



# INVESTOR PRESENTATION

NOVEMBER 29<sup>th</sup>, 2021

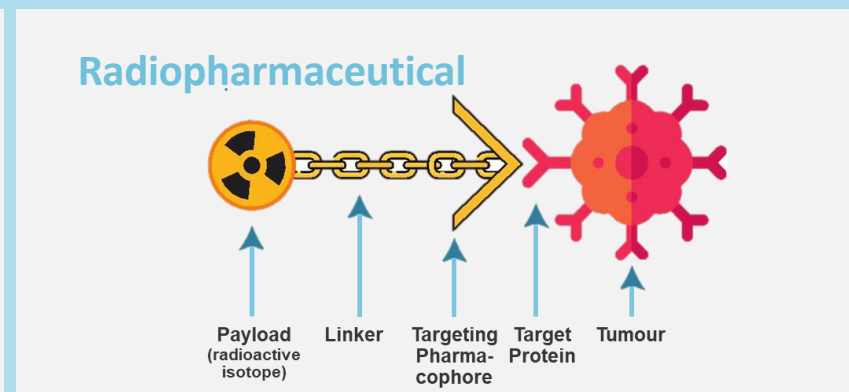
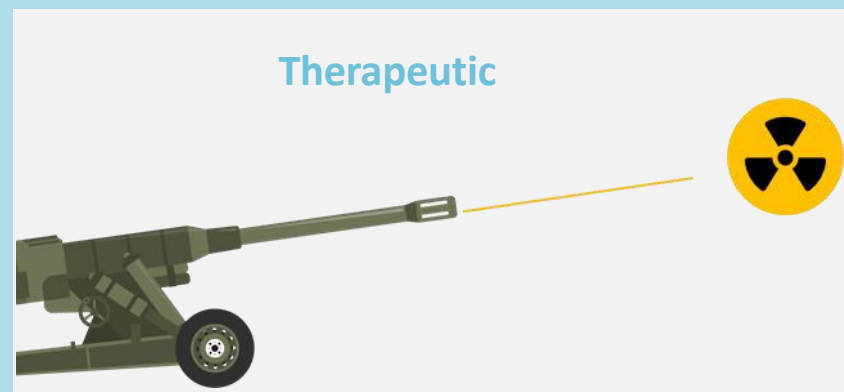
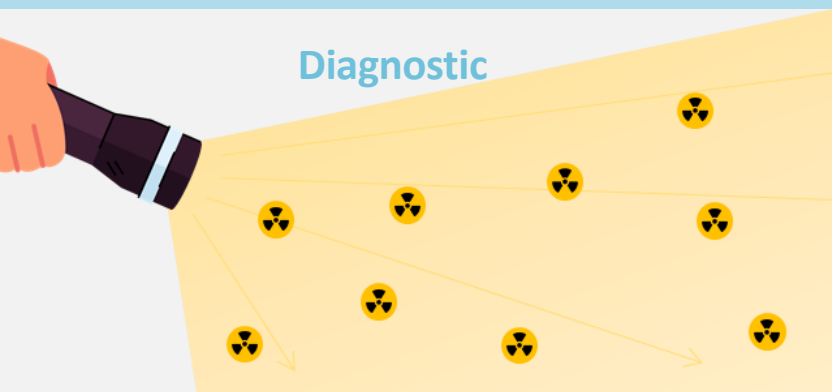


RADIOPHARM THERANOSTICS

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# WHAT ARE RADIOPHARMACEUTICALS?



## Radiopharmaceuticals deliver radioactive isotopes to the tumour cells

- Diagnostics: low energy radioisotopes which allow physicians to **SEE** and to measure disease within the body
- Therapeutics: high energy particle emitters to **TREAT** malignant tumours, cancer, and other diseases

## Process involves attaching a radioactive isotope to a targeting agent such as a small molecule or antibody

- Peptides or mAbs specifically binds tumour cells
- Peptides or mAbs are loaded with Imaging Isotopes to **SEE** the tumour cells
- Peptides or mAbs are loaded with Therapeutic Isotopes to **TREAT** tumour cells, being extremely selective to damage cancer cells DNA, while not damaging healthy tissues

# INVESTMENT HIGHLIGHTS

Highly prospective portfolio comprising clinical & pre-clinical stage radiopharmaceutical assets for both diagnostic & therapeutic applications

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Four distinct and well differentiated clinical platforms spanning peptides, small molecules & antibodies – 133 patients dosed to date

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Deep clinical program on-foot with five Phase 2 clinical trials and two Phase 1 clinical trials ongoing

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One of the deepest clinical pipelines on the ASX

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Commercially attractive license arrangements

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Broad & robust IP portfolios



World-class management team comprising C-suite executive team recruited from the most prestigious radiopharmaceuticals companies & universities globally

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Manufacturing utilizing many of the widely adopted radioisotopes in the existing supply chain

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Raised A\$50m in IPO to list on the ASX  
25 November 2021

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Rich news flow generated by four platforms over next 24 months

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R&D engine secured with lab and facilities access via Sponsored Research Agreements

# FOUR DISTINCT & WELL DIFFERENTIATED PLATFORMS

BALANCED PORTFOLIO OF SMALL MOLECULES, PEPTIDES AND MONOCLONAL ANTIBODIES,  
WITH DIAGNOSTIC & THERAPEUTIC POTENTIAL

## Pivalate

Phase 1 & Phase 2 | N= 49

- Phase 2 kidney diagnostic
- Phase 2 Brain mets diagnostic
- Phase 2 glioma diagnostic
- Phase 2 solid tumour
- Pre-clinical companion therapeutic

## Nano-mAbs

Phase 1 | N=74

- Phase 2 HER-2 breast diagnostic
- Phase 1 HER-2 breast therapeutic
- Pre-clinical PD-L1 NSCLC Therapeutic
- Pre-Clinical Trop 2 & PTK7 diagnostic

## Avb6 Integrin

Phase 1 | N=10

- Phase 1 diagnostic pancreatic, head & neck
- Pre-clinical therapeutic, pancreatic, head & neck

## PSA-mAb

Pre-clinical

- Pre-clinical diagnostic and therapeutic in prostate cancer



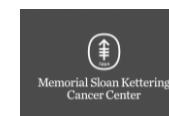
KING'S  
College  
LONDON



UNIKLINIK  
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University Medicine Essen  
University Hospital



LUNDS  
UNIVERSITET

# 18F-Pivalate PHASE 1 & PHASE 2 N=49

Pivalate  
Phase 1 & Phase 2 | N= 49



RPT 18F-FPIA radiotracer is the invention of Professor Eric Aboagye of Imperial College London

NIH U.S. National Library of Medicine

ClinicalTrials.gov

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	<input type="checkbox"/>	Recruiting	Measuring Fatty Acid Oxidation in Gliomas Using 18F-FPIA PET/MRI	• Glioma	• Other: PET/MRI	• Imperial College Healthcare NHS Trust/ Imperial College London, United Kingdom
2	<input type="checkbox"/>	Recruiting	Measuring Fatty Acid Oxidation in Cerebral Metastases Using 18F-FPIA	• Cerebral Metastases	• Other: PET/MRI	• Imperial College Healthcare NHS Trust London, United Kingdom
3	<input type="checkbox"/>	Not yet recruiting	18F-FPIA PET/CT Imaging in Patients With Solid Tumours	• Cancer • Tumor, Solid	• Drug: [18F]Fluoropivalate ([18F]Fluoro-2,2-Dimethylpropionic Acid) • Procedure: PET/CT	
4	<input type="checkbox"/>	Not yet recruiting	Measuring Treatment Response in Metastatic Renal Cell Cancer Using FPIA PET/CT	• Metastatic Renal Cell Carcinoma	• Other: PET/CT	• Imperial College Healthcare NHS Trust/Imperial College London, United Kingdom

Based on a short chain carbohydrate which utilizes the early steps of fatty acid oxidation and is very stable

In comparison to the clinical standard in PET imaging, 18F-FDG, in prostate and brain cancers, 18F-FPIA showed superior imaging performance, and was equally good for 2 breast cancer models

Phase 1a in 24 healthy patients completed

Phase 1b study complete in glioma

Phase 2 kidney and Brain mets studies currently recruiting

Phase 2 study in resected solid tumours to be opened in Nov/Dec 2021

Phase 2 study for glioma to be opened in Nov/Dec 2021

Sponsored Research Agreement to be entered with Imperial over three years with a focus on therapeutic use

Candidate selection of Pivalate therapeutic to be completed by 1 half 2022

The technology is based on single-domain camelid antibodies known as nano-mAbs derived from camels

The technology is the invention of Dr Hong Hoi Ting formerly of Oxford University, GE Healthcare, and Shanghai National Technology Centre

A therapeutic product is made by a genetic engineered camelid antibody labelled with a radioisotope of therapeutic radiation.

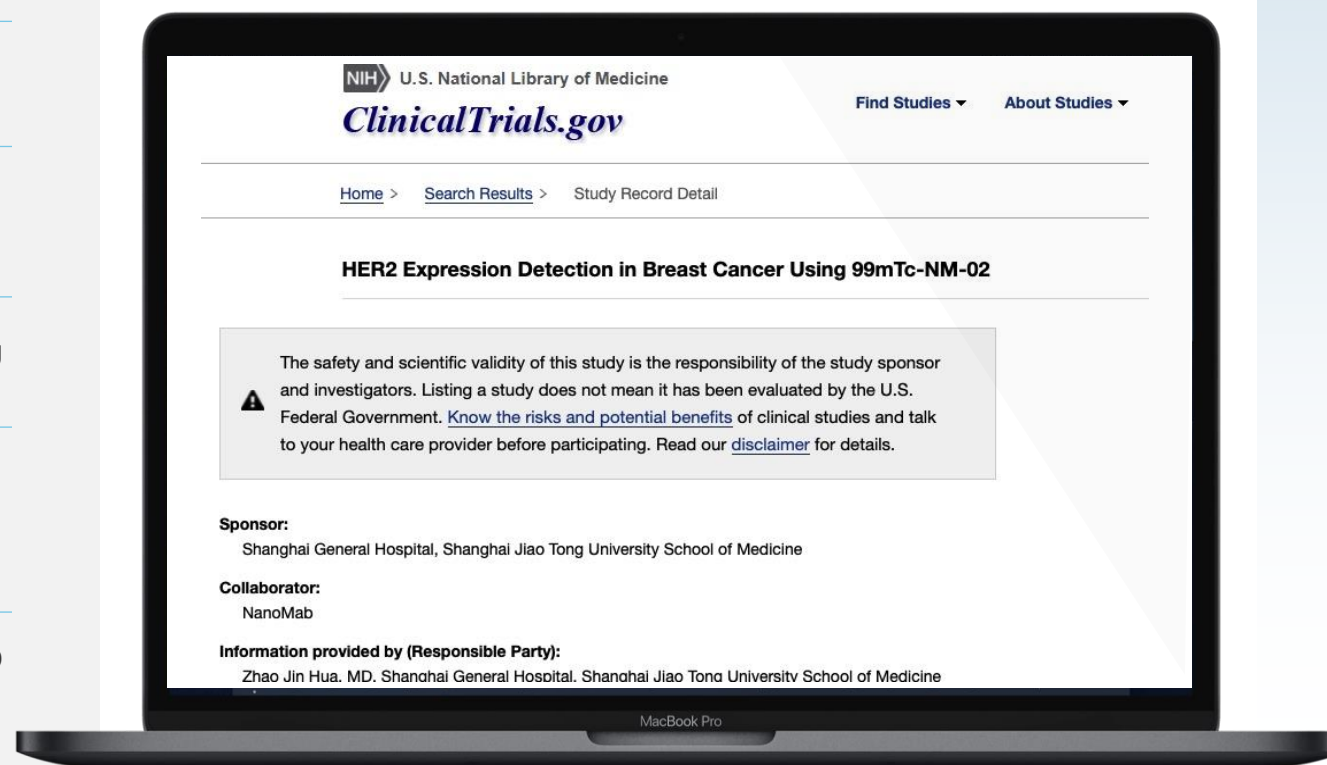
This therapeutic product is paired with a diagnostic, using the same antibody vector but labelled with a lower radiation radioisotope for imaging

Initial targets are HER-2 for breast cancer, PD-L1 for non small cell lung cancer, TROP-2 for TNBC, PTK7 for multiple solid tumours.

A Phase 1 imaging study for HER-2 breast cancer has been completed on 33 patients in Shanghai & Germany. A Phase 1 therapeutic compassionate use study is expected to dose the first patient before December 2021

A Phase 1 imaging study for PD-L1 in NSCLC has been completed in 40 patients in Shanghai & London

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# AV $\beta$ 6 INTEGRIN PHASE 1 IMAGING N=10

AV $\beta$ 6 Integrin  
Phase 1 | N=10

AV $\beta$ 6 is the invention of internationally regarded integrin expert Professor Johannes Notni, formerly at the Technical University of Munich and now Professor at Essen University

A Phase 1 compassionate use diagnostic clinical study is ongoing in Germany in pancreatic and head & neck cancer, with 10 patients to date. Published in European Journal of Nuclear Medicine Sep 2021.

AV $\beta$ 6 is a strong and selective ligand for a cell surface protein called  $\alpha$ v $\beta$ 6-integrin. As such, it can accumulate in tissue areas characterized by high  $\alpha$ v $\beta$ 6-integrin levels

There is compelling evidence that  $\alpha$ v $\beta$ 6-integrin is found in many of the most challenging cancers, such as pancreatic carcinoma, cervical, head-and-neck, and certain lung cancers

AV $\beta$ 6 offers an unparalleled performance for radiolabelling with Gallium-68

AV $\beta$ 6 is a highly promising clinical candidate for early detection of the aforementioned conditions by PET imaging

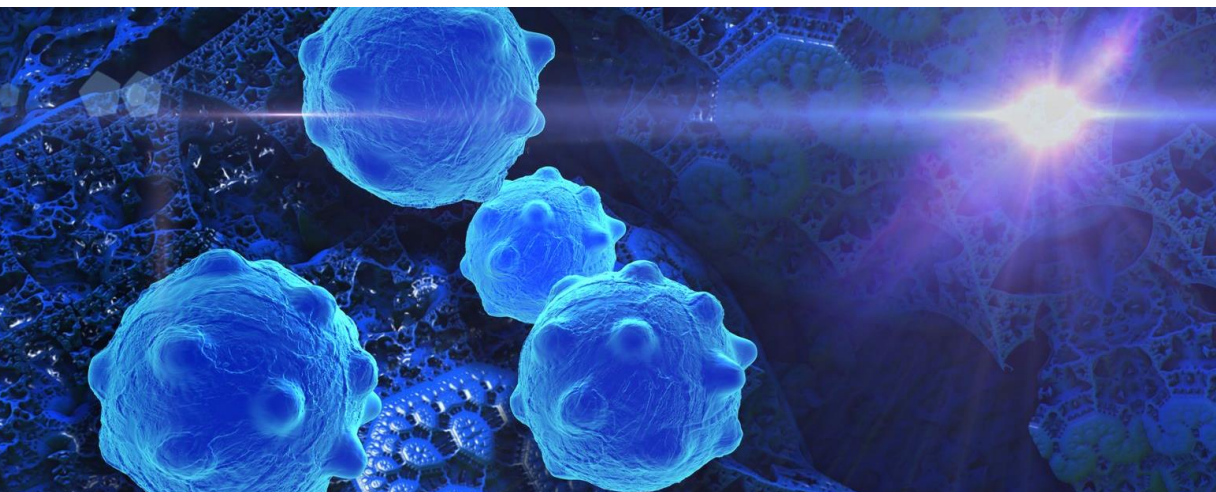
Our plan is to design & synthesise a number of conjugates for a therapeutic approach and enter clinical trials at the earliest opportunity

Radiopharm has entered into a three year Sponsored Research Agreement with Professor Notni and his scientific team to develop a therapeutic application at the earliest opportunity



# 2ND GEN PSA-mAb ANTIBODY PRE-CLINICAL

PSA-mAb  
Pre-clinical



Proprietary humanized monoclonal antibody (hu PSA), capable of targeting free human prostate kallikrein (PSA) in prostate cancer cells and internalizing payload.

PSA-mAb is the discovery of Prof David Ulmert formerly of Memorial Sloan Kettering and now UCLA. An earlier generation of this antibody h11B6 invented by Prof Ulmert was sold to Janssen in 2020 for approx. USD\$100m \*

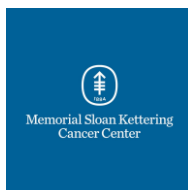
The antibody platform enables a radiotheranostic applicable therapy of prostatic cancer through radioimmunotherapy as well as diagnostics of advanced prostate cancer.

10 000-fold + higher expression of KLK3 (PSA) in prostate tissue, compared to other tissue.

[225Ac]-hu PSA results in curative treatment by sustained tumour regression and a significant increase in median survival time.

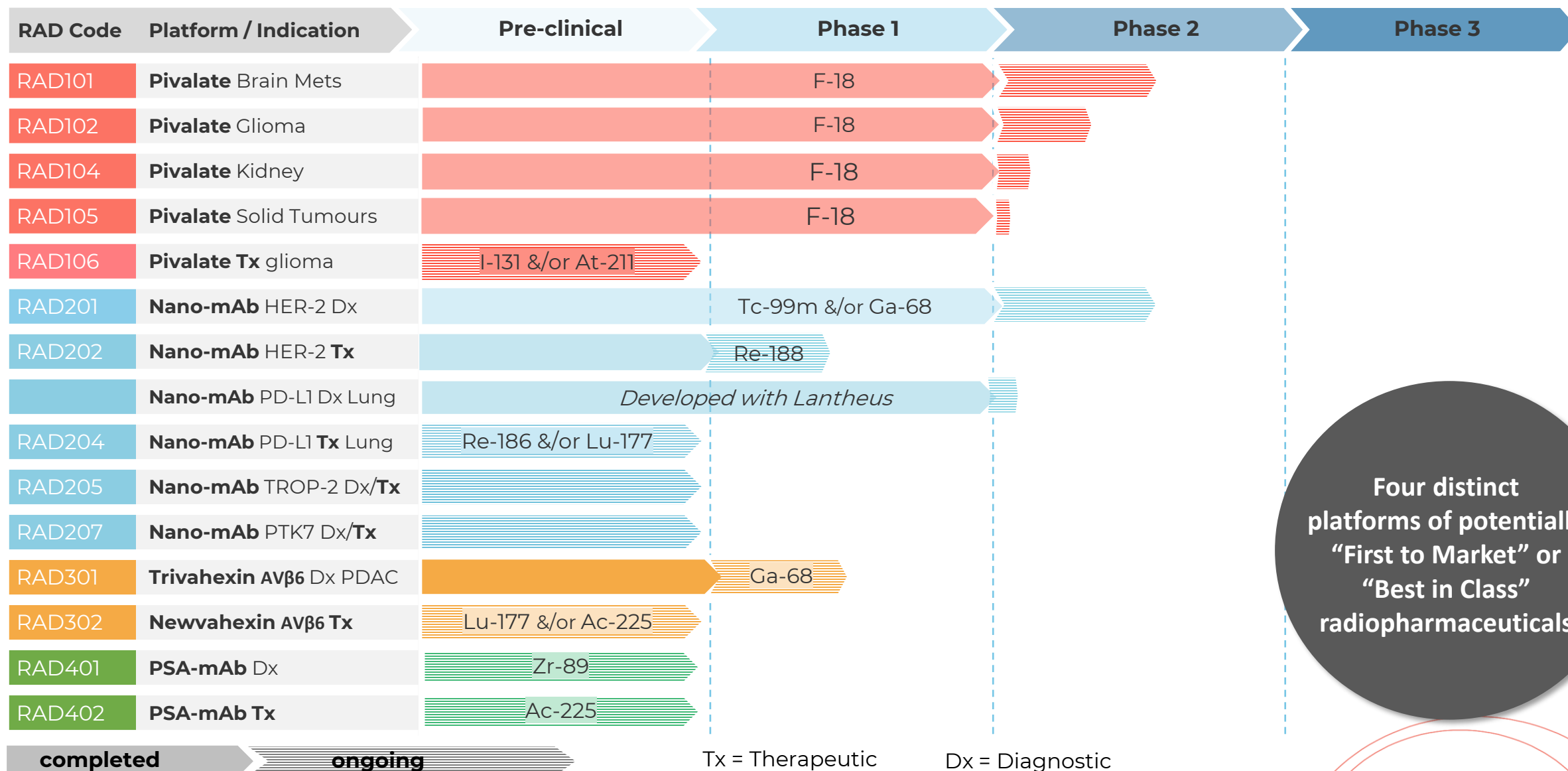
Developability data demonstrates a stable humanized antibody, without signs of degradation and aggregation.

IP-portfolio includes issued patent and applications for substance matter for imaging and therapy with hu PSA



\* LUND, Sweden, Jan. 21, 2020 /PRNewswire/ -- Diaprost entered into an exclusive Research and Option Agreement with a Top 10 Pharmaceutical company strategic partner in October 2017. Diaprost now announces that its strategic partner has exercised its option to acquire rights to its h11B6 antibody. An upfront payment and research funding has already been paid and an early-stage clinical trial has been initiated. In payments made prior to option exercise, Diaprost received \$13M. The option fee and potential future payments, including commercial milestones, for its h11B6 antibody for prostate cancer may be up to \$90 million. No royalties are payable.

# RAD CLINICAL DEVELOPMENT PIPELINE



Four distinct platforms of potentially "First to Market" or "Best in Class" radiopharmaceuticals

# EXECUTIVE LEADERSHIP TEAM



**RICCARDO  
CANEVARI**

## MANAGING DIRECTOR / CEO

Riccardo was most recently Chief Commercial Officer of Novartis company Advanced Accelerator Applications, one of the leading radiopharmaceutical and nuclear medicine companies globally. He was responsible for global commercial strategy and country organisations in ~20 countries across North America, Europe and Asia. He was lead for Lutathera in-market growth strategy and execution to build a blockbuster asset and lead on the prelaunch plan for Lu-PSMA 617 in metastatic prostate cancer. Prior to this he was Senior VP and Global Head, Breast Cancer Franchise for Novartis Oncology from 2017, overseeing the launch of major breast cancer products including KISQALI and PIQRAY. He has held various management roles with Novartis Pharma and Ethicon/Johnson&Johnson.



**PROF DAVID  
MOZLEY**

## CHIEF MEDICAL OFFICER

David was most recently at Cornell University where he was Prof of Nuclear Medicine, Medical Director of the imaging research centre, and Director of the Multi-Center Clinical Translational Science Center. He was an active member of the ethics board and a past chair of the Cornell ethics board for cancer research. He has participated in over 60 clinical trials at Eli Lilly and over 100 trials at Merck in novel radio-pharmaceutical or drug development. He was the principal investigator of 11 first-in-human studies of novel radiopharmaceuticals at the University of Pennsylvania, and the sponsor of nine investigational radiopharmaceuticals at Cornell. Previously he was at Endocyte as Vice President of Imaging. He has co-authored more than 100 peer-reviewed publications.



**DR THOM  
TULIP**

## CHIEF TECHNICAL OFFICER

Thom has spent more than 25 years in the development and commercialization of radiopharmaceuticals and imaging agents. He has served in senior leadership roles at Navidea BioPharmaceuticals Inc, Alseres Pharmaceuticals, Lantheus Medical Imaging (LMI), Bristol Myers Squibb (BMS), and DuPont. He was a Board Member of the Academy of Molecular Imaging and Chairperson of its Institute for Molecular Technologies.



**PAUL  
HOPPER**

## EXECUTIVE CHAIRMAN

Paul is the Founder of Radiopharm Theranostics. 25 years experience in biotech, healthcare and life sciences focused on start-up and rapid growth companies. Previous and current Boards include Imugene, Chimeric Therapeutics, Viralytics (sold to Merck in 2018 for \$500m), Prescient, Polynoma, Arovella Therapeutics.



# RECENT IPOS IN RADIOPHARMACEUTICAL SPACE

**NOV 2020**

\$1.1B gross proceeds



**SEP 2019**

\$250M gross proceeds



**JUN 2020**

\$212.5M gross proceeds



**JUN 2020**

\$144M gross proceeds



**AUG 2021**

A\$92M gross proceeds



**DEC 2020**

\$98.6M gross proceeds



**SEP 2020**

DKK273M gross proceeds



**SEP 2018**

\$96M gross proceeds



# KEY ACQUISITIONS IN RADIOPHARMA SPACE

**JAN 2018**  
US\$3.9B



Approved ✓

**DEC 2018**  
US\$2.1B



Phase 3 >>>

**JUN 2019**  
US\$450M +



Approved ✓

**MAR 2021**  
US\$300M

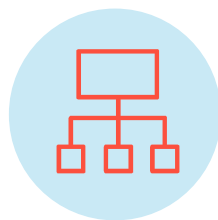


Phase 3 >>>

# INVESTMENT SUMMARY



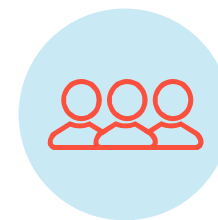
Radiopharmaceuticals experiencing a high level of investor interest and M&A activity globally including China



Radiopharm's portfolio is a balanced pipeline with risk diversification – many shots on goal



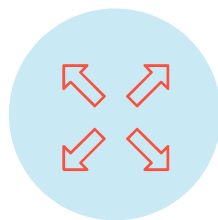
Over 130 patients treated to date across seven clinical trials. Multiple programs already in the clinic



World class management team including CEO, CMO & CTO from some of the most prestigious radiopharmaceuticals companies & universities globally



Regular news flow arising from numerous projects



Broad and robust IP portfolio



Established links into China with two Phase 1 trials completed at Shanghai General Hospital



Maintain opportunistic Business Development strategy



## CONTACT US

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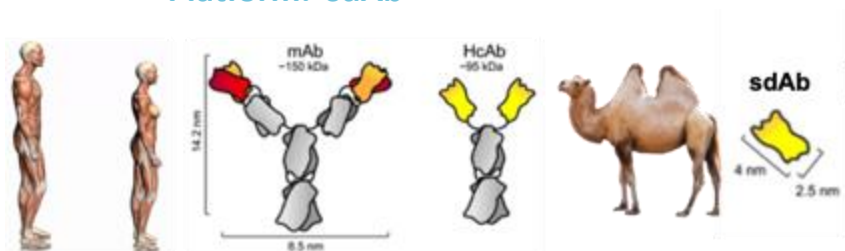
## APPENDIX



# NANO-MABS PHASE 1 & PHASE 2 N=73

Nano-mAbs  
Phase 1 | N=74

Platform: sdAb



Human Antibody → sdAb (Camelid Antibody)

Highly Stable	New Binding Domain	Faster Imaging Turnaround	Good Tumor Penetration and Retention	Customized Manipulation	Easy Manufacturing
Temperature and pH Resistant	Smaller Size for More Binding Options	Rapid Blood Clearance with Kidney	Smaller Size and Higher Affinity	Multivalent and Radiolabeling	Low Cost Production ( <i>Pichia/E.coli</i> )

A therapeutic product is made by a genetic engineered camelid antibody labelled with a radioisotope of therapeutic radiation.

This therapeutic product is paired with a diagnostic, using the same antibody vector but labelled with a lower radiation radioisotope for imaging.

Application: Theranostic

STEP #1 See Cancer

Diagnostic

Payload Radioisotope  
Low Energy ( $\beta^+$  or  $\gamma$ )

Scanning

Imaging

Imaging:  
✓ Full Body  
✓ Non-invasive  
✓ Repeatable  
✓ Instant (~2 hr)

STEP #2 Kill Cancer

Therapeutic

Payload Radioisotope  
High Energy ( $\beta$  or  $\alpha$ )

Before

6 mth

Therapy:  
✓ Confirm and hit  
✓ Time optimization  
✓ Dose optimization  
✓ Low dose low toxicity

Initial targets are HER-2 for breast cancer, PD-L1 for Non-Small Cell Lung Cancer & TROP-2 for Triple Negative Breast Cancer

# HER-2 PHASE 1 BREAST IMAGING COMPLETE N=33

Nano-mAbs  
Phase 1 | N=74

Phase 1 imaging has been completed on 33 patients with Technetium-99m: 30 in Shanghai; 3 in Germany

Non-invasive and demonstrated safety

Accumulation / high uptake in target within 2 hours post injection

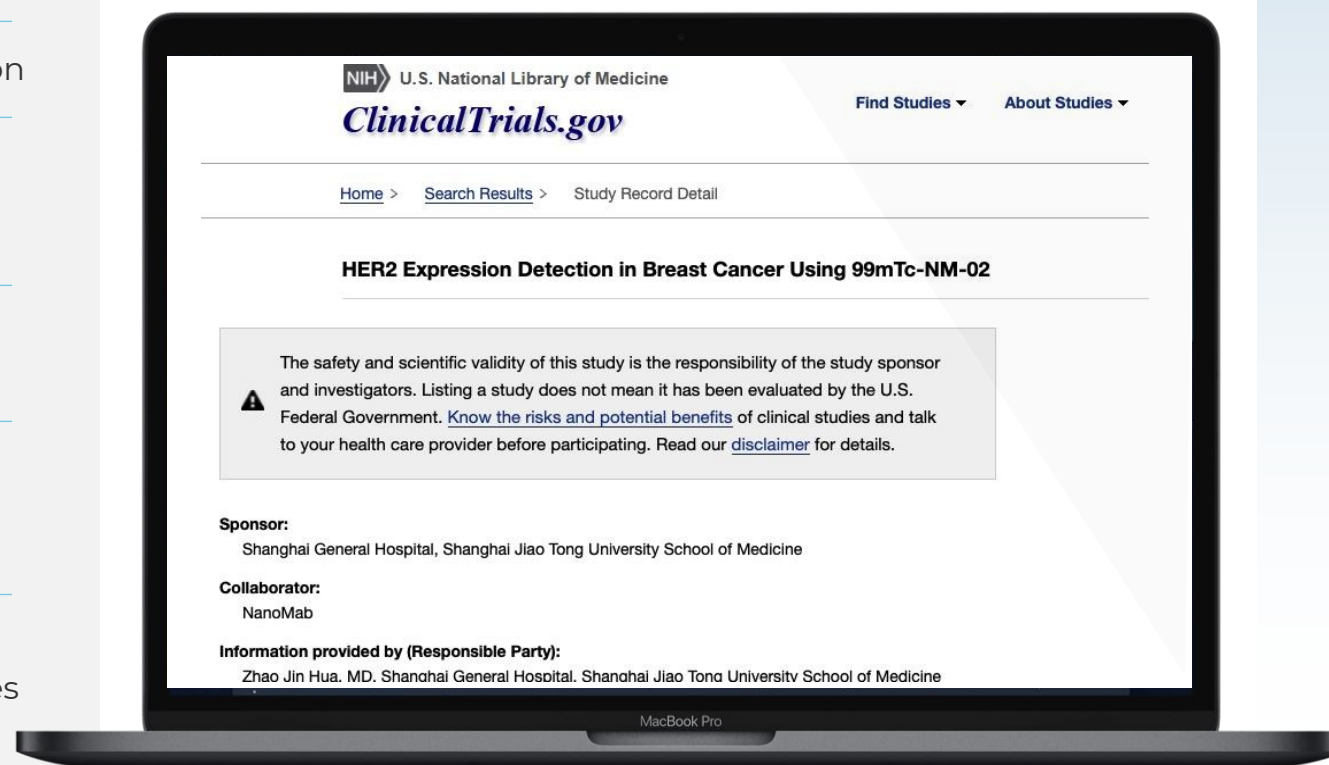
Acceptable biodistribution and dosimetry (Renal protection can be achieved by standard pre-injection of gelufusin/amino acids mixture)

Shows clear intra- and inter-tumoural heterogeneity of HER-2 expression.

Provide more accurate, and informative information on HER-2 cancers in comparison to existing IHC / FISH detections from biopsy samples.

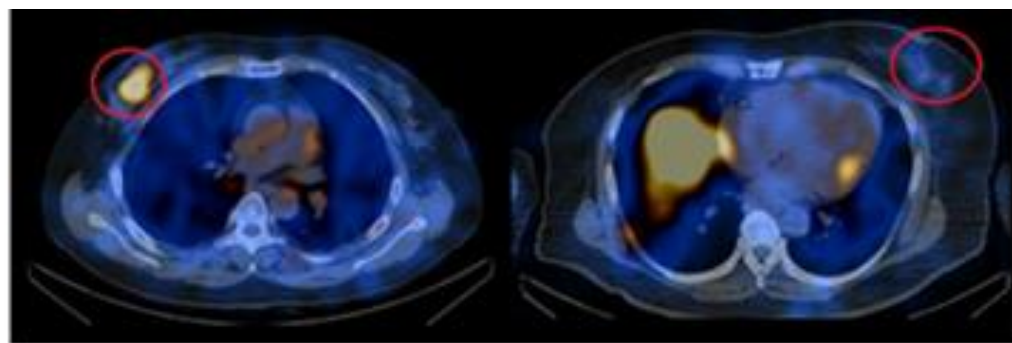
Potential to be used for whole body assessment and treatment of HER-2+ cancers with different medical radioisotopes

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# HER-2 PHASE 1 BREAST THERAPEUTIC COMMENCING

**Nano-mAbs**  
Phase 1 | N=74



HER2 3+

HER2 0

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Phase 1 therapeutic about to launch in late stage HER-2+ breast cancer at Aachen and Curanosticum Centres in Germany with Re-188, and Lu-177

1<sup>st</sup> patients dosing ~September/October 2021

Can be easily adopted for therapeutic with Re-186, Lu-177 or Ac-225

High Probability of success as a therapeutic agent:

- Patients' safety data
- Same targeting as imaging but just change of war-head (Tc-99m to Re-188, or Ga-68 to Lu-177)
- Re- and Tc- structural and reaction chemistry is the “same” – easy conversion.
- Apply to patients with good images and dosimetry – SEE then TREAT

# PD-L1 PHASE 1 NSCLC IMAGING COMPLETE N=40

Nano-mAbs  
Phase 1 | N=74

PD-L1 is a pan-cancer biomarker, and immuno-checkpoint blockers are becoming the most important treatment of multiple cancers

Imaging technology is licensed to **Lantheus** for research collaborations in diagnostic imaging

Worldwide exclusive license to Radiopharm for therapeutic use

Imaging done on 40 lung NSCLC patients: in Shanghai General and at Kings College London

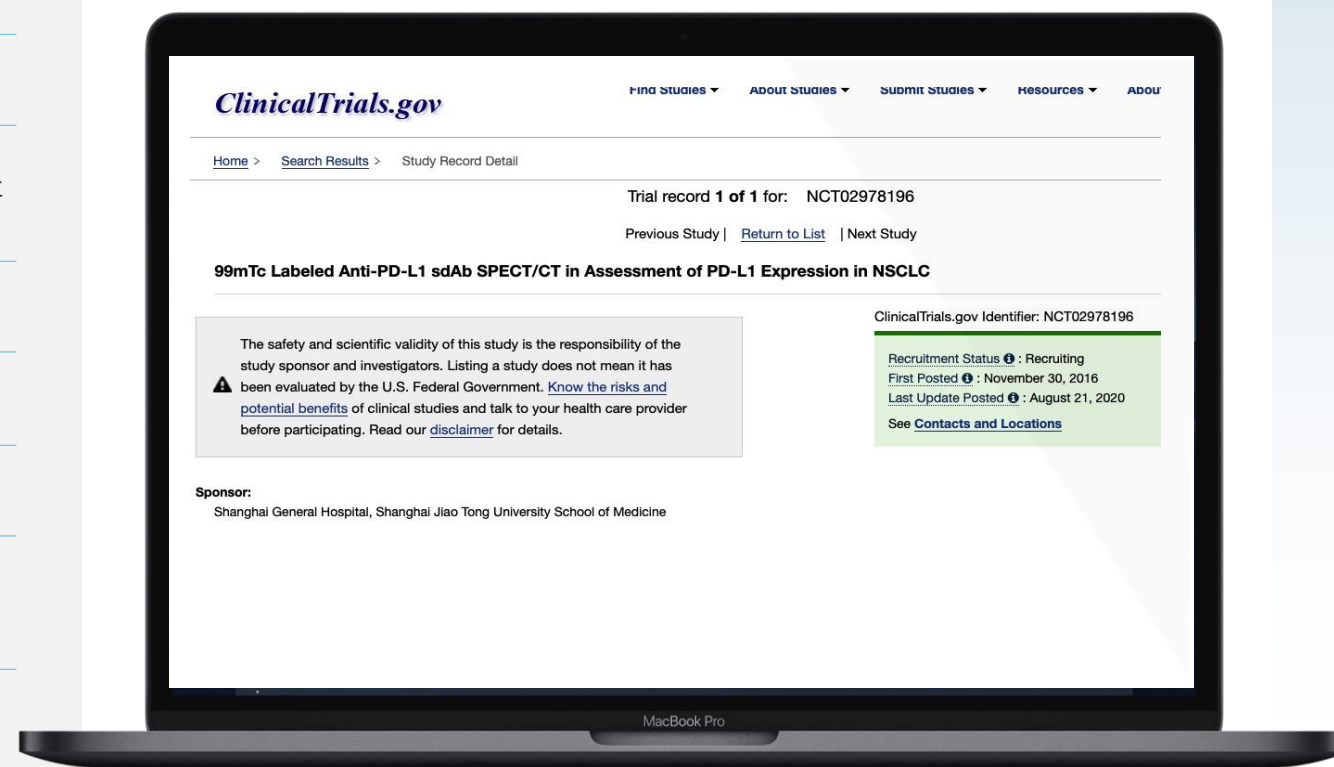
Approved for Phase 2 Imaging Clinical Trial by MHRA

DMF for Imaging filed with FDA in US

Easy adopted for therapeutic

High Probability of success as therapeutic agent: Patients safety data; same cold kit as imaging but just change of war-head

Apply to patients with good images – SEE than TREAT

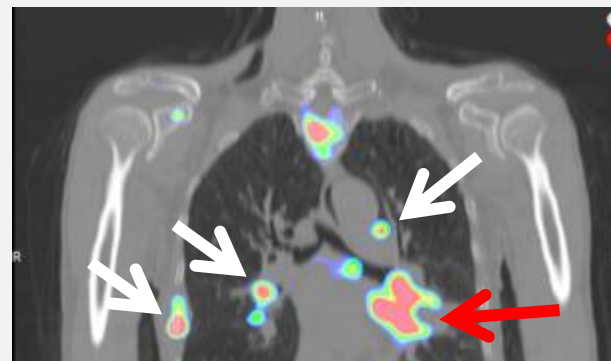
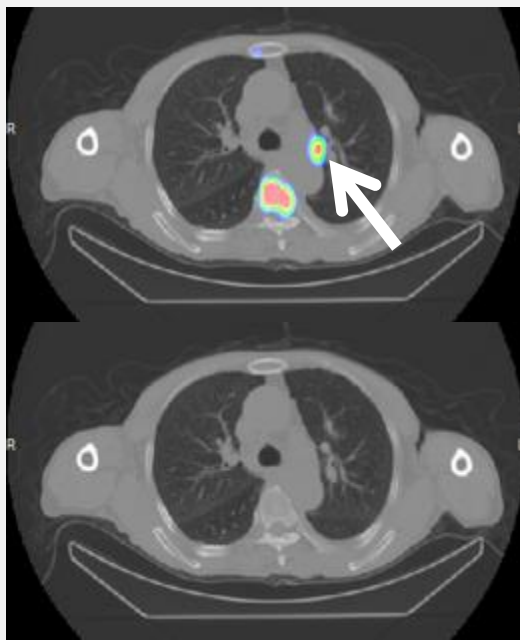
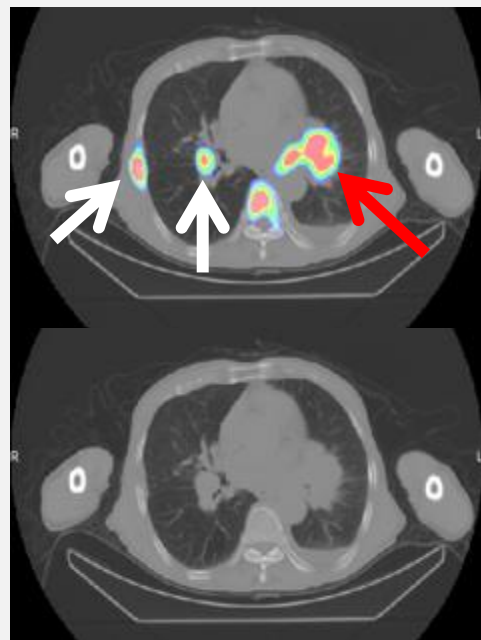


# PD-L1 CLEAR UPTAKE & ADVANTAGES

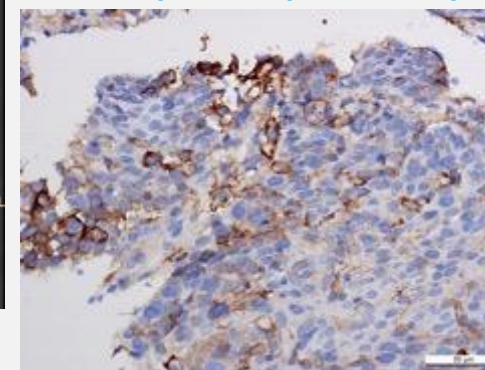
OF IMAGING V. BIOPSY

Nano-mAbs  
Phase 1 | N=74

TC002-High PD-L1 expression within Primary tumour and Multiple Mets



PD-L1 expression (DAKO 22C3) =



**Primary NSCLC T:BP=3.09**  
Hilar Lymph Nodes (LEFT) T:BP=3.25  
Hilar Lymph Nodes (RIGHT) T:BP=3.40  
Chest wall/Pleura (Right) T:BP=3.28

SPECT-CT <sup>99m</sup>Tc-NM-01 2hr pi

Patient TC002: Male, 75 YO, chest x-ray showed lung shadow, CT scan confirmed multiple lesions. Biopsy confirmed squamous cell carcinoma, a lower left lobe lung hilar tumour, 44 x 48mm is size with multiple metastases, nodal and distant. <sup>99m</sup>Tc-NM-01 scan results had uptake in primary tumour (T:BP = 3.09) (2h) and multiple metastatic lesions (2h) all >2.3 cut-off, therefore, a strong positive image. PD-L1 IHC likely understated PD-L1 expression for this patient, PD-L1 treatment prognosis for such a patient is expected to be favourable, though further investigation is required.

# TROP-2 AND PTK7 PRE-CLINICAL CANDIDATES

Nano-mAbs  
Phase 1 | N=74

## TROP-2

<b>Target</b>	tumour-associated calcium signal transducer
<b>Gene</b>	TACSTD2
<b>Cancer Hallmarks (MoA):</b>	Sustaining proliferative signaling; Activating invasion and survival
<b>Indications:</b>	TNBC, SCLC, NSCLC, HNSCC Pancreatic/Colorectal/Gastric/Ovarian/Prostate Cancer (6.4M overall new cases/year)

### Current Status of Development:

High Binding Candidates selected

- Preclinical theranostic required ( 6 months )
- Clinical samples ( +6 months )
- First-in-human imaging within 12 months

## PTK7

<b>Target</b>	Protein Tyrosine Kinase 7
<b>Gene</b>	PTK7
<b>Cancer Hallmarks (MoA):</b>	Activating invasion and metastasis; Inducing angiogenesis
<b>Indications:</b>	TNBC, Ovarian Cancer, NSCLC, Colorectal (2.6M overall new cases/year)

### Current Status of Development:

High Binding Candidates selected

- Preclinical theranostic required ( 8 months )
- Clinical samples ( +6 months )
- First-in-human imaging within 14 months

### PET/CT imaging of pancreatic carcinoma

AV $\beta$ 6-specific peptide

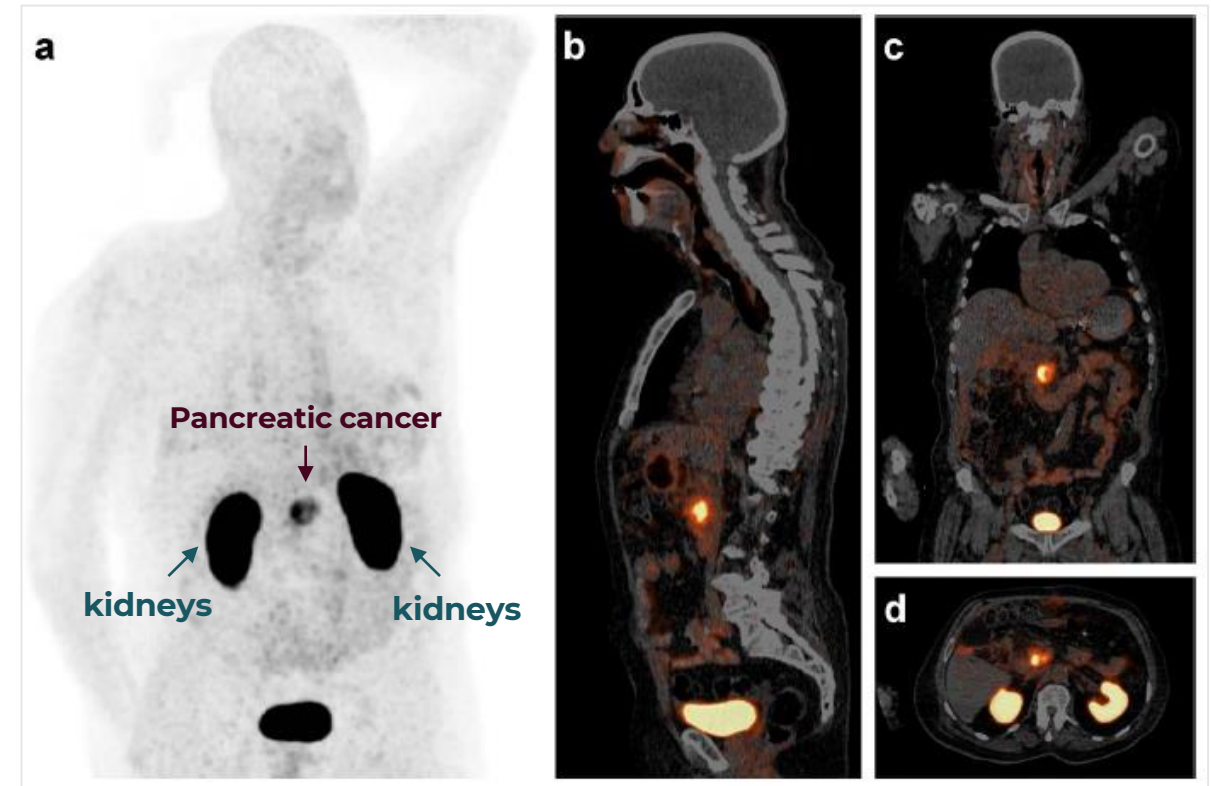
PET/CT image of solitary tumour in pancreatic head

Pancreatic ductal carcinoma confirmed histologically

Prominent signals are observed only in kidneys and urinary bladder due to rapid renal excretion

No relevant uptake is seen in head & neck, lungs, stomach, liver, and intestines

Potential applications for PDAC and other carcinomas (head-and-neck squamous cell, lung adenocarcinoma, colon, cervical, mammary).



Reference:

Quigley, N.G., Czech, N., Sendt, W. et al. PET/CT imaging of pancreatic carcinoma targeting the "cancer integrin"  $\alpha\text{v}\beta 6$ . *Eur J Nucl Med Mol Imaging* (2021).

<https://doi.org/10.1007/s00259-021-05443-8>

# AV $\beta$ 6 BEST-IN-CLASS: PHASE 1A COMMENCED

AV $\beta$ 6-Integrin

Phase 1 | N=10

BIODISTRIBUTION GENERALLY (HEALTHY SUBJECT COMPARISON)

[<sup>18</sup>F]FP-R01-MG-F2

Unacceptable biodistribution

Considerably high background due to the unspecific distribution

Hepatobiliary excretion – how to detect PDAC or ist mets in abdominal region?

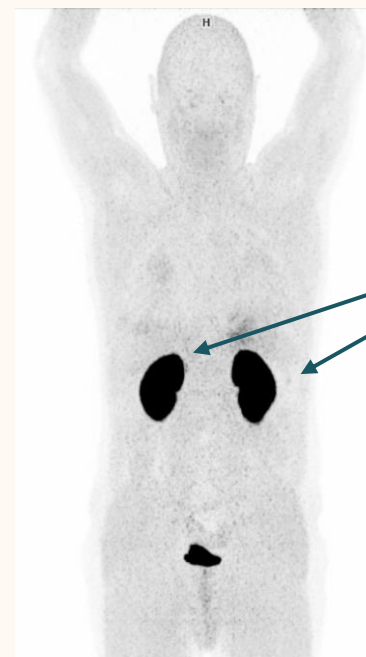
Direct transformation into a therapeutic close to impossible.  
Completely new research to be started.



Healthy subject

Kimura, Gambhir et al.,  
*Nat. Commun.* **2019**;10:4673.

AV $\beta$ 6 Integrin



No deposition in healthy tissues

Exclusively renally excreted

The formal, for-registration Phase I trial will begin in 2022

Healthy subject  
90 min p.i.

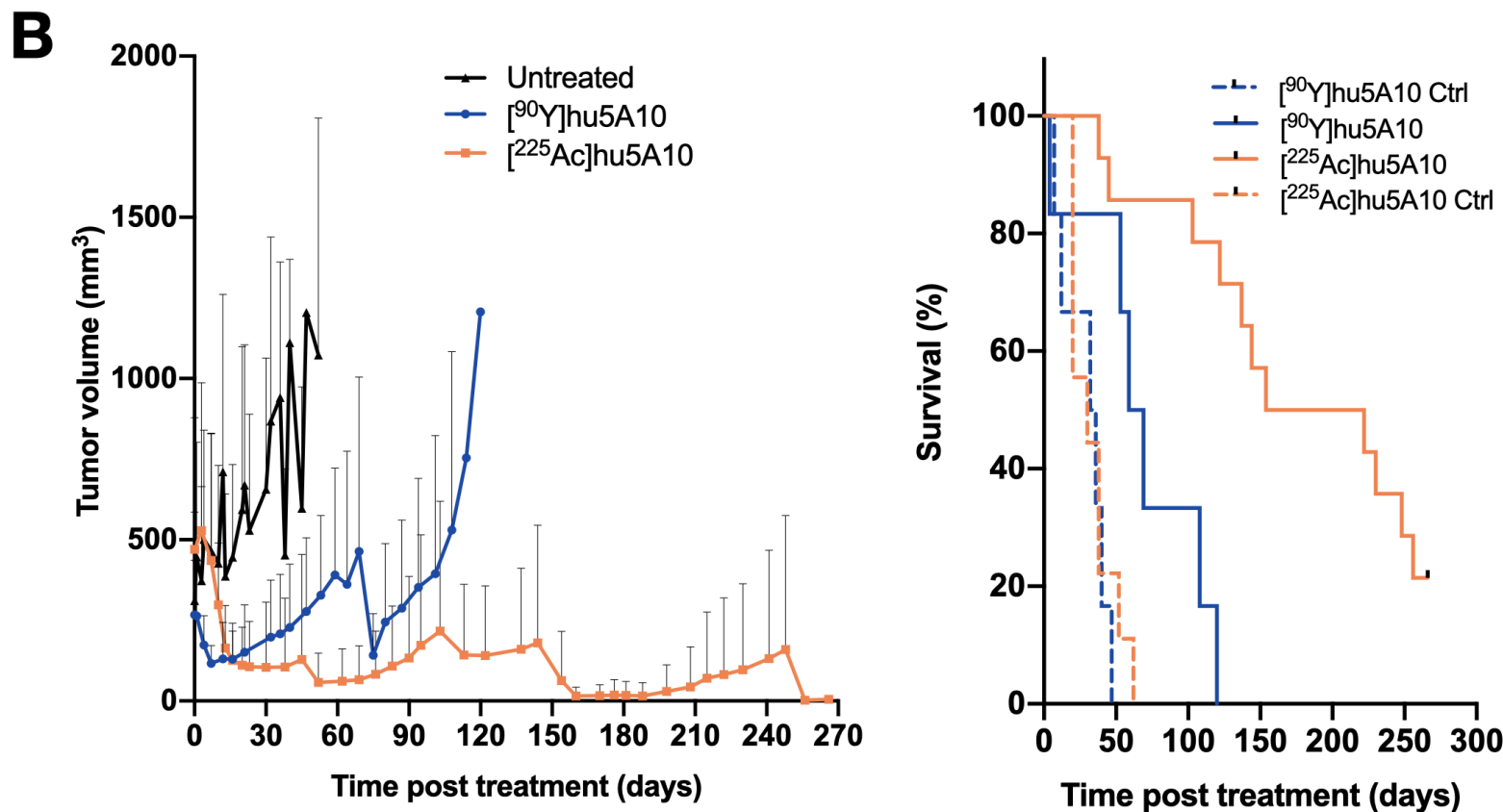
Quigley et al., unpublished results

# THERAPY SUSTAINED TUMOUR REGRESSION

PSA-mAb  
Pre-clinical

AND A SIGNIFICANT INCREASE IN MEDIAN SURVIVAL TIME

Prostate mouse model

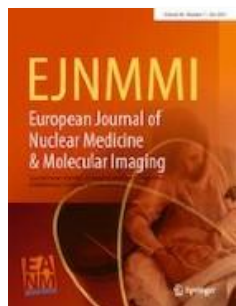


While beta-emitting [<sup>90</sup>Y]hu PSA had a more immediate effect on tumour volume, treatment with [<sup>225</sup>Ac]hu PSA resulted in sustained tumour suppression and provided a significant increase in median survival time.

The faster response time seen in Yttrium-90 treatment could be attributed to the difference between the chosen radionuclides in half-life and path length.

# PEER REVIEWED PUBLICATIONS

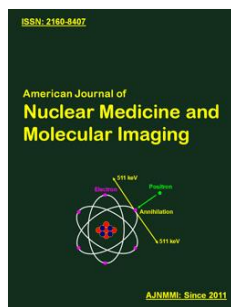
2021



[\*Eur J Nucl Med Mol Imaging.\*](#)  
2021 May;48(5):1371-1389

HER2-directed antibodies, affibodies and nanobodies as drug-delivery vehicles in breast cancer with a specific focus on radioimmunotherapy and radioimmunomaging

2021



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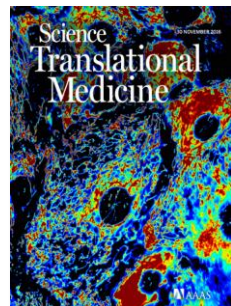
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