

BELL POTTER PRESENTATION

NOVEMBER 2021

RAD

RADIOPHARM THERANOSTICS

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RADIOPHARM THERANOSTICS LTD 2021

WHAT ARE RADIOPHARMACEUTICALS?



Radiopharmaceuticals deliver radioactive isotopes to the tumour cells

- Diagnostics: low energy radioisotopes which allow physicians to <u>SEE</u> and to measure disease within the body
- Therapeutics: high energy particle emitters to **TREAT** malignant tumours, cancer, and other diseases RADIOPHARM THERANOSTICS LTD 2021

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 tumor cells
- Peptides or mAbs are loaded with Therapeutic Isotopes to **TREAT** tumor cells, being extremely selective to damage cancer cells DNA, while not damaging healthy tissues

INVESTMENT HIGHLIGHTS

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

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

> > Targeting ASX IPO November 2021

Rich news flow generated by four platforms over next 24 months

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

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

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

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

One of the deepest clinical pipelines on the ASX

Commercially attractive license arrangements

Broad & robust IP portfolios



FOUR DISTINCT & WELL DIFFERENTIATED PLATFORMS

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



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18F-Pivalate PHASE 1 & PHASE 2 N=47



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

NoF	Saved	Status	Study Title	Conditions	Interventions	Locations
1		Recruiting	Measuring Fatty Acid Oxidation in Gliomas Using 18F-FPIA PET/MRI	• Glioma	Other: PET/MRI	Imperial College Healthcare NHS Trust/ Imperial College Iondon London, United Kingdom
2		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		Not yet recruiting	[18F]FPIA PET/CT Imaging in Patients With Solid Tumours	CancerTurnor, Solid	Drug: [18F]Fluoropivalate ([18F]Fluoro-2,2- Dimethylpropionic Acid) Procedure: PET/CT	
4		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 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 I half 2022

NANO-MABS N=73

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



UNIKLIN

RNTHAACHEN

AV β 6 INTEGRIN PHASE 1 IMAGING 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 $\alpha\nu\beta 6\text{-integrin}.$ As such, it can accumulate in tissue areas characterized by high $\alpha\nu\beta 6\text{-integrin}$ levels

There is compelling evidence that $\alpha \nu \beta 6\text{-}integrin$ is found in

-and-neck,

many of the most challenging cancers, such as pancreat

carcinoma, cervica

TECHNISCHE UNIVERSITÄT MÜNCHEN $AV\beta 6$ 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





*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. 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

RAD CLINICAL DEVELOPMENT PIPELINE



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EXECUTIVE LEADERSHIP TEAM



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.

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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 Lily 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





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.

Navidea

Bristol-Myers Squib

ALSERES

PHARMACEUTICALS

Lantheus

Aedical Imaging



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, Suda Pharmaceuticals.



RECENT IPOS IN RADIOPHARMACEUTICAL SPACE



KEY ACQUISITIONS IN RADIOPHARMA SPACE



INVESTMENT SUMMARY



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



Maintain opportunistic Business Development strategy



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



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



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

 \bigtriangledown

Broad and robust

IP portfolio



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



Regular news flow arising from numerous projects

CONTACT US

Riccardo Canevari CEO & MANAGING DIRECTOR Radiopharm Theranostics Limited

T +1 862 309 0293

E rc@radiopharmtheranostic.com
W www.radiopharmtheranostics.com

Paul Hopper Executive Chairman Radiopharm Theranostics Limited T +61 406 671 515 E paulhopper@lifescienceportfolio.com W www.radiopharmtheranostics.com



Back up - Scientific Deep dive



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NANO-MABS PHASE 1 & PHASE 2 N=73

Nano-mAbs Phase 1 | N=74



Human Antibody →

sdAb (Camelid Antibody)



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 Triple Negative Breast Cancer

HER-2 PHASE 1 BREAST IMAGING COMPLETE N=33

Phase 1 imaging has been completed on 33 patients with Tecnetium-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





NIH U.S. National Library of Medicine About Studies ClinicalTrials.gov Search Results > Study Record Detail Home > HER2 Expression Detection in Breast Cancer Using 99mTc-NM-02 The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details. Sponsor: Shanghai General Hospital, Shanghai Jiao Tong University School of Medicine Collaborator: NanoMab Information provided by (Responsible Party): Zhao Jin Hua, MD, Shanghai General Hospital, Shanghai Jiao Tong University School of Medicine MacBook Pro

HER-2 PHASE 1 BREAST THERAPEUTIC COMMENCING



HER2 3+

HER20



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

1st patients dosing ~September/October 2021

Can be easily adopted for the rapeutic 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

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







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Nano-mAbs Phase 1 | N=74

PD-L1 CLEAR UPTAKE & ADVANTAGES

OF IMAGING V. BIOPSY

TCOO2-High PD-LL expression within Primary tumour and Multiple Mets



SPECT-CT 99mTc-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. 99mTc-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

TROP-2

Target	tumour-associated calcium signal transducer
Gene	TACSTD2
Cancer Hallmarks (MoA):	Sustaining proliferative signaling; Activating invasion and survival
Indication s:	TNBC, SCLC, NSCLC, HNSCC Pancreatic/Colorectal/Gastric/Ovaria n/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

Target	Protein Tyrosine Kinase 7
Gene	PTK7
Cancer Hallmarks (MoA):	Activating invasion and metastasis; Inducing angiogenesis
Indication s:	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

AVβ6 - EUROPEAN JOURNAL OF NUCLEAR MEDICINE

AND MOLECULAR IMAGING - IMAGE OF THE MONTH

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" $av\beta 6$. Eur J Nucl Med Mol Imaging (2021). https://doi.org/10.1007/s00259-021-05443-8



AVβ6-Integrin

Phase 1 | N=10

AV_{β6} BEST-IN-CLASS: PHASE 1A COMMENCED

BIODISTRIBUTION GENERALLY (HEALTHY SUBJECT COMPARISON)



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AV86-Integrin

Phase 1 | N=10

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THERAPY SUSTAINED TUMOUR REGRESSION

AND A SIGNIFICANT INCREASE IN MEDIAN SURVIVAL TIME



Prostate mouse model

While beta-emitting [⁹⁰Y]hu PSA had a more immediate effect on tumour volume, treatment with [²²⁵Ac]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.

PSA-mAb

Pre-clinical

PEER REVIEWED PUBLICATIONS



Eur J Nucl Med Mol Imaging. 2021 May;48(5):1371-1389

HER2-directed antibodies, affibodies and nanobodies as drugdelivery vehicles in breast cancer with a specific focus on radioimmunotherapy and radioimmunoimaging

2019



<u>J Nucl Med</u>. 2019 Sep;60(9):1213-1220

Early Phase I Study of a ^{99m}Tc-Labeled Anti-Programmed Death Ligand-1 (PD-L1) Single-Domain Antibody in SPECT/CT Assessment of PD-L1 Expression in Non-Small Cell Lung Cancer

5057



<u>Am J Nucl Med Mol Imaging</u> 2021;11(3):XXX-XXX

Preclinical development and characterisation of 99mTc-NM-01 for SPECT/CT imaging of human PD-L1

5016



Expert Opin Biol Ther. 2016 Aug;16(8):1035-47

Targeted alpha therapy using short-lived alpha-particles and the promise of nanobodies as targeting vehicle

5057



<u>Clin Cancer Res.</u> 2021 Apr 1;27(7):2050-2060

PSA-targeted Alpha-, Beta-, and Positron emitting immunotheranostics in murine prostate cancer models and non human primates



<u>Sci Transl Med.</u> 2016 Nov 30;8(367)

Internalization of secreted antigen-targeted antibodies by the neonatal Fc receptor for precision imaging of the androgen receptor axis

2057



<u>Nat Rev Urol.</u> 2021 Mar;18(3):131

Radiotheranostic targeting of fPSA

2014



Expert Opin Drug Deliv. 2014 Dec;11(12):1939-54

Radiolabeled nanobodies as theranostic tools in targeted radionuclide therapy of cancer

2020



<u>Drug Discov Today.</u> 2020 Dec;25(12):2074-2075

Why next generation radiopharmaceuticals will play a key role in the quest for precision medicine

5075



<u>Cancer Discov.</u> 2012 Apr;2(4):320-7

Imaging androgen receptor signaling with a radiotracer targeting free prostate-specific antigen

5050



<u>EJNMMI Res.</u> 2020 Dec 1;10(1):145

Inter- and intraobserver agreement of the quantitative assessment of [^{99m}Tc]-labelled anti-programmed death-ligand 1 (PD-L1) SPECT/CT in non-small cell lung cancer

8005



Current Radiopharmaceuticals 2008;1(1):37-41 99mTc-Labeled Nanobodies: A New Type of Targeted Probes for Imaging Antigen Expression