTION IN LIQUID SAMPLES



inPROBE signal measurements (a.u.) was recorded for the PBS solution of recombinant human ECD HER2-Fc chimeric protein within a concentration range of 1 pg-10 mg/ml.

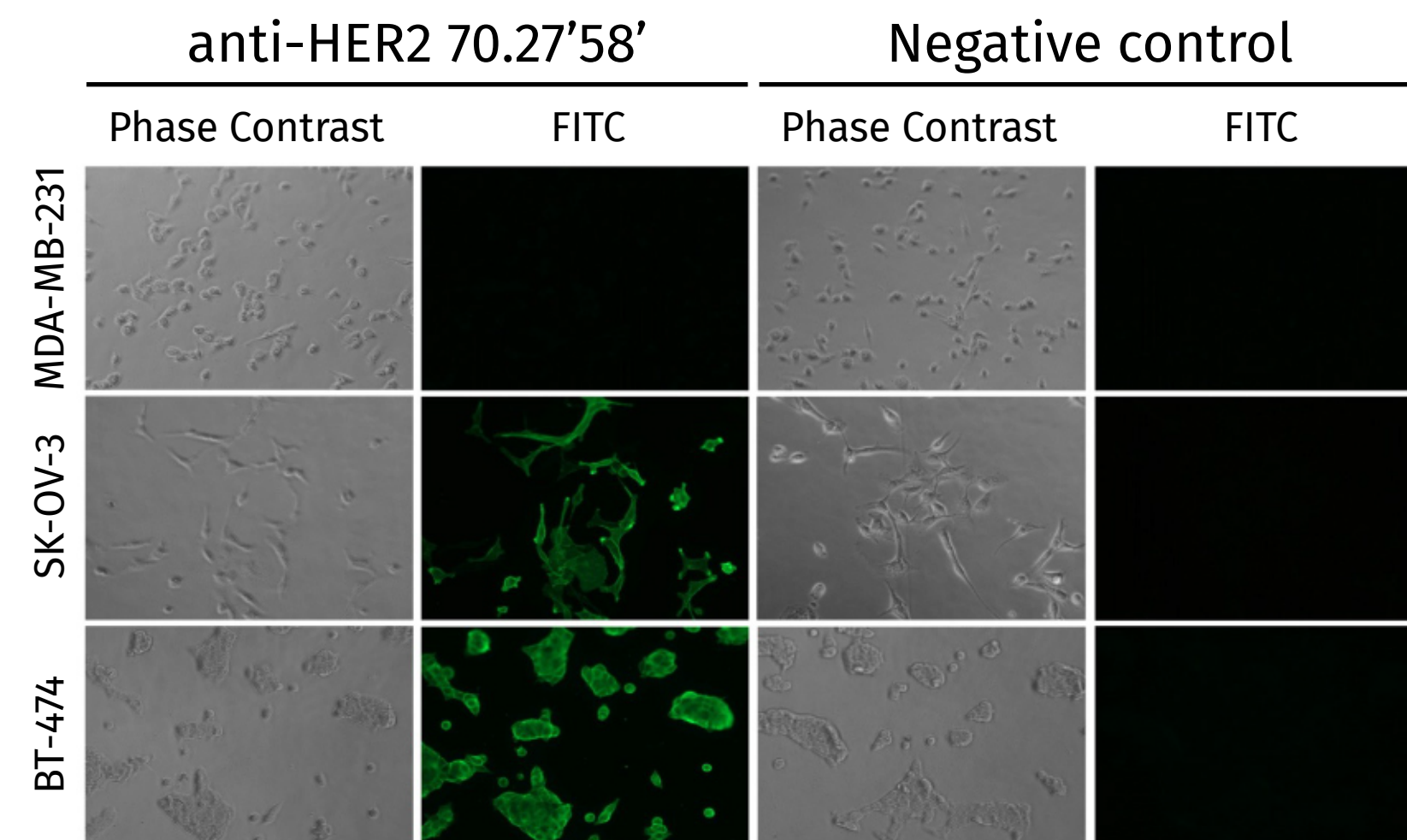
ESMO (2023), EORTC-NCI-AACR (2022)



Calibration curve for HER2 detection

inPROBE® PRE-CLINICAL STUDY (PoC)

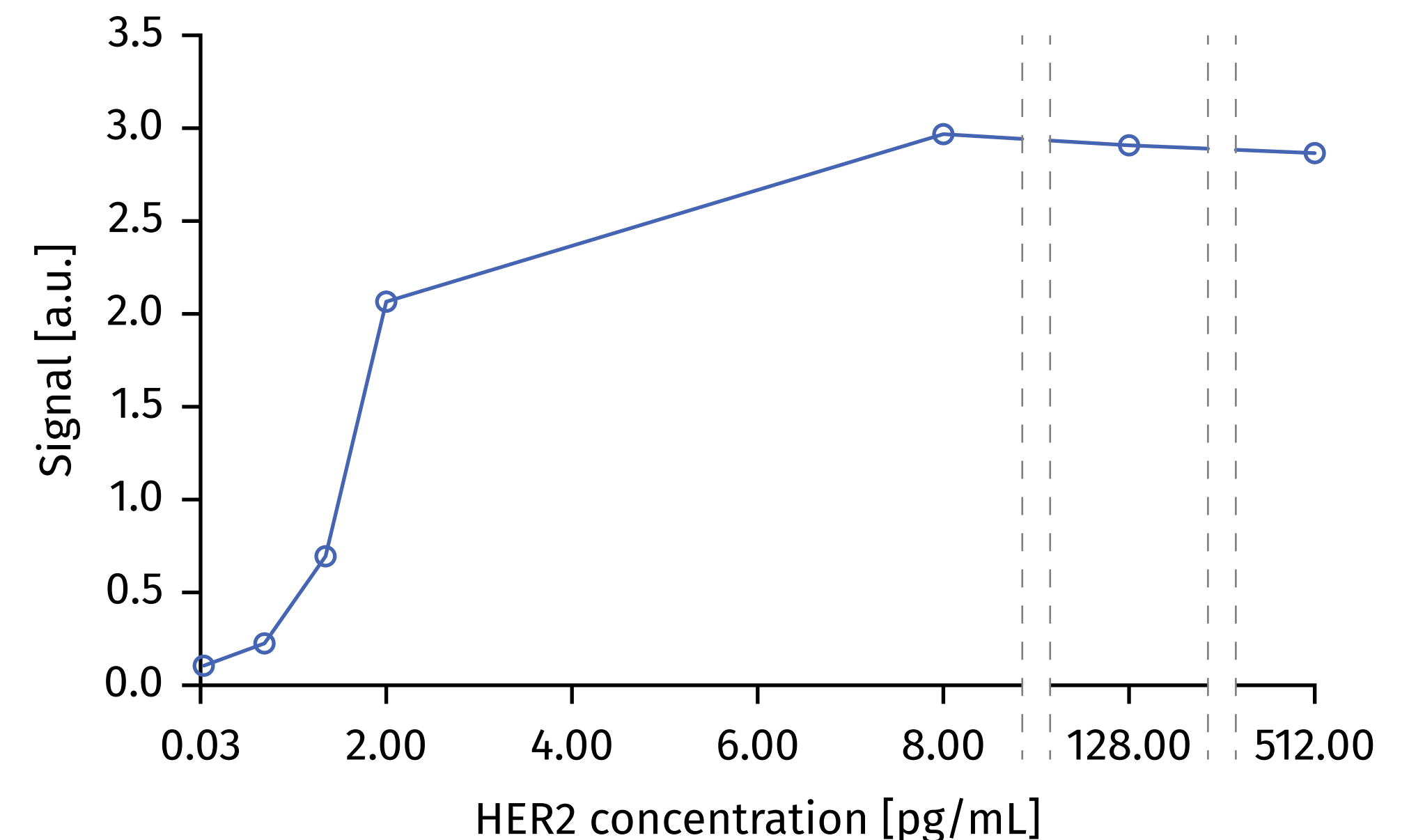
inPROBE® ANTIBODY SPECIFICITY AND SENSITIVITY FOR HER2 BIOMARKER DETECTION



Antibody specificity

HER2- (MDA-MB-231) and HER2+ (SK-OV-3, BT-474) human cancer cells were observed under light microscope (Phase contrast) and stained with SDS proprietary anti-HER2 antibody followed by FITC secondary antibody (green) or FITC secondary antibody alone (Negative control).

ESMO (2023), EORTC-NCI-AACR (2022)



Antibody sensitivity

ELISA on a plate with the immobilized recombinant ECD HER2-Fc chimeric protein was performed using the anti- HER2 antibody further applied for inPROBE sensor.

PUBLICATIONS 2024-2025

HER2-low and HER2-ultra-low 2024-2025 updates

ENHERTU® (fam-trastuzumab deruxtecan-nxki) approved in the US as first HER2-directed therapy for patients with HER2-low or HER2-ultralow metastatic breast cancer following disease progression after one or more endocrine therapies

PUBLISHED
27 January 2025

Based on DESTINY-Breast06 Phase III trial results which showed ENHERTU demonstrated superiority vs. chemotherapy with a median progression-free survival of more than one year

Approval brings AstraZeneca and Daiichi Sankyo's ENHERTU to an earlier HR-positive treatment setting and broadens the patient population eligible for treatment with a HER2-directed therapy to those with HER2-ultralow disease

Journal of Clinical Oncology®
An American Society of Clinical Oncology journal

Meeting Abstract: 2024 ASCO Annual Meeting I
FREE ACCESS | Breast Cancer—Metastatic | May 29, 2024

DESTINY-Breast07: Dose-expansion interim analysis of T-DXd monotherapy and T-DXd + pertuzumab in patients with previously untreated HER2+ mBC.

Authors: Fabrice Andre, Erika P. Hamilton, Sherene Loi, Carey K. Anders, Peter Schmid, Daniil Stroyakovskiy, Rafael Villanueva, ... SHOW ALL ... and Komal L. Jhaveri | [AUTHORS INFO & AFFILIATIONS](#)

Publication: Journal of Clinical Oncology • Volume 42, Number 16, suppl • <https://doi.org/10.1200/JCO.2024.42.16-suppl.1009>

ASCO Guidelines COLLEGE of AMERICAN PATHOLOGISTS

HER2 TESTING IN BREAST CANCER

GUIDELINE UPDATE

The 2018 ASCO-CAP recommendations for HER2 testing in breast cancer are affirmed.

The Panel recommends against creating new HER2 testing reporting categories such as "HER2 Low," because of a current lack of data on prediction of differential treatment response relative to patients with HER2 IHC 0 results. Standard semi-quantitative HER2 IHC results (0, 1+, 2+, 3+) should continue to be reported and best practices should be employed to distinguish these categories to identify patients eligible for approved HER2-related treatments, including those that meet DESTINY-Breast04 criteria (IHC 1+ or 2+/ISH negative). A new HER2 testing report comment is recommended to clarify the current clinical relevance of these semi-quantitative IHC results.

Wolff et al J Clin Oncol 2023
ascopubs.org/breast-cancer-guidelines

Abbreviations: ASCO, American Society of Clinical Oncology; CAP, College of American Pathologists; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, in situ hybridization.

Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: ASCO–College of American Pathologists Guideline Update

Antonio C. Wolff, MD¹ ; Mark R. Somerfield, PhD² ; Mitchell Dowsett, PhD³ ; M. Elizabeth H. Hammond, MD⁴ ; Daniel F. Hayes, MD⁵ ; Lisa M. McShane, PhD⁶ ; Thomas J. Saphner, MD⁷ ; Patricia A. Spears, BS⁸; and Kimberly H. Allison, MD⁹

DOI <https://doi.org/10.1200/JCO.22.02864>

ABSTRACT

PURPOSE To update ASCO–College of American Pathologists (CAP) recommendations for human epidermal growth factor receptor 2 (HER2) testing in breast cancer. The Panel is aware that a new generation of antibody–drug conjugates (ADCs) targeting the HER2 protein is active against breast cancers that lack protein overexpression or gene amplification.

ACCOMPANYING CONTENT

[Appendix](#)
[Data Supplement](#)

Accepted March 29, 2023
Published June 7, 2023

COLLEGE of AMERICAN PATHOLOGISTS

FAQs

Topic: HER2 Testing in Breast Cancer: Guideline Update
Date: June 7, 2023

What was the impetus of this guideline update?
In 2022, based on results of the DESTINY-Breast04 trial, the United States Food and Drug Administration (FDA) expanded the approval of the HER2 antibody–drug conjugate, trastuzumab deruxtecan, from metastatic breast cancer patients with HER2 protein over-expression/amplification to also include metastatic patients with HER2 IHC 1+ or 2+/ISH negative results. This clinical trial adopted new terminology, "HER2 Low," as short-hand for the HER2 IHC 1+ or 2+/ISH negative breast cancer cases that were in the trial (patients with IHC 0 results were excluded). Since the CAP/ASCO Guideline does not include "HER2 Low" as an interpretive category, a systematic review of the literature was performed to determine if changes to the guideline were needed.

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY
driving innovation in oncology

SPECIAL ARTICLE

ESMO expert consensus statements (ECS) on the definition, diagnosis, and management of HER2-low breast cancer

P. Tarantino^{1,2,3}, G. Viale⁴, M. F. Press⁵, X. Hu⁶, F. Penault-Llorca⁷, A. Bardia^{2,8}, A. Batistatou⁹, H. J. Burstein^{1,2}, L. A. Carey¹⁰, J. Cortes^{11,12}, C. Denkert¹³, V. Diéras¹⁴, W. Jacot¹⁵, A. K. Kouttras¹⁶, A. Lebeau¹⁷, S. Loibl^{18,19}, S. Modi²⁰, M. F. Mosele²¹, E. Provenzano²², G. Pruneri^{13,23}, J. S. Reis-Filho²⁴, F. Rojo²⁵, R. Salgado^{26,27}, P. Schmid²⁸, S. J. Schnitt^{2,29}, S. M. Tolaney^{1,2}, D. Trapani^{1,30}, A. Vincent-Salomon³¹, A. C. Wolff³², G. Pentheroudakis³³, F. André³⁴ & G. Curigliano^{1,30,*}

SDS OPTIC POSTERS

Full texts available upon request

2024 ASCO[®]
ANNUAL MEETING

May 31–June 4, 2024
McCormick Place | Chicago, IL & Online

#ASCO24

Innovative fiber-optic-based approach of HER2 expression quantitative assessment using inPROBE technology.

Dariusz M. Stencel, Marcin Staniszewski, Wojciech Polkowski, Andrzej Kurylcio, Przemysław Kopyto, Magdalena Staniszewska; SDS Optic Inc., Lublin, Poland; Medical University of Lublin, Lublin, Poland; Medical University, Lublin, Poland

Is HER2-negative breast cancer really negative? Clinical implication of novel assessment method using inPROBE technology.

Dariusz M. Stencel, Wojciech Polkowski, Andrzej Kurylcio, Przemysław Kopyto, Marcin Staniszewski, Magdalena Staniszewska; SDS Optic Inc., Lublin, Poland; Medical University of Lublin, Lublin, Poland; Medical University, Lublin, Poland; Institute of Health Sciences Faculty of Medicine The John Paul II Catholic University of Lublin, Lublin, Poland



SAN ANTONIO
BREAST CANCER
SYMPOSIUM[®]
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AACR
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for Cancer Research

DECEMBER 10–13, 2024
HENRY B. GONZALEZ CONVENTION CENTER • SAN ANTONIO, TX





P3-01-29 – Open, single-arm clinical trial with innovative inPROBE[®] technology for *in vivo*, real-time, quantitative HER2 expression assessment
D. Stencel¹; W. Polkowski¹; A. Kurylcio¹; P. Kopyto¹; P. Bogacz¹; K. Gęca¹; M. Staniszewski¹; M. Staniszewska¹
¹SDS Optic SA, Lublin, Poland; ²Department of Surgical Oncology, Medical University of Lublin, Poland



Abstract
HER2 expression status on breast cancer (BC) cells significantly implies therapy and prognosis. Defining of HER2-low and ultra-low BC subtype requires developing of more sensitive and qualitative diagnostic tests. We developed a new, innovative inPROBE[®] technology for quantitative, real-time, *in vivo* assessment of HER2 expression on BC cells, merging molecular biology with photonics technology. We conducted an interventional, open-label, single-arm safety and efficacy clinical trial in female BC patient with known HER2 status with the primary endpoint to correlate HER2 concentration ranges detected with microprobe with HER2 receptor status identified by IHC/FISH. The key secondary endpoint was to assess the relation between inPROBE[®] assessment in tumor mass and surrounding area in HER2-positive BC patients. inPROBE[®] technology could become promising tool, providing the oncologist with new, modern, real-time, *in vivo* diagnostic method; thus, meeting a pressing clinical need.

Introduction
Traditional methods such as immunohistochemistry (IHC) and fluorescence *in situ* hybridization (FISH) depend on subjective assessment of tissue samples, sometimes leading to imprecise results. This can result in either under-treatment or over-treatment, highlighting the need for more accurate diagnostics. The inPROBE[®] technology marks a pivotal shift in oncology towards personalized medicine, particularly in the assessment of protein expression like HER2 in breast cancer. This novel *in vivo* approach allows the examination with optic fiber probe directly in the patient's body without the need for tissue extraction. The interaction between the protein and the biosensor generates an optical signal, which is converted into a numerical value representing the protein expression level, thereby providing objective and real-time results.

Materials and Methods
We conducted an interventional, open-label, single-arm safety and efficacy clinical investigation in female BC patient aged 18 to 75 years with known HER2 status based on IHC/FISH (clinicaltrials.gov NCT05415943). The patient population in this study was represented by women with a confirmed diagnosis of breast cancer based on a core needle biopsy and known HER2 receptor expression status, referred for surgical treatment. A total number of 22 patients were enrolled and signed ICF; however, 18 patients were finally analysed for efficacy-related objectives, while 21 for safety profile analysis. The objectives were fulfilled. Out of 18 patients included in PP1, 12 (66.7%) had HER2 negative status and 6 (33.3%) had HER2 positive status confirmed by standardized methods (IHC / FISH). inPROBE microprobe was inserted into the breast (with two simultaneous punctures) prior to the surgical resection of breast tumour with known HER2 receptor status. In one patient HER2 status at the time of the procedure was unclear and verified after resection. The **primary endpoint** was identification of HER2 concentration ranges detected with microprobe corresponding to HER2 receptor status identified by IHC/FISH. The **key secondary endpoint** was to assess the relation between inPROBE assessment in tumor mass and surrounding area in the direct tumor vicinity in HER2-positive patients. **Safety endpoint:** occurrence of defects, damage, failures and fractures of probe during the diagnostic procedure, leading to AE / SAE.

Results
The study met its primary endpoint, i.e. it was determined the HER2 receptor concentration ranges detected with inProbe corresponding to HER2 receptor status (positive/negative) identified by the current diagnostic standard (IHC/FISH). The study did not meet secondary endpoint in terms of correlation of HER2 receptor concentrations detected with the inProbe probe located in the tumour and in the direct tumour area in HER2-positive patients. However, statistically significant positive correlation of moderate magnitude was observed in overall population (HER2-positive and HER2-negative patients), mainly driven by HER2-negative patients, possibly due to difference regarding sample size. Safety profile of inPROBE device seems to be good and promising. No adverse events were observed during the course of the study.

Table 1. Comparison of inPROBE optical results between groups by HER2 status.

inProbe [®] optical results in	HER2-pos (N=6)	HER2-neg (N=12)	P-value
Mean of all measurements			
Mean (SD)	6.497 (10.939)	1.178 (2.387)	
Median [IQR]	2.511 [1.540, 3.625]	1.324 [0.138, 2.836]	.250
Range	0.08, 28.67	-3.20, 5.21	
Median of all measurements			
Mean (SD)	6.161 (10.578)	1.683 (1.568)	
Median [IQR]	2.109 [1.489, 3.169]	1.705 [0.988, 2.131]	.291
Range	0.30, 27.65	-0.71, 5.21	
Min of all measurements			
Mean (SD)	4.893 (10.125)	-3.634 (6.360)	
Median [IQR]	1.144 (0.941, 2.110)	-0.644 [-5.826, 0.300]	.041
Range	-1.62, 25.38	-16.41, 3.08	
Max of all measurements			
Mean (SD)	8.782 (12.509)	5.012 (2.685)	
Median [IQR]	4.681 [2.233, 6.106]	4.463 [2.771, 7.091]	.750
Range	1.34, 33.99	1.69, 10.40	
*Wilcoxon rank-sum exact test			

Conclusions

- The current standard IHC/FISH method for HER2 expression assessment could be questioned and advances in targeted therapy may require more sophisticated technologies.
- inPROBE[®] technology shows promise of becoming a tool providing the oncologist with new, modern, real-time, *in vivo* diagnostic method.
- Tumor HER2 status might be determined without need for tissue biopsy, lowering a risk of cancer dissemination
- Further studies are needed to establish the correlations between HER2 expression assessed with inPROBE[®] with the results obtained with standard IHC/FISH methods
- Further clinical development of inPROBE[®] can be continued with no risks for patients' safety.

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Website: <https://sdsoptic.pl>
Phone: +48 605428690



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1. Stencel D, Polkowski W, Kurylcio A, Kopyto P, Bogacz P, Gęca K, Staniszewski M, Staniszewska M. Innovative fiber-optic-based approach of HER2 expression quantitative assessment using inPROBE technology. *Ann Oncol*. 2024;35(1):1-10. doi:10.1016/j.annonc.2023.11.010.
2. Stencel D, Polkowski W, Kurylcio A, Kopyto P, Bogacz P, Gęca K, Staniszewski M, Staniszewska M. Innovative fiber-optic-based approach of HER2 expression quantitative assessment using inPROBE technology. *Ann Oncol*. 2024;35(1):1-10. doi:10.1016/j.annonc.2023.11.010.

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Smart Cancer Diagnostics

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inPROBE® POTENTIAL FUTURE APPLICATIONS

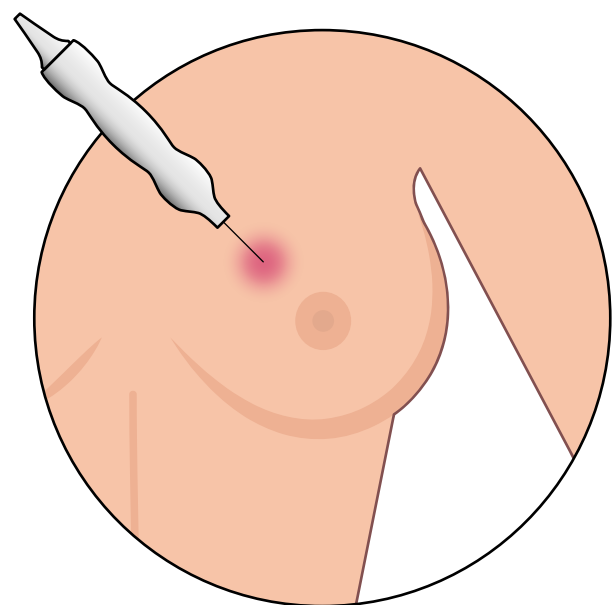
Clinical needs

- disease risk for prognosis evaluation
- clinical diagnosis support
- therapeutic intervention monitoring

Possible detection

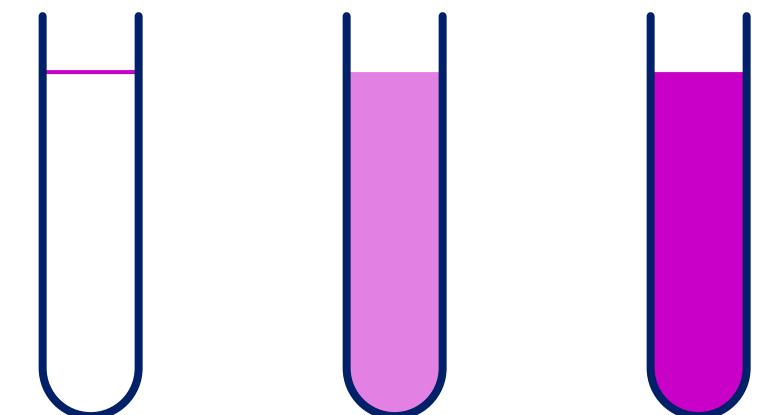
- targeted proteins and ADCs
- cell membrane fragments
- vesicles and viruses

SOLUBLE BIOMARKERS DETECTION AND QUANTIFICATION (AFTER A SENSOR CALIBRATION)



In vivo (in situ)
Solid tumours biomarkers
eg. breast cancer (HER2)

In vitro (liquid samples)
• cerebrospinal fluid
• blood
• urine
• saliva



COMPETITIVE LANDSCAPE

inPROBE® is less-invasive, point-of-care and less expensive

Feature	inPROBE®	Current diagnostic standard		ELISA	ForteBIO Octet®
		IHC	ISH		
Tissue Biopsy	NO	YES	YES	YES	YES
Real time result	YES	NO	NO	NO	NO
Location of test	In vivo in vitro point of care	In vitro – external laboratory	In vitro – external laboratory	In vitro – external laboratory	In vitro – external laboratory
Quantitative results	YES	NO	NO/YES	NO	YES
Estimated investment needed (€k)	30	260	110	80	120
Core technology	Photonics Biosensing	Immunohistochemistry	Fluorescence/ Molecular Cytogenetic	Enzyme-linked Immunosorbent Assay	Photonics Biosensing

COMPETITIVE LANDSCAPE (CONT.)

inPROBE® is less-invasive, point-of-care and less expensive

Feature	inPROBE®	Northern Blot	SAGE (Serial Analysis of Gene Expression)	MicroArray	RT-PCR (qPCR)
Tissue Biopsy	NO	YES	YES	YES	YES
Real time result	YES	NO	NO	NO	NO
Location of test	In vivo in vitro point of care	In vitro – external laboratory	In vitro – external laboratory	In vitro – external laboratory	In vitro – external laboratory
Quantitative results	YES	NO	NO	NO	YES
Estimated investment needed (€k)	30	X	X	X	X
Core technology	Photonics Biosensing	Hybridization of immobilized RNA	Transcriptomic	Chip binding / RNA isolated bath	Transcription

SENIOR MANAGEMENT TEAM



Marcin Staniszewski

Co-Founder

CEO

Chief Technology Officer



Magdalena Staniszewska

Co-Founder

CSO

Head of Scientific Advisory Board



SDS OPTIC FACILITY

- Own machine park valued at approximately \$1M for the production of photonic components for inPROBE® biosensors
- Ability to scale up production from laboratory-scale to semi-industrial
- Full control of the quality of all production processes
- Planned production capacity of over 50,000 biosensors per year
- Confirmed compliance of process, technological, and manufacturing documentation audit by Orange (photonic division)
- **Dedicated Clean Room production and quality control facility compliant with EN ISO 14644**
- **Monoclonal antibody production facility**



PHILIPS & CSEM / MEDPHAB

The Analyzer (detection device) industrialization and certification

- Scaling up from the clinical to the commercial prototype of the inPROBE® detection device (analyzer) and initiating medium-scale contract production
- Scaling up the project of optoelectronic and electronic elements of the analyzer
- Production (Philips) of a commercial prototype of the analyzer with comprehensive testing of its functional and systemic features
- Compliance with EU-MDR and EN ISO 13485 regulations
- Two optoelectronic system prototypes (System 1 & System 2) designed and tested, with quality set up and documentation preparations at PHILIPS – System SW 1 and System 2 Sprint
- 3D printed Housing design for System 1 (outer & inner) done with with elements and materials bill
- Risk analyses complianed with EU-MDR and EN ISO 14791 regulations
- Software designed according to EN 62304 and delivered

PHILIPS

Engineering Solutions

csem
FACING THE CHALLENGES OF OUR TIME

MedPhab
Photonic Medical Devices

Funded by:



ANTIBODY MANUFACTURING SERVICES



MONOCLONAL ANTIBODIES CAPABILITIES

for academic, biopharmaceutical and diagnostic entities

CUSTOM MONOCLONAL ANTIBODY SERVICES

Monoclonal antibodies discovery platform: hybridoma antibody production – up to 30 mg per month.

Hybridoma cell
recovery



Cell
adaptation



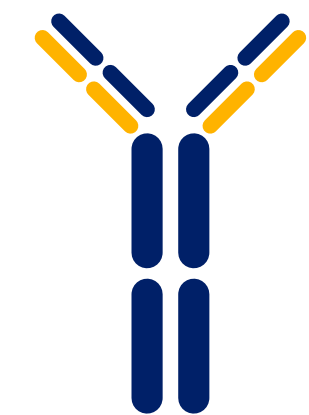
Cell
culture



Antibody
purification



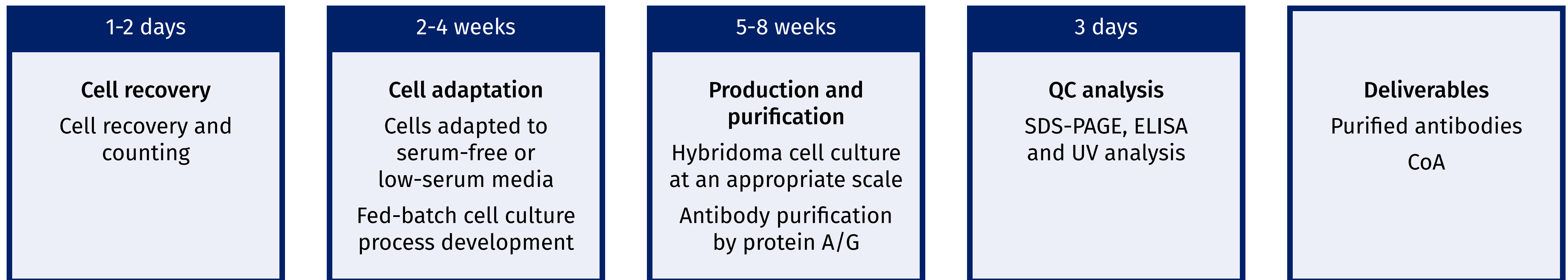
Product
delivery



MONOCLONAL ANTIBODIES CAPABILITIES

for academic, biopharmaceutical and diagnostic entities

HYBRIDOMA CELL CULTURE AND ANTIBODY PRODUCTION TIMELINE



- High purity
- Batch-to-batch reproducibility

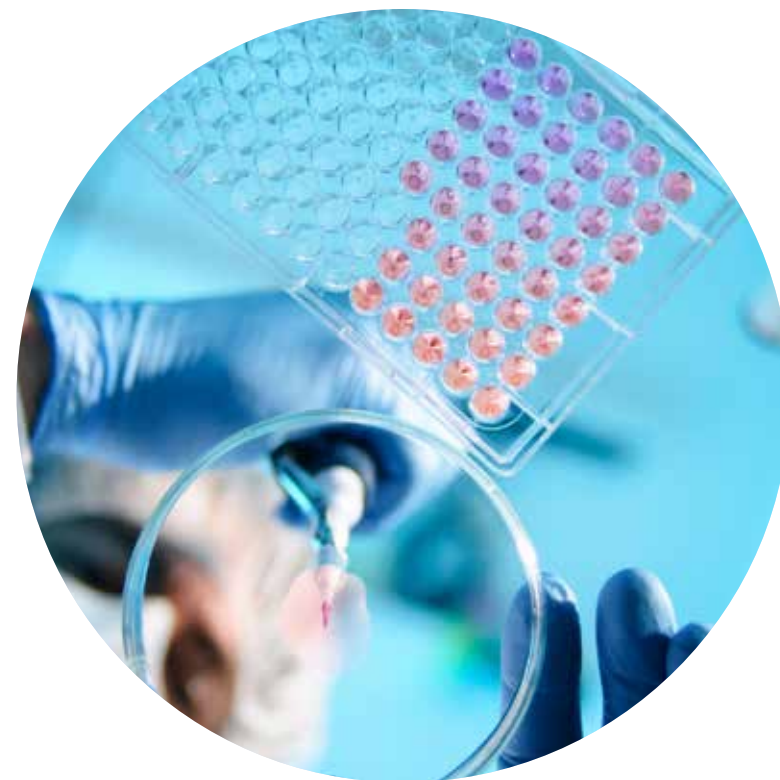
- Low-serum or serum-free media
- Mycoplasma tested by PCR

INVESTMENT & PARTNERING OPPORTUNITIES



+€22 mln

raised for inPROBE®
research & development



€10 mln

EIB financing (venture
debt for 2024-2028)



€4 mln

Highest ever
Horizon2020 SME grant



€4 mln

Publicly listed

THANK YOU

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