Date: 21 November 2018 **Sydney, Australia**

ASX: NOX

Noxopharm Limited

ABN 50 608 966 123

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Chairman
Non-Executive Director

Dr Graham Kelly
Chief Executive Officer
Managing Director

Dr Ian Dixon
Non-Executive Director

ASX Limited
20 Bridge Street
SYDNEY NSW 2000

NOXOPHARM 2018 ANNUAL GENERAL MEETING PRESENTATIONS

- **2018 AGM Corporate Presentation**
- **CEO address**
- **Guest presenter, Professor Nat Lenzo, presentation**

Sydney, 21 November 2018: Noxopharm (ASX: NOX) is pleased to provide shareholders and the market generally with the materials for today's Annual General Meeting.

Professor Nat Lenzo will be presenting a review of the opportunity of theranostic therapy in cancer.

The Noxopharm 2018 AGM will take place at 2pm today, Wednesday 21 November, at the following location:

Boardroom at the Automic Group
Level 5
Deutsche Bank Place
126 Phillip Street
Sydney NSW 2000

The results of the meeting will be released to the ASX at the conclusion of the Annual General Meeting.

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About Noxopharm Group
The Noxopharm Group includes Noxopharm Ltd, Nyrada Inc, and NoxAsia Ltd with offices in Sydney, New York and Hong Kong. The Group's drug pipeline contains 4 drug candidates: Veyonda®, NYX-104, NYX-205, NYX-330. Veyonda® is being developed as an enhancer of radiotherapy across a range of cancers being treated with both standard external beam radiotherapy and intravenous radionuclide (^{177}lutetium-PSMA-617) therapy; NYX-104 is a neuroprotectant being developed to limit secondary brain damage (glutamate-induced excitotoxicity) following ischaemic stroke and concussion; NYX-205 is an anti-inflammatory being developed for the treatment of peripheral neuropathy associated with diabetes and chemotherapy; NYX-330 is a PCSK9 inhibitor being developed for the treatment of high blood LDL cholesterol levels that fail to respond adequately to statin therapy alone.

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Forward Looking Statements

This announcement may contain forward-looking statements. You can identify these statements by the fact they use words such as “aim”, “anticipate”, “assume”, “believe”, “continue”, “could”, “estimate”, “expect”, “intend”, “may”, “plan”, “predict”, “project”, “plan”, “should”, “target”, “will” or “would” or the negative of such terms or other similar expressions. Forward-looking statements are based on estimates, projections and assumptions made by Noxopharm about circumstances and events that have not yet taken place. Although Noxopharm believes the forward-looking statements to be reasonable, they are not certain. Forward-looking statements involve known and unknown risks, uncertainties and other factors that are in some cases beyond the Company’s control that could cause the actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statement. No representation, warranty or assurance (express or implied) is given or made by Noxopharm that the forward-looking statements contained in this announcement are accurate and undue reliance should not be placed upon such statements.

21 November 2018

Dear Shareholders

I am pleased to report on a year of considerable activity and growth, with the next year emerging as one of even greater activity and growth.

While the past year has had its share of delays, there also have been some unexpected advances. Such is the nature of drug discovery and clinical trials. The challenge in this field is to learn how to fix problems early and how to recognise opportunity when it strikes.

Importantly, overall we have made better progress than I had anticipated, to the point where the Company is ever more confident of having a potentially disruptive technology with the capacity to bring a fundamental improvement in the management of many forms of cancer. While it's easy to make such a claim, the history of progress in oncology has been one of incremental steps, even with the much-lauded immuno-oncology drugs which have turned out to date to have had just a modest overall impact on the survival of most patients.

But with Veyonda® now having been used in over 50 patients, plus what we are seeing in the laboratory, the evidence just continues to get stronger that this is a drug candidate with an extraordinarily promising future. Providing the detailed clinical proof for this is what we are now fully focussed on achieving.

We foresee it becoming a standard companion drug to radiotherapy in the broadest practice of radiotherapy. And not just offering a better outcome for patients with late-stage cancer. By way of example, a group of US radiation oncologists urged us recently to consider using it in the situation where tens of thousands of men newly diagnosed with aggressive prostate cancer find themselves. They saw an opportunity to use a mix of Veyonda® and radiotherapy to enable men to avoid the perils of prostate gland surgery or even to avoid or delay the much-dreaded chemical castration therapy with its unwanted side effects.

And then there is the back-up opportunity to use Veyonda® in combination with chemotherapy, a place where this drug started some 18 years ago when Yale University oncologists declared idronoxil such a bright prospect in the treatment of late-stage ovarian cancer. Having finally discovered how to make idronoxil work in the form of Veyonda®, we have been able to revisit this application in our CEP-1 study. The final report on this study is expected to come next week, and I look forward to sharing the details of this with you.

But in the face of multiple opportunities, we need to have a focus, and that focus very clearly is on developing Veyonda® as an enhancer of radiotherapy, with 2019 the year that we take the important final step in that objective.

With the Company transiting from an early-stage clinical phase to a pre-commercial phase, that means needing to bring onboard additional expertise.

The appointment of Dr Greg van Wyk as our Chief Medical Officer is the first of a number of steps in that transition. Greg brings enormous experience in shepherding drugs from the lab through the clinic to regulatory approval. And behind him is the core of a clinical team with the necessary experience. More key appointments are expected to be made over the next 12 months as we head into what we expect will be the advanced stages of drug development. These will be appointments of a commercial nature as we prepare for what we hope will be marketing approval in the not too distant future.

There also already are inevitable changes in roles and workload. As these additional appointments are being made, my role as CEO is becoming less focussed on the detail of clinical strategy and clinical trial management, and more concerned with broader corporate strategy. Greg is highly experienced in late-stage drug development and regulatory affairs strategies and he will be the main driver of these strategies in association with our medical advisory boards. Raising the profile and presence of the Company particularly in the US and Asia is something that I will be looking to do this coming year. While biotech is a crowded market and investors have significant choice, I intend to ensure that Noxopharm is on the watch-list of global biotech investors as our clinical data grows.

The Board also reflects on the changing nature of the Company and environment in which it operates and, as such, the current Board is mindful of ensuring it has the best possible blend of skills and experiences on hand as it progressed through the various stages of growth.

Thank you for your trust, and I look forward to rewarding that trust by building the Company's intellectual property portfolio and the market's appreciation of the value of that portfolio.

Yours sincerely

Graham Kelly
Chief Executive Officer and Managing Director


2018
Annual General Meeting
NOXOPHARM
ASX: NOX
DISCOVER
DEVELOP
DELIVER

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Noxopharm *at-a-glance*

- Australian biotechnology company. Offices Sydney, New York, Hong Kong
- Playing to our strength…. isoflavonoid drug platform
- Aiming to bring Veyonda® to market as a first-in-class companion drug to radiotherapy
- Mixture of out-licensing and in-house sales/marketing
- Cash: AUD$9.6 million (Sept 30) (+ R&D rebate pending)

PIPELINE:

- **1 CLINICAL**
- **3 PRE-CLINICAL**
- **2 DISCOVERY PROGRAMS**

NOXOPHARM

DARRT: Broad Potential Utility In Solid Tumors

Veyonda®

PROGRAM STRATEGY 2018/2019

DARRT

DARRT-1
Prostate cancer (current)

Major need. Early evidence of safety and efficacy

DARRT-2
Lung cancer Q1 2019

Major need. Lung cancer known to be susceptible to immune activation

DARRT-3
Sarcomas Q1 2019

Very limited treatment options. Radiotherapy rarely used.

DARRT-4
Brain cancer (GBM) Q3 2019

Major need. Radiotherapy main form of therapy

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Strategy For Bringing Veyonda® To Market

Primary focus on prostate cancer and sarcoma. Aim for marketing applications for each indication, but sarcomas and other rare cancers (eg cholangiocarcinoma) could be faster path

Sarcomas (and rare cancers generally) offer Fast-Track Approval and Orphan Drug Status and approval based on smaller patient numbers

DARRT in prostate cancer. Aim to commence Phase 2/Phase 3 adaptive study H2 2019. Multi-national study

DARRT in sarcomas (eg.osteosarcoma). Aim to commence Phase 2 study H1 2019. Multi-national study

Q1 2019. Appoint 2 CROs. Appoint Prostate Cancer AdBoard and Sarcoma AdBoard

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Veyonda® Pre-Commercial Planning

Clinical and Regulatory Affairs: ☑ Team in place (CMO: Dr Greg van Wyk)

Experienced big pharma medical officer driving strategy and operations.

Manufacture:

☑ *Experienced big pharma manufacturing team appointed (Dr Lara Babich)*

☑ Large-scale idronoxil manufacture (India)

☑ Final dosage form manufacture (Australia)

Business development director: *Mid-2019. (Licensing relationships; RoW territories to be retained)*

Commercial director: *Early-2020. (Pricing, health economics etc.)*

Board: *Early-2019. Appointment of additional Board member(s) with pharma industry experience*

Potential commercial value of a radio-enhancer

Veyonda®

DARRT

- Long identified need by radiation oncologists and health regulators.
- Potential to shift effect of radiotherapy (RT) from mostly palliative to curative.
- Potential to allow use of RT in tumors where RT not currently used.
- No drug successfully developed that has met market need for safety and efficacy.
- Veyonda® expected to be first such radio-enhancer.
- Half of all cancer cases believed potentially to benefit from RT = 7M globally*
- RT use in middle- to high-income countries est. to be 4.2M cases p.a.*
- Potential market size in first and second world countries is $42 billion for every $10K treatment course cost.

* Yap et al. Journal of Global Oncology (2018) 2, 207.

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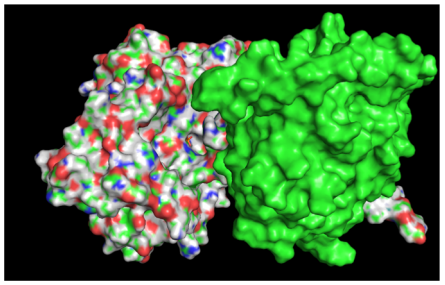
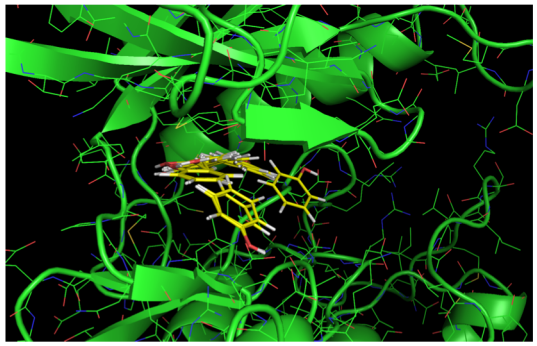
NOX technologies finally allowing therapeutic potential of isoflavonoid drugs to be exploited



Target identified



Best fitting drug designed

LIPROSE delivery technology ensures effective blood levels of active drug and ability to cross blood-brain barrier

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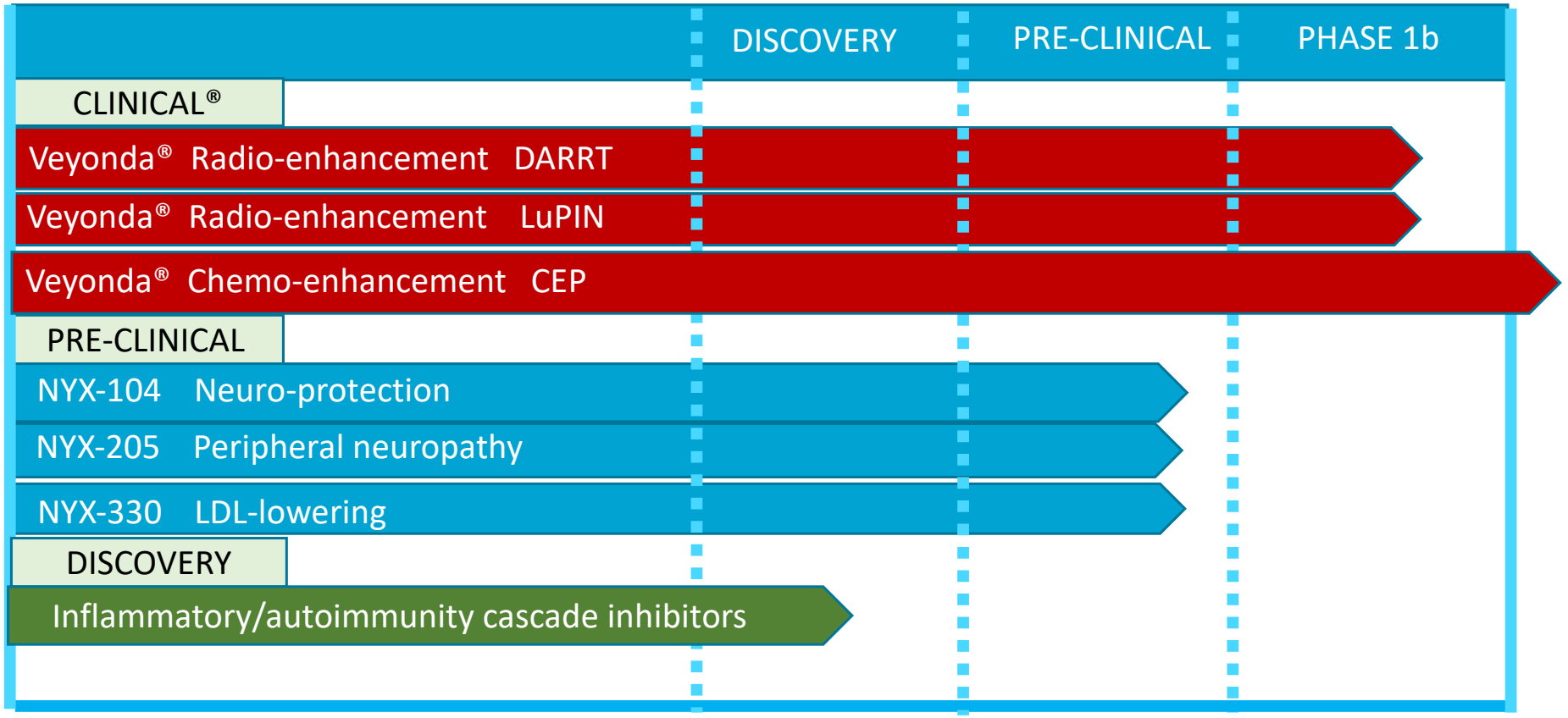
Pipeline



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Veyonda® & Radiotherapy

Two clinical programs

Veyonda® Radio-enhancement DARRT Program

DARRT - Direct and Abscopal Response to RadioTherapy

Veyonda® Radio-enhancement LuPIN Program

LuPIN - ^{177}Lutetium-PSMA-617 In Combination with Veyonda

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Veyonda® DARRT Program

Purpose:

- Provide greater shrinkage of irradiated tumors
- + shrinkage of non-irradiated tumors (‘**abscopal response**’)

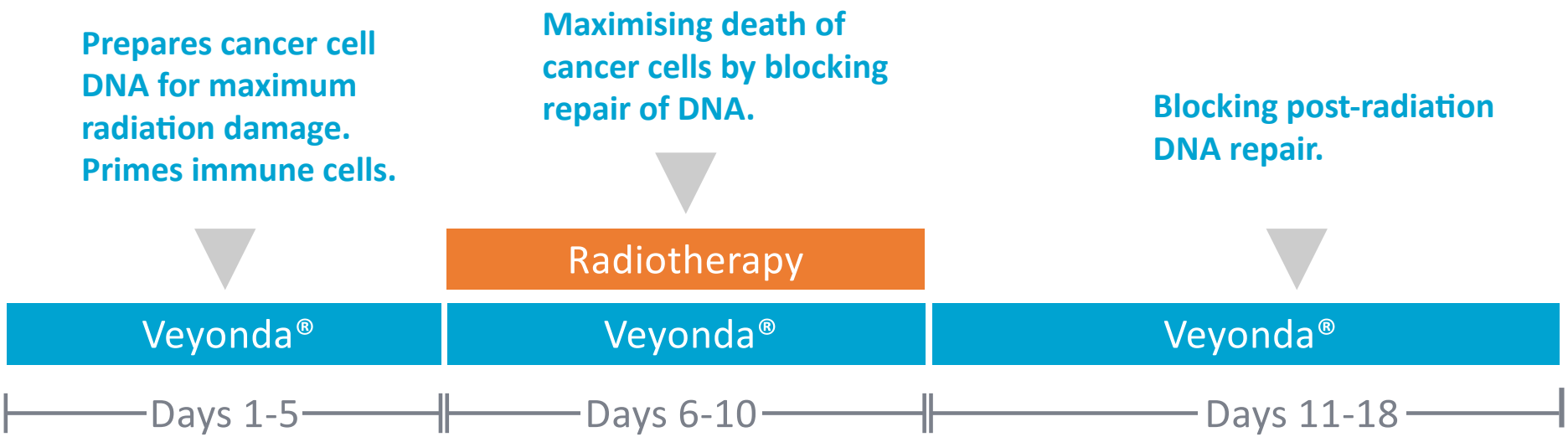
Advantages:

- Allowing radiotherapy to be used with cancers (eg. sarcomas) where radiotherapy not commonly used currently
- Allowing lower dose of radiotherapy to be used near sensitive tissues

Aim:

- Reduced tumor load → **better pain relief and better quality of life**
- Blocked tumor growth → **improved survival**

DARRT – A treatment regimen intended for patients with late-stage solid cancers who are eligible for palliative radiotherapy



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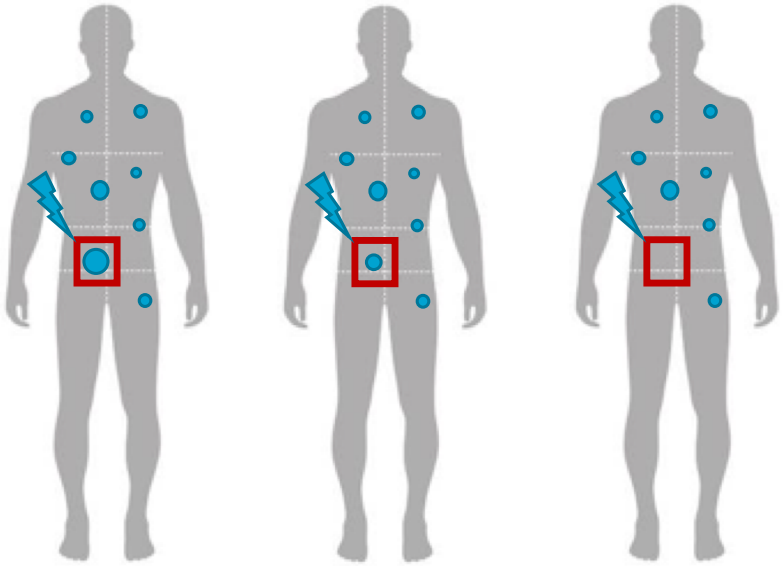
DAART – Anticipated Clinical Benefits

Veyonda® DARRT

DIRECT RESPONSE

At a minimum, Veyonda® is expected to lead to better DIRECT responses to radiotherapy by functioning as a **radio-enhancer**

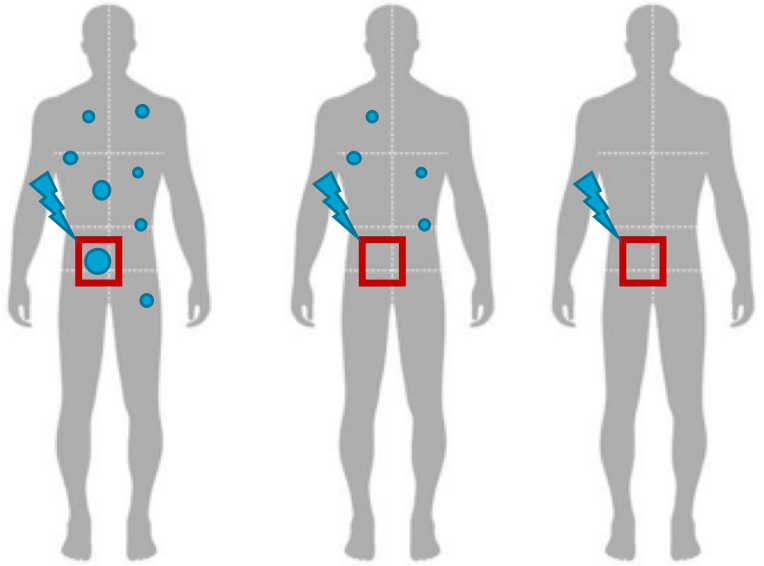


Shrinkage of Irradiated tumor

Complete resolution of Irradiated tumor

ABSCOPAL RESPONSE

The best expected outcome would be an improved DIRECT response, plus an ABSCOPAL response driven by its i-o drug properties



Partial abscopal response

Complete abscopal response

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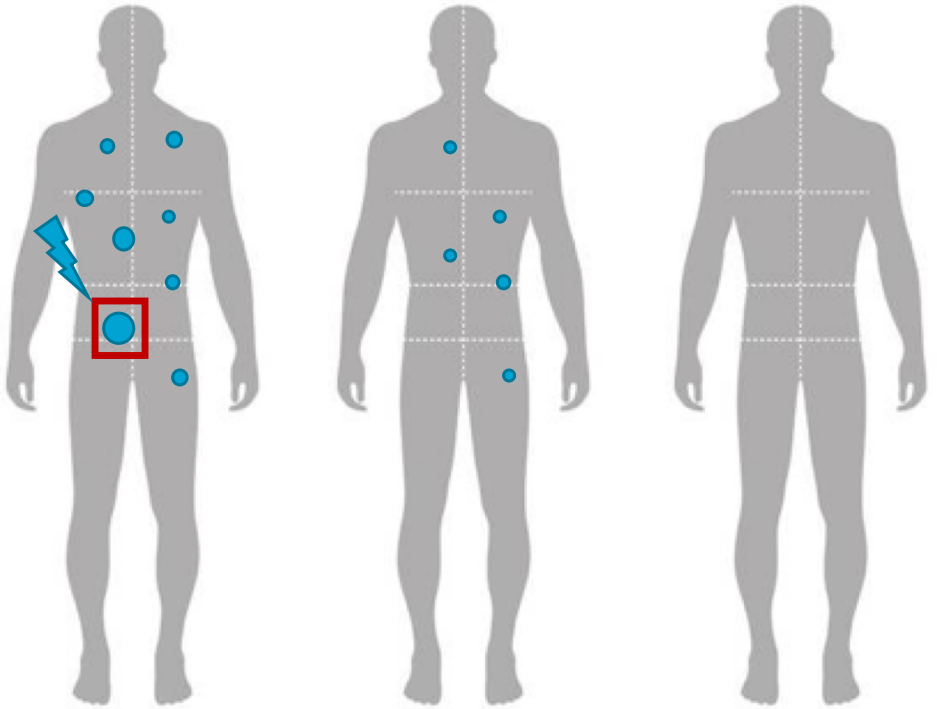
The *'ABSCOPAL RESPONSE'*

An **ABSCOPAL RESPONSE** refers to an anti-cancer effect in tumors **outside of the field of radiation**

An abscopal response can have the following response spectrum:

- **Stable disease** - <30% shrinkage; no new tumors
- **Partial abscopal response -** >30% shrinkage
- **Complete abscopal response** - no tumors evident
- **A mixture in the one patient of all of the above**

The mechanism of the abscopal response remain unknown but is believed to involve both immunological and epigenetic (miRNA) components



Radiotherapy to single tumor | Partial abscopal response | Complete abscopal response

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An Abscopal Response Can Be Induced Deliberately

Veyonda®

DARRT

Abscopal responses now recognized as a likely quantum leap forward in the treatment of cancer.

Up to 2010, very rare phenomenon

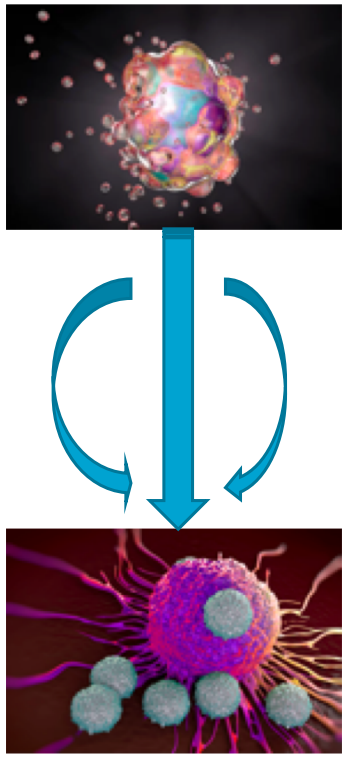
Since then, the introduction of immuno-oncology (i-o) drugs including PD-1 and PD-L1 inhibitors has increased the frequency of abscopal responses

Exciting data shows combining i-o drugs with radiotherapy results in abscopal response rates of between 20-25% in certain cancers

Noxopharm believes that Veyonda® will exceed the response benefits seen with other i-o drugs because:

a) Veyonda® has multiple mechanisms of action, and

b) Veyonda® is active across a broader spectrum of cancers.



Cancer cell damaged by radiation and dies …..

… releasing antigens and epigenetic signals ….

… that activate immune cells (NK cells/T cells) that then attack distant cancer cells

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DARRT-1: Phase 1b clinical trial evaluating the safety and efficacy of Veyonda® in men with late-stage prostate cancer who are eligible for palliative (low dose) radiation for pain and symptom management

Veyonda®

DARRT

Objectives:

- To determine safety of Veyonda® + radiotherapy across three drug dosages (400, 800, 1200 mg)
- To determine best dosage for Phase 2/3 registration study
- To obtain signals of efficacy to support expansion of trial to additional solid tumor indications (lung, sarcoma)
- Secondary endpoints include:
  - *Longer progression-free survival (through stable disease or abscopal response)*
  - *Change in tumor size in target irradiated or non-irradiated lesions measured by RECIST*
  - *PSA response*

Aim of the DARRT regimen is to slow or stop cancer progression → meaningful survival benefit

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Comments on Preliminary DARRT-1 Data

Veyonda®

- **Note:** All patients entered study with late-stage, metastatic, progressive disease with no remaining treatment options. Historical survival of such patients is **3-6 months**.
- **Note:** Patients are receiving a palliative dose (20 Gy) of radiotherapy; not a salvage dose (45-60 Gy). Intended to provide symptomatic (pain) relief only with little expectation of any survival benefit.
- **DARRT** intended to provide symptomatic relief PLUS **increased survival benefit** by stopping tumor growth or causing tumor remission. Marketing approval will likely be on effect on PFS
- **Stable Disease** or **Partial Response** in these late-stage patients agreed by KOLs to be indicative of a significant anti-cancer effect → likely meaningful increased survival benefit (increased PFS)
- At 3-months, **6/8 patients** had stable disease or better; at 6-months**, 3/7 patients** had stable disease or better
- 800 or **1200 mg** likely therapeutic dose. 2 of 4 patients in Cohorts 2 and 3 to date showing 30-99% shrinkage of tumors at 3 and 6 months respectively
- Treatment well-tolerated; no serious adverse events
- Next scheduled review point December 2018. [*All 3-month, some 6-month, Cohort 2 and 3*]

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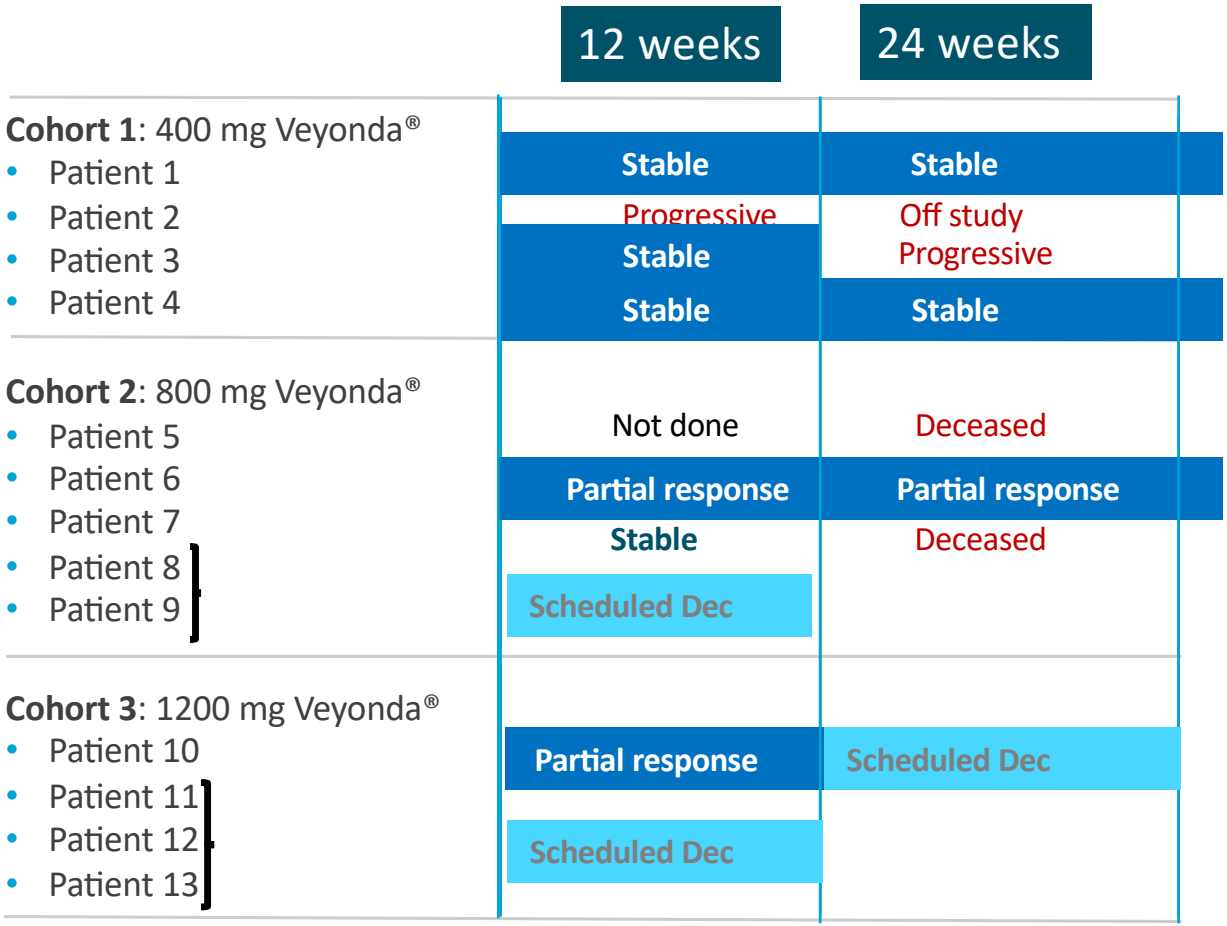
DARRT-1: Early Clinical Evidence of Durable Halt to Disease Progression

Veyonda®

DARRT

Scheduled Dec



Stable Disease and Partial Response determined by RECIST (*Response Evaluation Criteria in Solid Tumors*)

Progressive Disease
- >20% expansion of measured tumors
- appearance of new tumors
- deterioration in quality of life

Stable Disease
- -29% to +19% change in size of measured tumors
- no new tumors
- no deterioration in quality of life

Partial Response
- 30-99% shrinkage of measurable tumors
- no new tumors

Assessment relates to **all** observable tumors (both measurable and non-measurable) and includes both irradiated and non-irradiated tumors.

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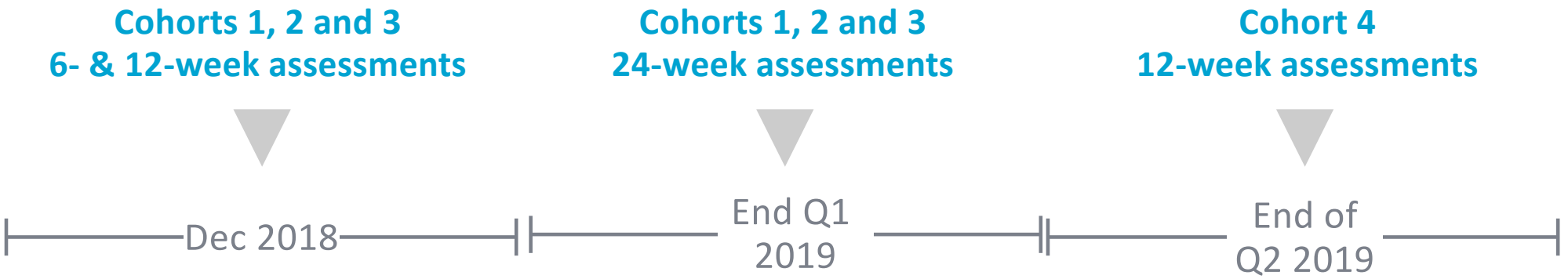
DARRT-1 Data Read-outs

Veyonda®
DARRT



Company planning to report 6-week and interim 12- and 24-weeks data from Cohorts 1-3 by year-end 2018

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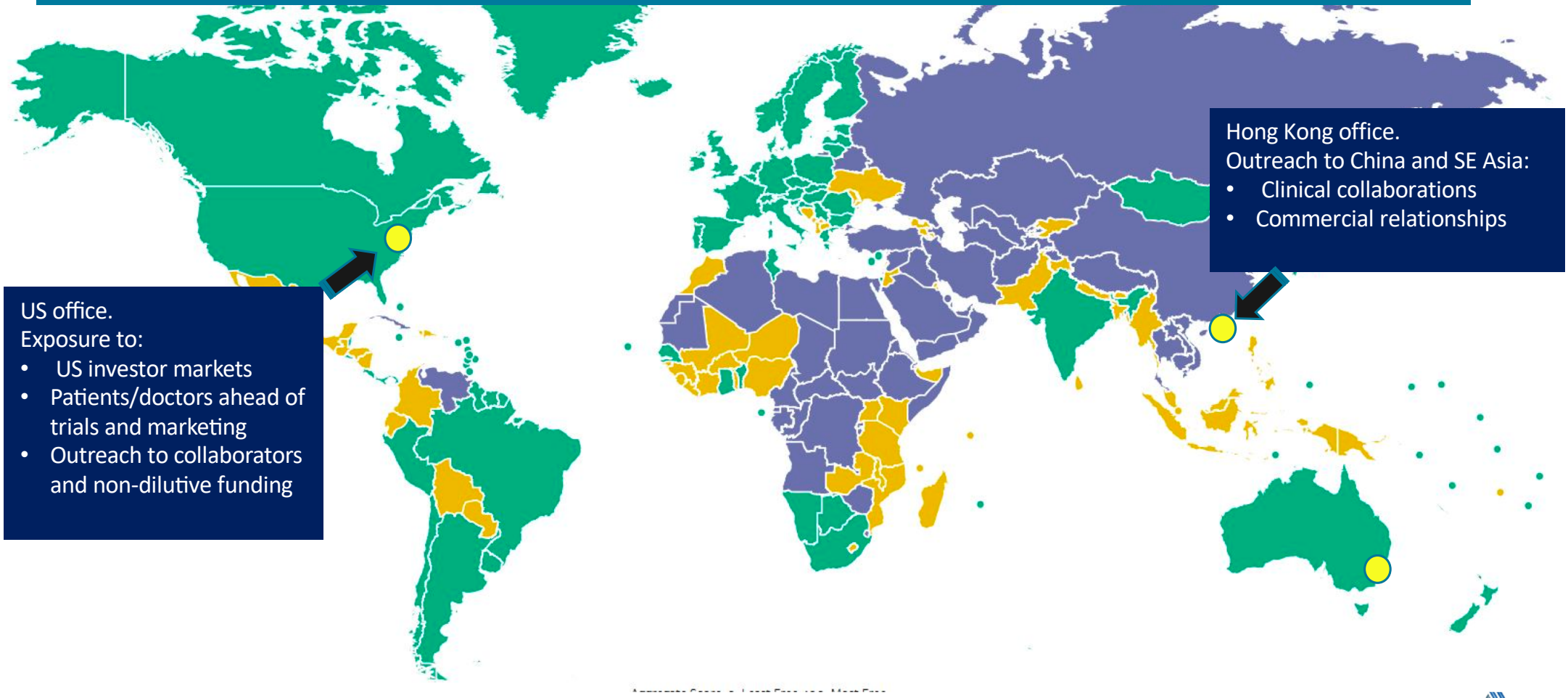
Preparing for Veyonda® clinical program and eventual marketing



US office.
Exposure to:
- US investor markets
- Patients/doctors ahead of trials and marketing
- Outreach to collaborators and non-dilutive funding

Hong Kong office.
Outreach to China and SE Asia:
- Clinical collaborations
- Commercial relationships

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Veyonda® LuPIN Program

Veyonda®
LuPIN

PSMA-617 is a peptide that recognizes and targets prostate specific membrane antigen (PSMA).
85-90% cases of prostate cancer are PSMA +ve

Lu-PSMA-617 links radioactive lutetium isotope to PSMA-617, delivering radioactivity directly to prostate cancer cells

While a very promising approach, efficacy has been limited:

- In previous trials, approx. 2/3 of patients fail to complete 36-week course of treatment due to non-responsiveness from outset or initial response but then relapse during treatment

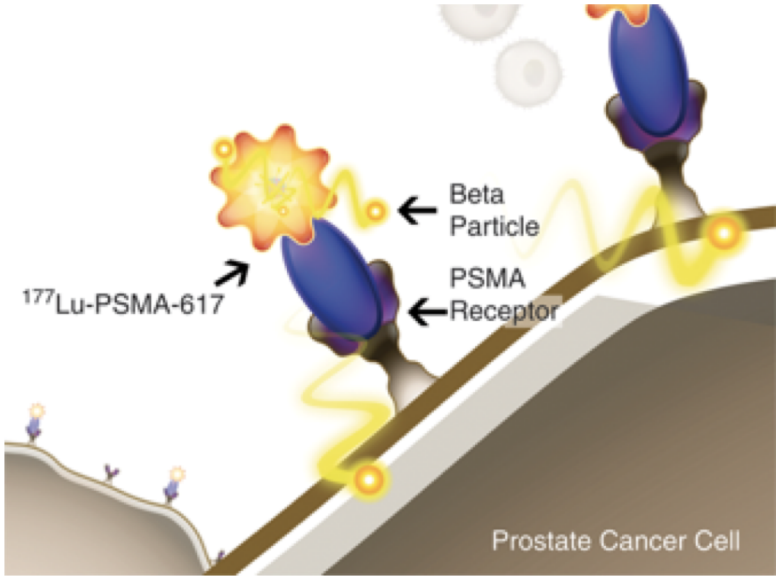

Image Source: Endocyte

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Novartis-Endocyte Deal Shows Growing Interest in Radiopharmaceuticals and Lu-PSMA

Veyonda®

LuPIN

Novartis pending acquisition of EndoCyte for $2.1 billion

Provides Novartis access to **177 Lu-PSMA-617 (Lu-PSMA)** currently being evaluated by Endocyte in a Phase 3 registrational study for metastatic castration-resistant prostate cancer

St Vincent's Hospital (Sydney) currently running a **Phase 1b trial** (LuPIN-1) using Veyonda® as a sensitizing agent in combination with ^{177}Lu-PSMA-617 provided by EndoCyte

ENDOCYTE

NOVARTIS

Significant positive potential implications for Noxopharm if Veyonda® is shown to boost Lu-PSMA efficacy

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LuPIN: Phase 1b investigator-initiated dose finding study evaluating the safety and efficacy of Veyonda® in combination with Lu-PSMA-617 in men with advanced, metastatic castrate-resistant prostate cancer

Veyonda®

LuPIN

Patients: Late-stage disease. No remaining standard treatment options.

Treatment: 6 x 6-weekly IV injections of ^{177}Lutetium-PSMA-617 + 10 days Veyonda® with each injection

- **Numbers**: 32 [*22 enrolled 21 Nov*]
- **Completion**: 12 months from enrolment of last patient. [*End-2019*]

Two dosing cohorts: 8 patients 400 mg Veyonda®; 24 patients 800 mg Veyonda®

Endpoints: (i) Safety; (ii) clinical response measured by PSA levels, scans and clinical evaluations at 3, 6 and 12 months

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LuPIN Program Rationale

Veyonda®

LuPIN

That combining Veyonda® with Lu-PSMA-617 will:

- Boost the cancer cell-killing effect of Lu-PSMA-617
- Improve the response rates to Lu-PSMA-617
- Mean that the majority of men will complete their full 36-week treatment course (compared to current 33% level)
- Deliver a more durable response that will deliver a meaningful increase in survival times

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Veyonda® CEP Program

Veyonda®
CEP

Rationale:

- Idronoxil sensitises cancer cells to platinum drugs (carboplatin, cisplatin, oxaliplatin) by > 2000x
- Restores sensitivity to platinum drugs in cancers that have become highly drug-resistant
- Allows lower dosages of platinum drugs to be used
- Aim is to provide access to chemotherapy for patients who would not otherwise be considered well enough to be treated
- Potentially reduces risk of long-term painful nerve damage and hearing loss (affecting 40-60% of patients)

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Veyonda® CEP-1 Phase 1b Study

Veyonda®

CEP

Headline results:

- 19 patients with solid cancers that had stopped responding to therapy including carboplatin
- Patients entered study with progressive disease
- Given Veyonda® (400 or 800mg) + carboplatin (50% or 75% normal dose)
- No nerve damage or hearing loss reported
- 45% of patients completed 7-month study with no disease progression (1 partial response)
- **CEP Phase 2 study currently under review.**

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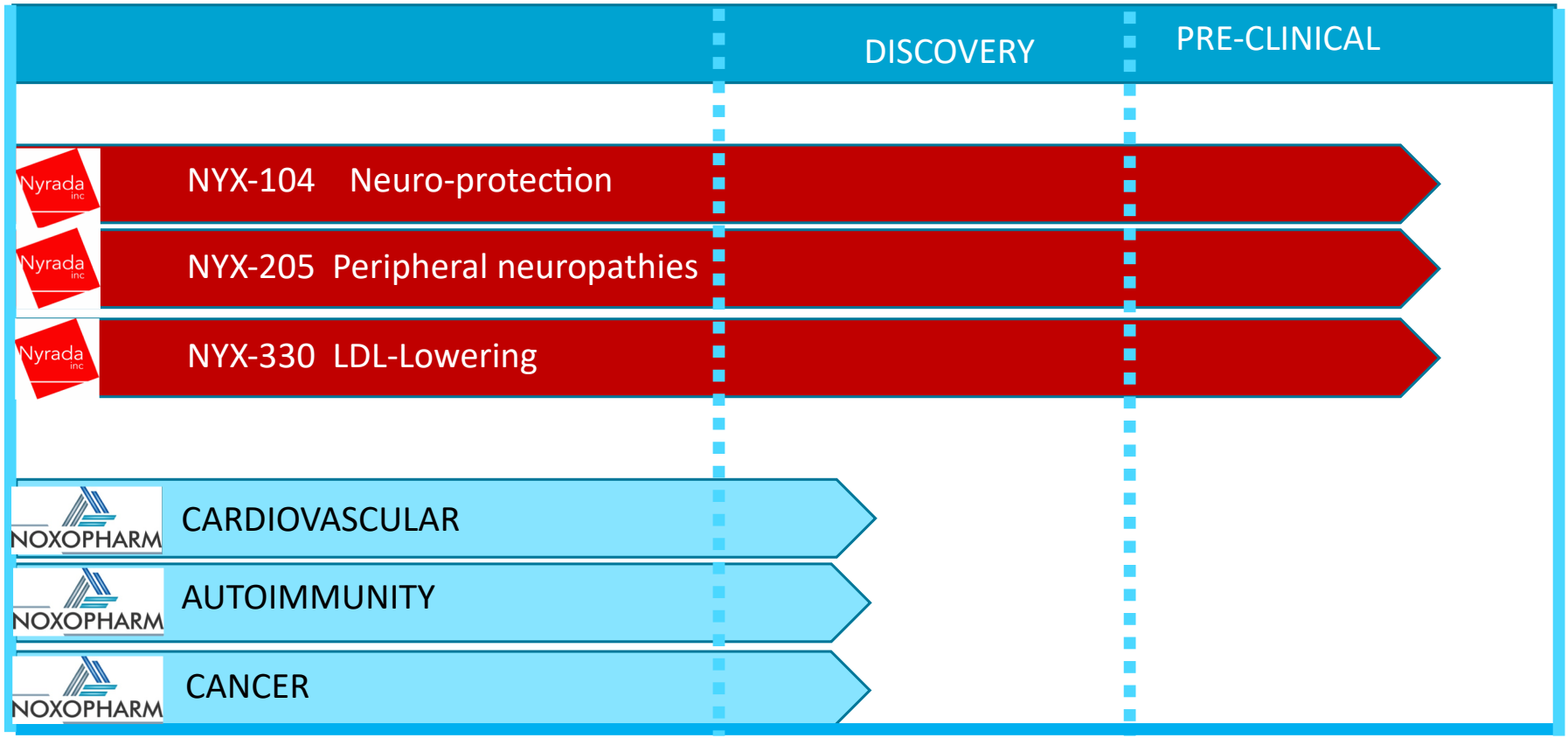
Pre-Clinical Pipeline



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Three first-in-class drug candidates aiming to meet significant unmet medical needs

	NYX-104	NYX-205	NYX-330
STATUS:	Lead optimization	Lead confirmed	Lead optimization
	First-in-class neuro-protectant To protect brain from secondary nerve damage caused by excitotoxicity associated with concussion, TBI, stroke and severe epilepsy Blocks glutamate-induced calcium overload from intra-cellular and extra-cellular sources Preclinical data demonstrates 56% reduction in excitotoxicity in mouse model of ischemic stroke	**First-in-class anti-inflammatory for peripheral neuropathy** Inhibits all major inflammatory cytokines and thromboxane; spares prostaglandins Readily crosses animal blood-nerve barrier and enters peripheral nerves 200 different causes of peripheral neuropathy Clinical indications(s) currently being evaluated in animal models	**First-in-class small molecule PCSK9 inhibitor** To inhibit binding between PCSK9 and LDL receptor Potential once a day oral treatment to be used in combination with statins to achieve better control of LDL cholesterol levels Potential to allow lower statin dosage to avoid negative side effects associated with statin use such as muscle damage and risk of diabetes

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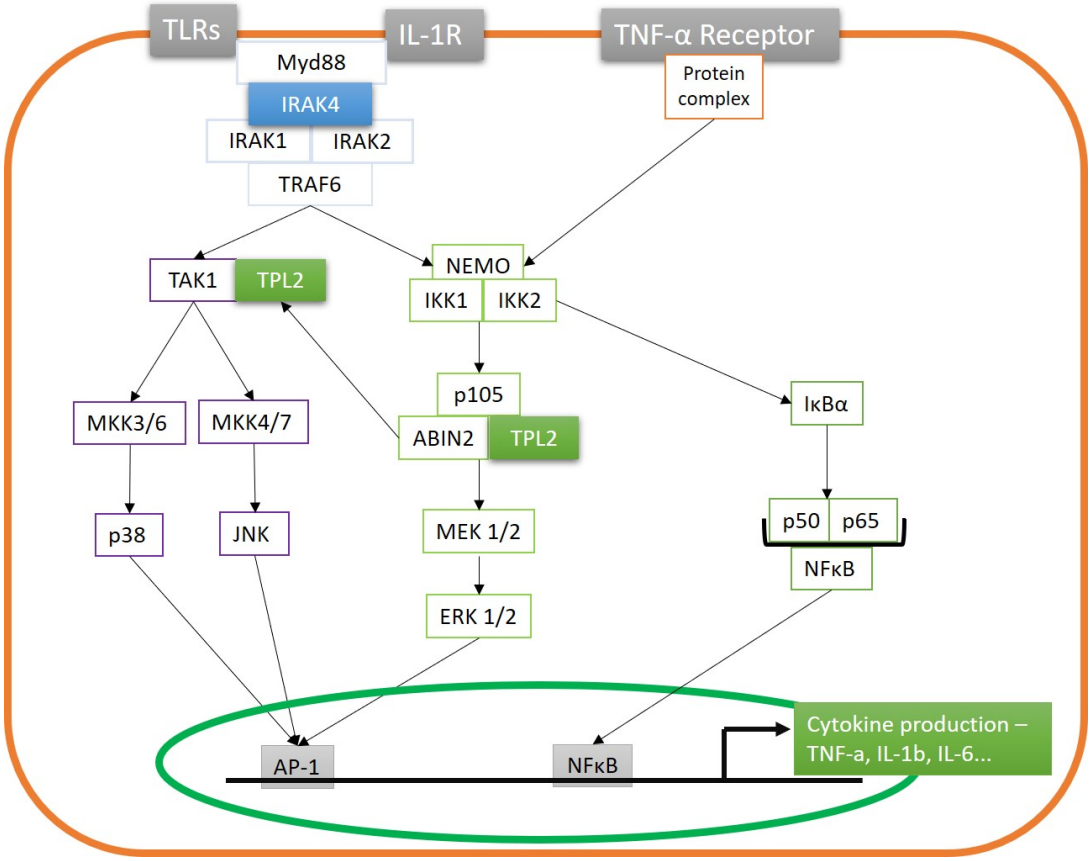
Drug Discovery Program



IRAK4 AND TPL2
Involved in:

Chronic inflammatory diseases:

- Ankylosing spondylitis
- Pulmonary fibrosis

Autoimmune diseases:

- Rheumatoid arthritis
- Psoriasis
- Lupus
- IBD, ulcerative colitis
- Motor neurone disease

Cancer:

- B-cell leukemias
- Melanoma

NOXOPHARM

NOX Isoflavonoid Technology Platform
Major opportunity to develop highly selective IRAK4 and TPL2 inhibitors

Targets	Inflammation	Autoimmunity	Cancer	Existing inhibitors and Competition
IRAK4	**++** Diabetes, Atherosclerosis, kidney, lung and cardiac fibrosis	**+++** Rheumatoid arthritis, Lupus, Psoriasis, AD, MS, ALS, Ankylosing spondylitis, IBD	**++**	Compound name: PF-06650833 Company: Pfizer Potential Indications: **Phase II** Rheumatoid arthritis **Phase I** Lupus vulgaris Compound name: CA-4948 Company: Curis Potential Indications: **Phase I** Non-Hodgkin's lymphoma
TPL2	**+++** Diabetes retinopathy, Atherosclerosis, Neuro-inflammation	**+++** IBD, MS, Rheumatoid arthritis, Lupus	**+**	Compound name: GS-4875 Company: Gilead Sciences Inc Potential indication: **Phase I** IBD

NOXOPHARM

Expected Upcoming Milestones

Dec 2018	DARRT 12-week assessments (Cohorts 1,2,3)
1Q 2019	DARRT 24-week assessments (Cohorts 1,2,3)
1Q 2019	Completion of LuPIN-1 enrolment
1Q 2019	Initiation of DARRT-2 (lung cancer)
1Q 2019	Initiation of DARRT-3 (sarcomas)
1Q 2019	DARRT 12-week assessment (Cohort 4)
2Q 2019	Interim Phase 1 LuPIN-1 results
3Q 2019	Initiation of DARRT-4 (brain cancer)
3Q 2019	Initiation of Phase 2/Phase 3 DARRT-5 (prostate cancer)

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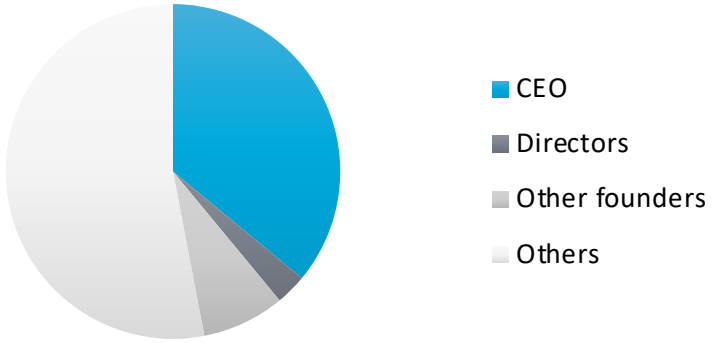
Experienced Leadership Team

	Executive	Title	Prior Experience
	Graham Kelly, PhD	Founder and CEO	Novogen, Marshall Edwards Inc (MEIP)
	Greg van Wyk, MD	Chief Medical Officer	Eli Lilly
	John Wilkinson PhD	Chief Scientific Officer (Oncology)	Biotron
	James Bonnar	Chief Scientific Officer (Non-Oncology)	Neuren
	Mark Waring	Senior Vice-President US Operations	IQVIA, Deloitte

NOXOPHARM

Key metrics

Number of Shares	**121.9M** : Free float 66.8%
Market Cap (1 Nov 2018)	AU$73M
IPO price **12 month high/low** **Average daily turnover**	20 cents $1.80/0.48 $0.54M
Cash position	AU$ 9.6 (30 Sept 2018)



NOXOPHARM

Dr. Graham Kelly

Chief Executive Officer

graham.kelly@noxopharm.com

NOXOPHARM

ASX: NOX

DISCOVER DEVELOP DELIVER

THERANOSTICS

Dr Nat Lenzo

BMedSci(Hons) MBBS MMed EMBA FRACP FAANMS

Clin. Assoc. Prof. in Medicine - Dept. of Medicine, University of WA

Hon Fellow in Medicine - Macquarie University, Sydney NSW

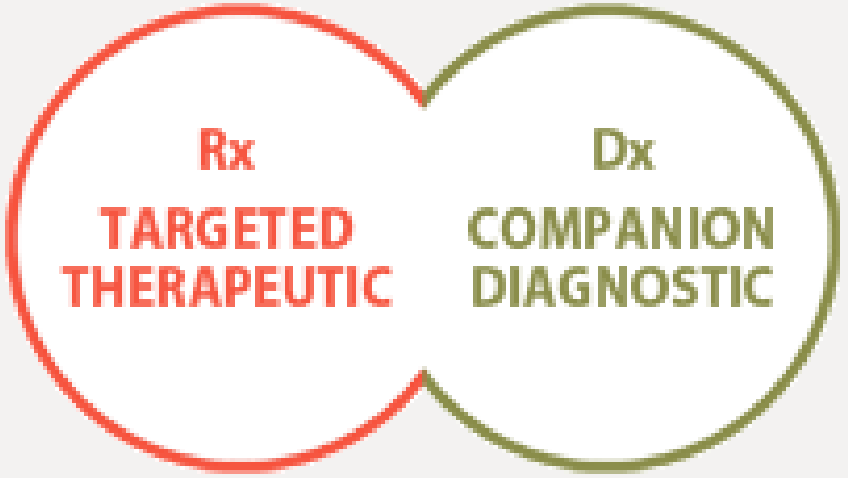
General Physician & Nuclear Physician

MACQUARIE University
SYDNEY·AUSTRALIA

THE UNIVERSITY OF WESTERN AUSTRALIA

GenesisCare

Theranostics

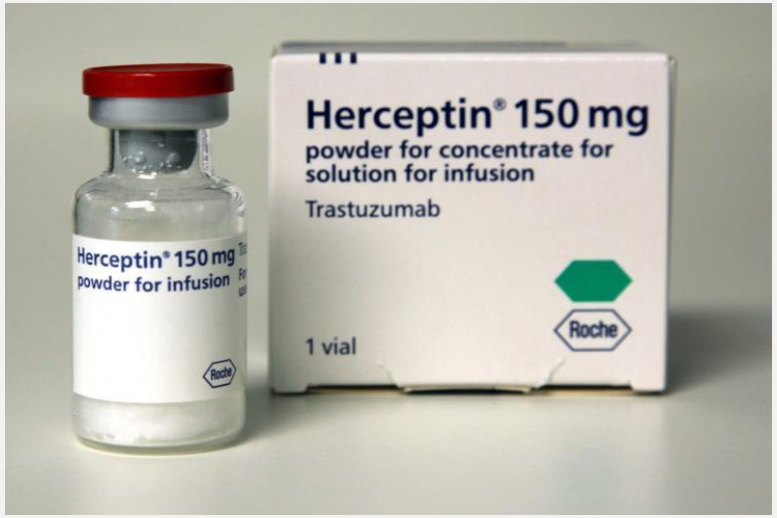


THERANOSTICS

The merging of drug therapy and diagnostics to advance personalized medicine

Theranostics

- September 25, 1998 - key day
  - FDA granted simultaneous approval for Genentech's **Herceptin®** for the treatment of Stage IV breast cancer and Dako's **HercepTest®** for diagnosis of Her2 overexpression



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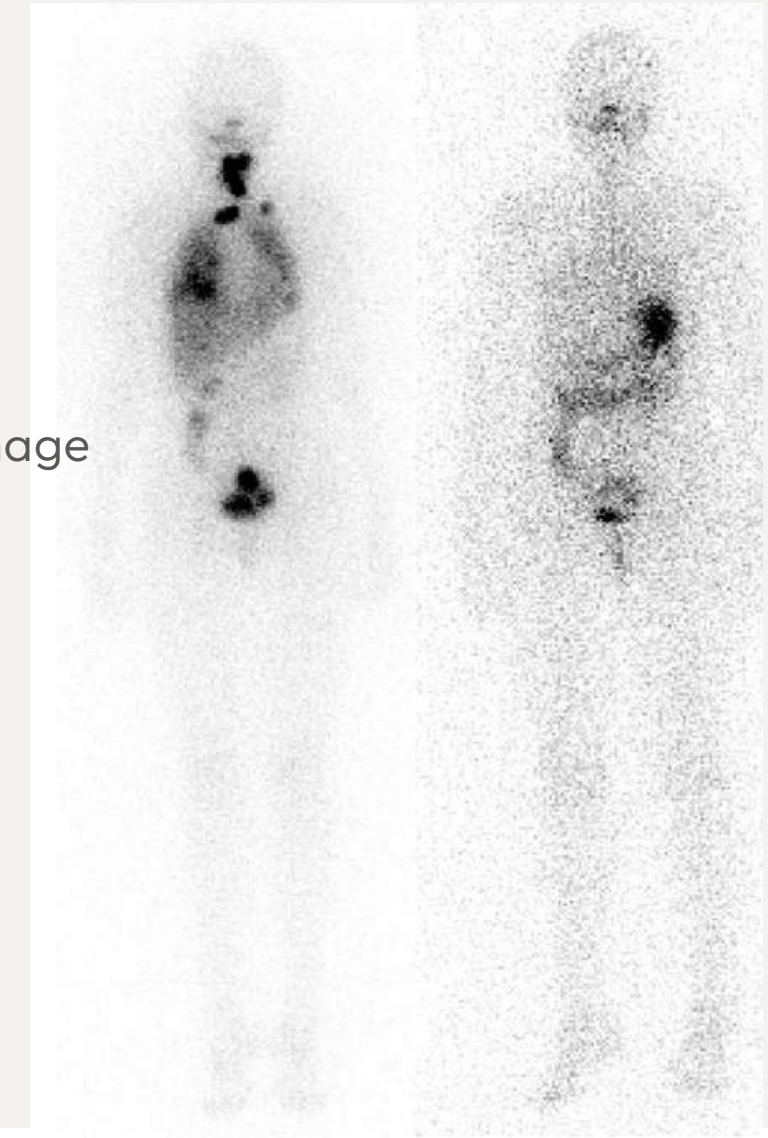
Theranostics in Nuclear Medicine

- Not a new paradigm
- Dr S Seidlin (1895-1955) Montefiore Hospital New York City 1943
  - Radioactive iodine (I-131) for metastatic thyroid cancer
- Tracer dose followed by therapeutic dose
  - Low dose I-131 or I-123 still used

Thyroid Cancer

Ablative Dose Image



1 year later

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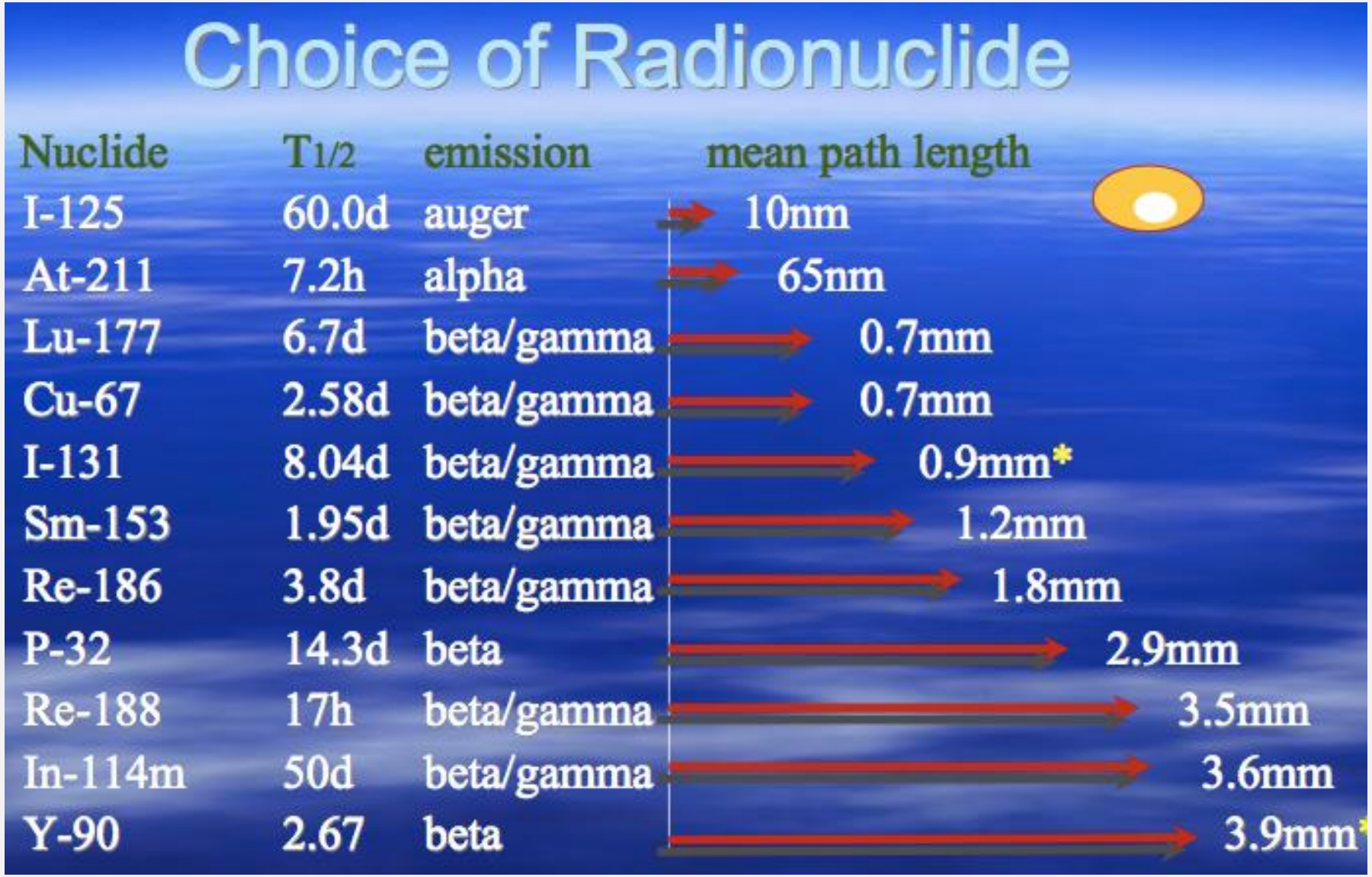
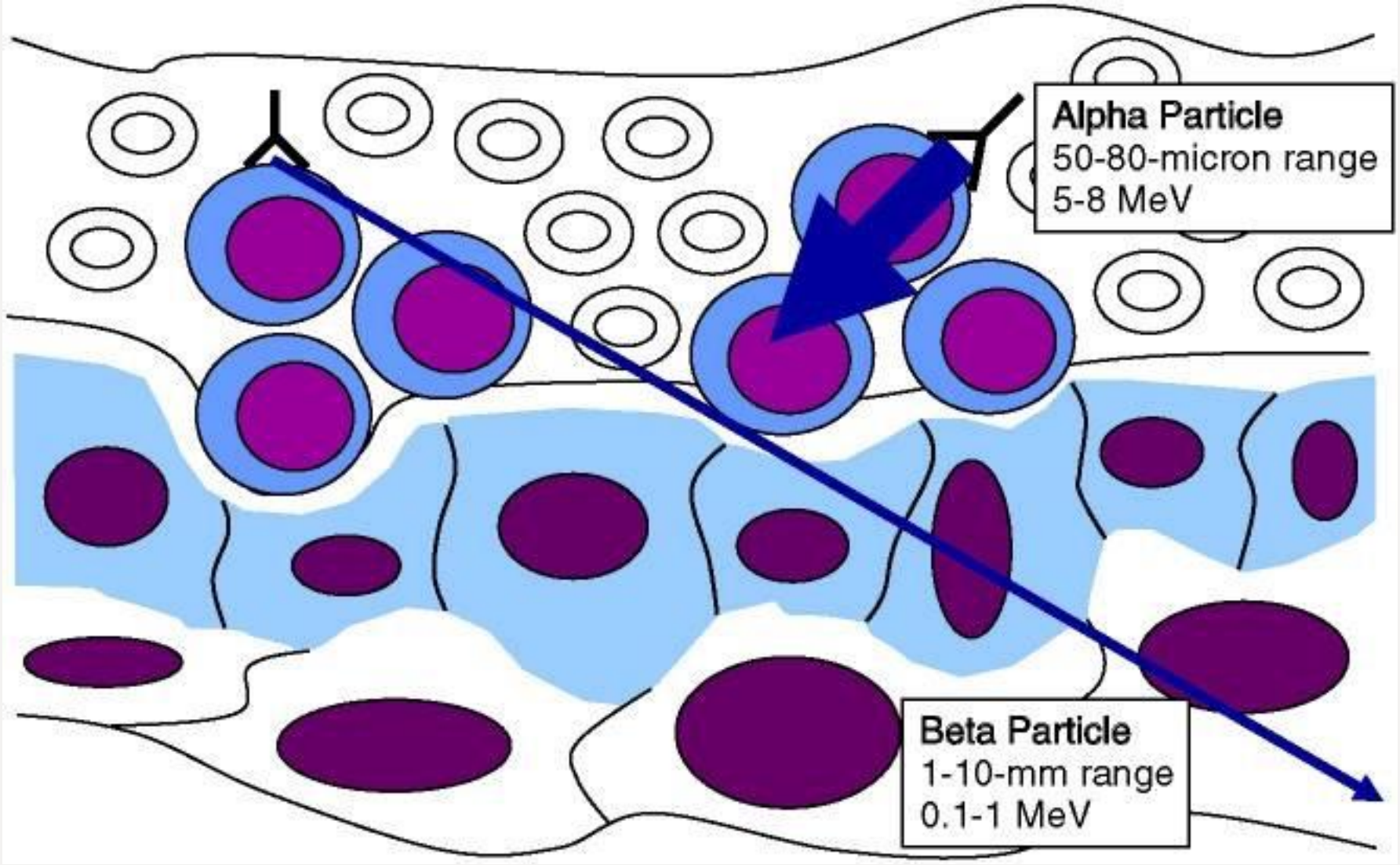
Targeted Radionuclide Therapy

- Benefits
  - Higher radiation dose deposited directly to target tissue (10-100x greater than external beam)
  - Decreased toxicity to adjacent tissue – short pathway
  - Selective targeting possible – e.g. anti-CD20, SSTR
  - Dosimetry possible
  - Can combine with chemotherapy or potentially other radionuclides
  - Various isotopes, energy and method of administration

Choice of Radionuclide



Radionuclide Therapy



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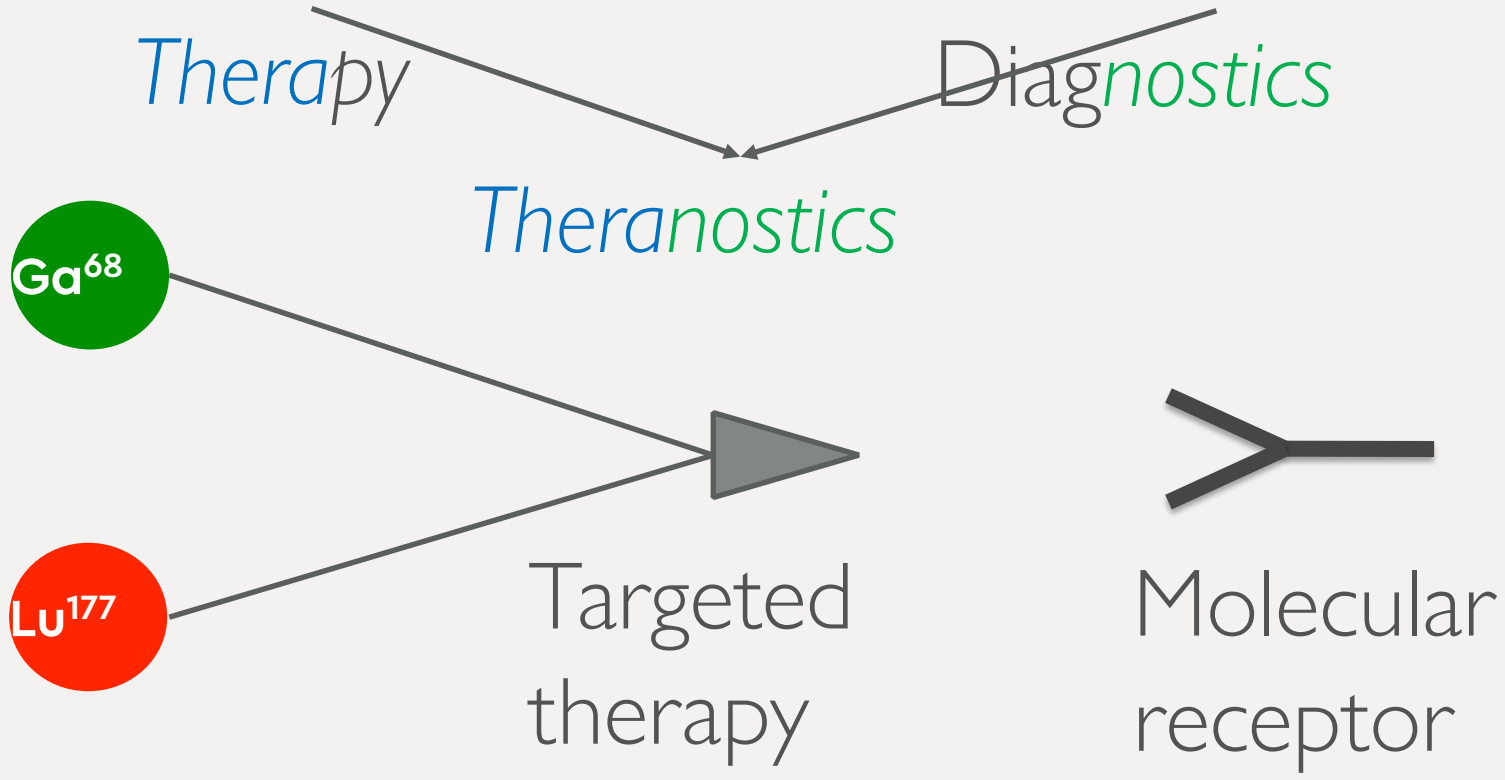
PERSONALISED MEDICINE, THERANOSTICS & RADIOPEPTIDE THERAPY (RPT)



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Gallium PET Radiotracers

Germanium - Gallium 68 Generators

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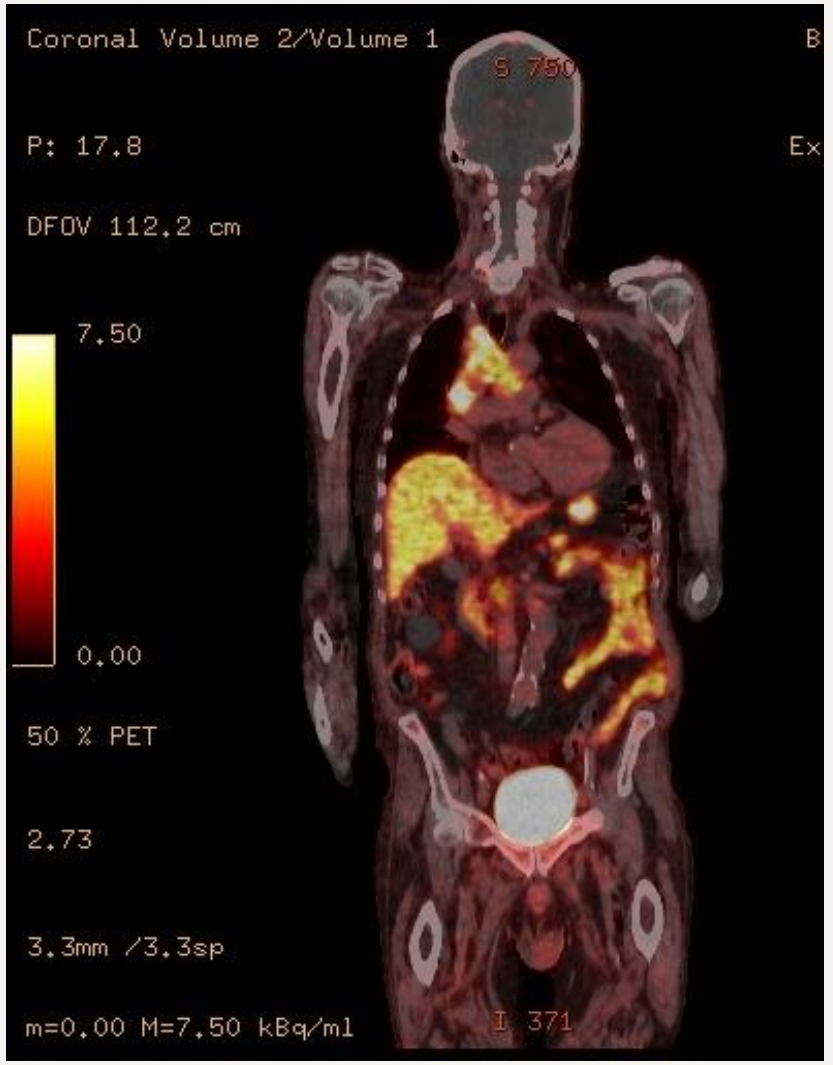
Gallium-68 Products

- Gallium Citrate
- Gallium MAA
- Gallium DTPA
- Gallium Octreotate
- Gallium PSMA
- Gallium Pentixafor
- Gallium Herceptin
- Gallium Exendin
- Gallium Satareotide
- Etc.



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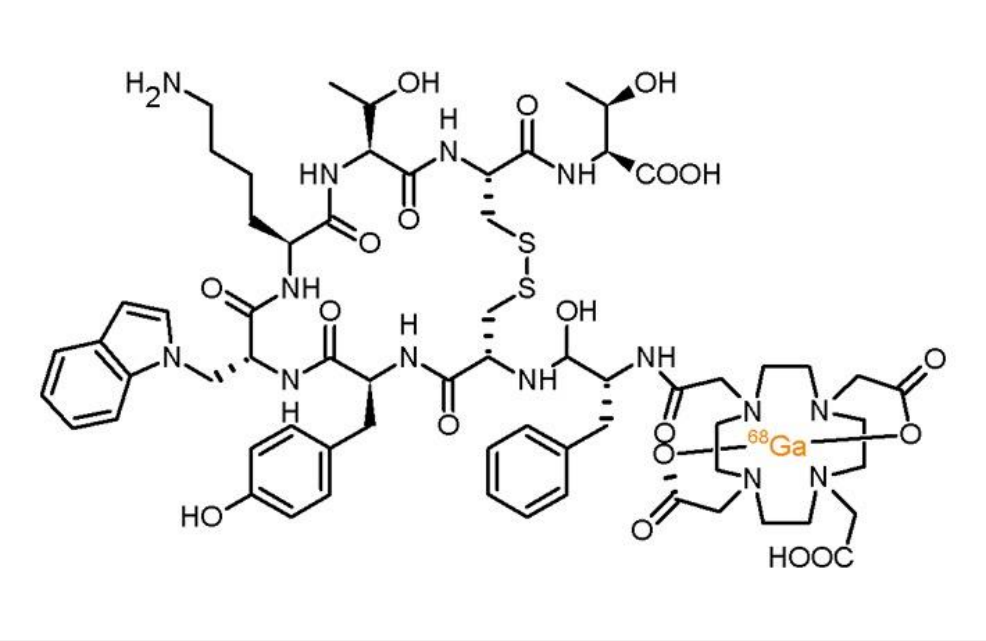
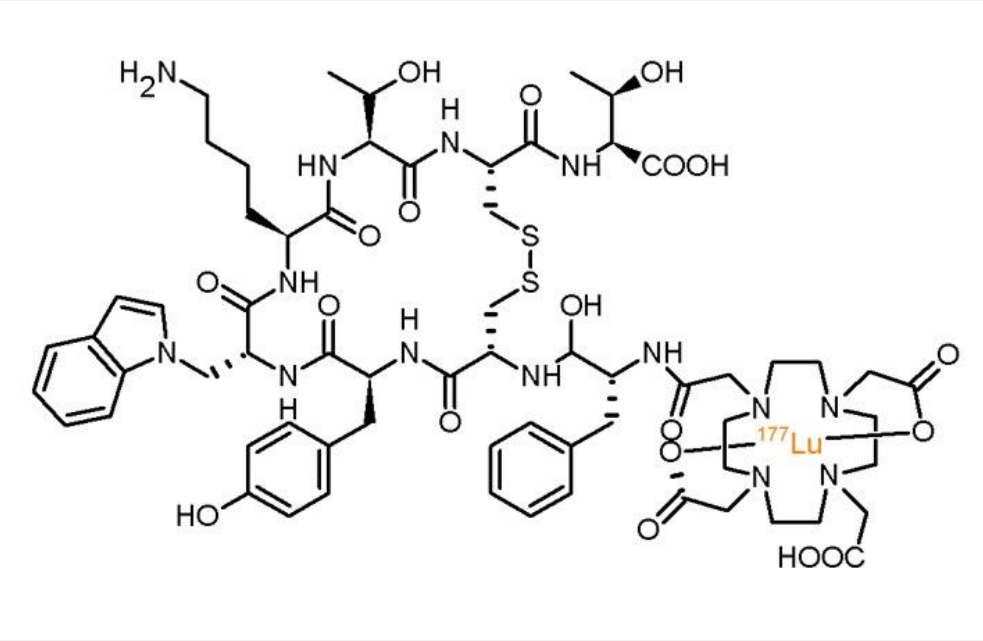
Ga-68/Lu-177 octreotate





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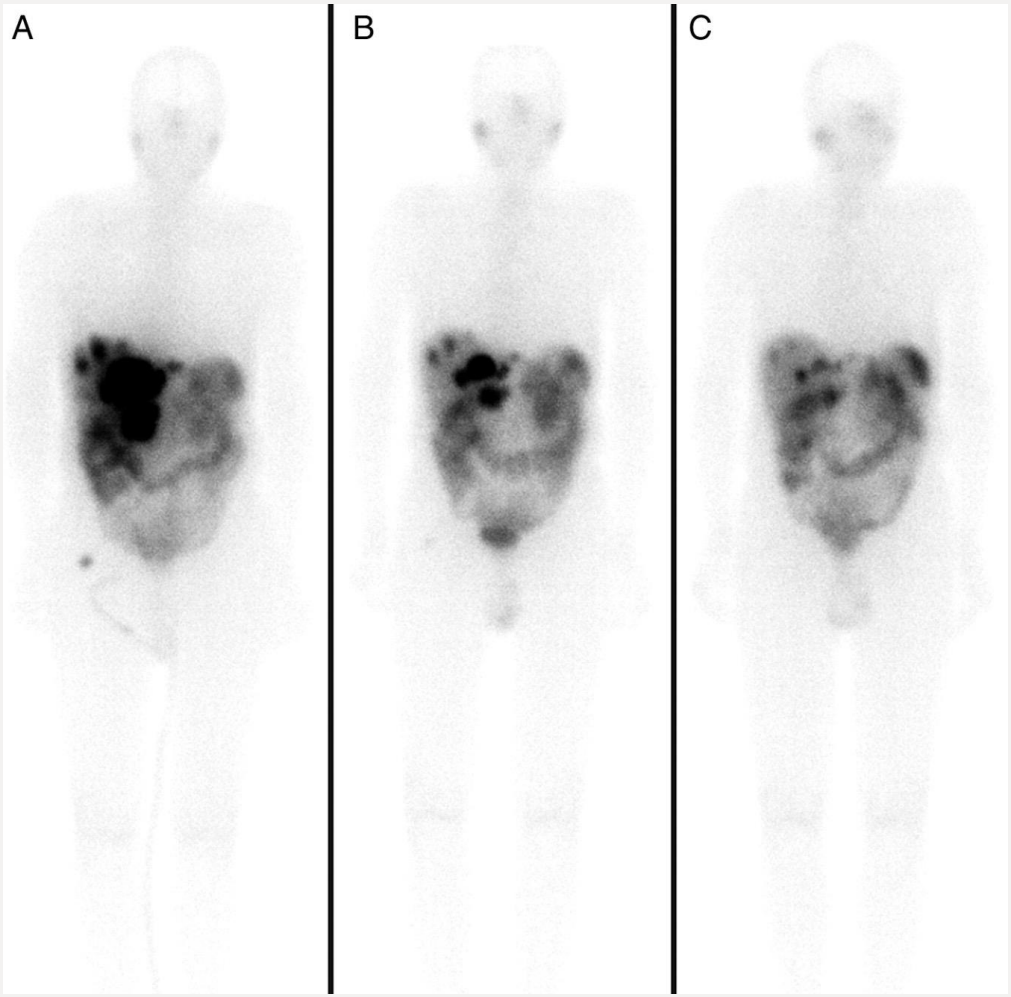
Metastatic Insulinoma Treated with Lu-177 octreotate



A. Initial B. 4 months C. 9 months after treatment

(Ong, Henley, Hurley, Turner et al. Eur J Endocrinol May 1, 2010 162 1001-1008)

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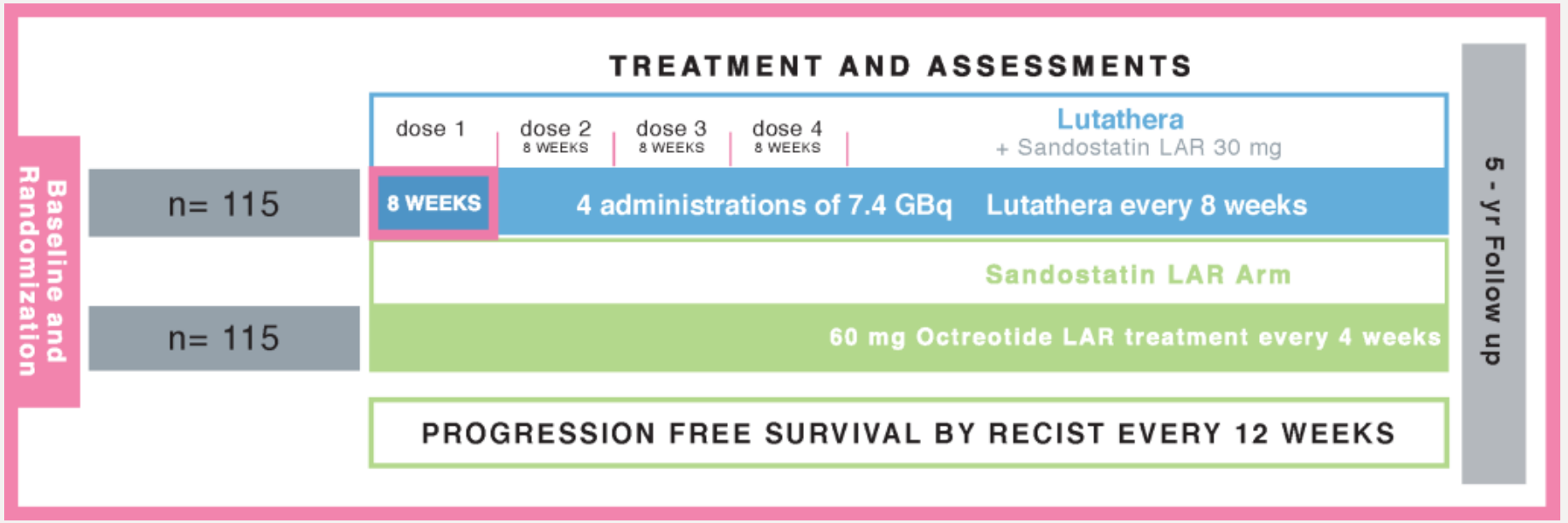
Netter I Study AAA

- Lu-177 octreotate vs sandostatin (standard of care)



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NETTER-1 Trial

Progression-Free Survival

N = 229 (ITT)

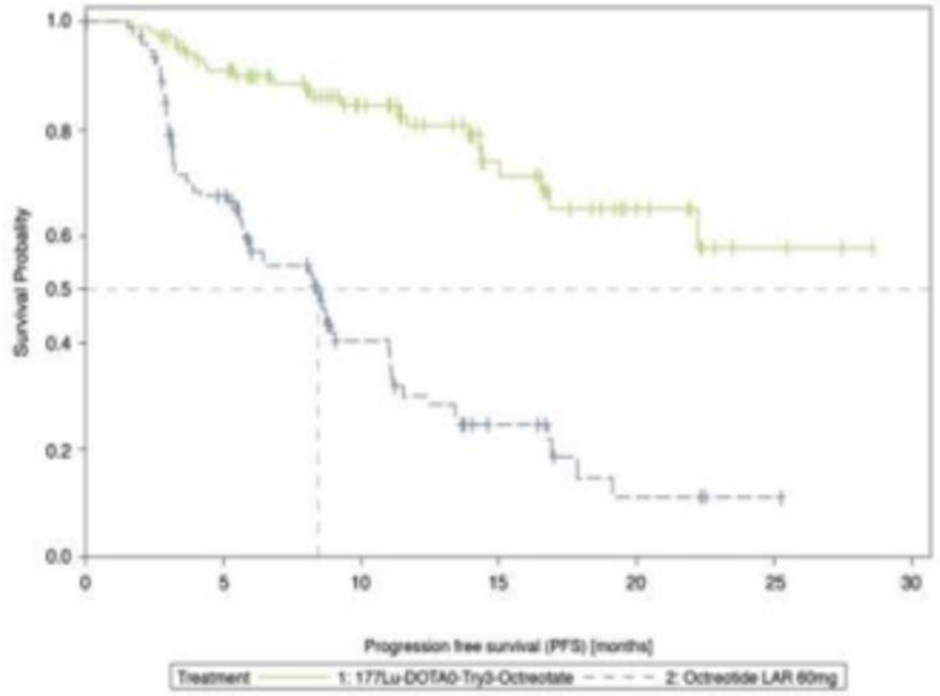
Number of events: 90

- ^{177}Lu-Dotatate: 23
- Oct 60 mg LAR: 67

Hazard ratio: **0.21**
[0.129 – 0.338] **p < 0.0001**

79% reduction in the risk of disease progression/death

Estimated Median PFS in the Lu-DOTATATE arm
≈ 40 month



All progressions centrally confirmed and independently reviewed for eligibility (SAP)

JNM The Journal of NUCLEAR MEDICINE

Jonathan Strosberg et al. J Nucl Med 2016;57:629

GenesisCare

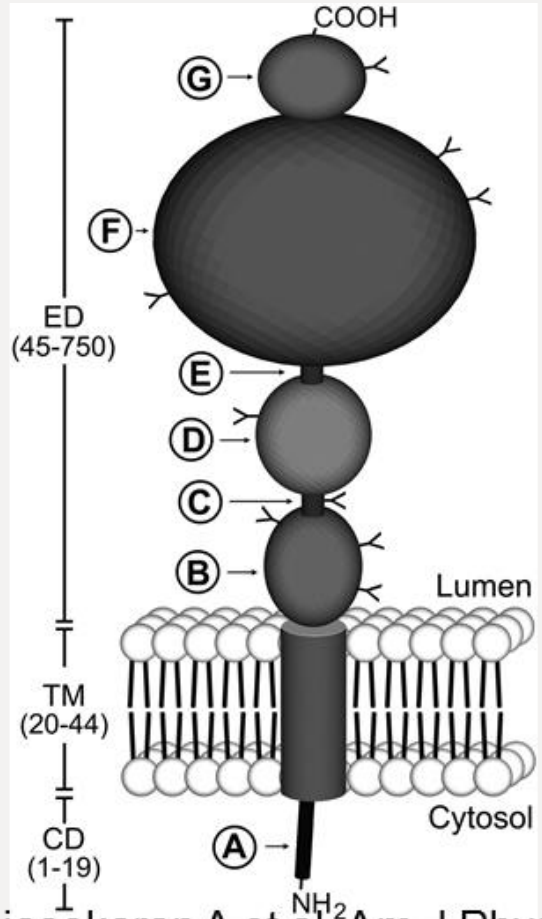
September 29, 2017 Advanced Accelerator Applications Announces European Approval of Lutetium (177Lu) Oxodotreotide (Lutathera®) for Gastroenteropancreatic Neuroendocrine (GEP-NET) Tumors – Completes First Thera(g)nostic Radiopharmaceutical Pairing in Oncology

October 30, 2017 Advanced Accelerator Applications Announces $3.9 Billion All Cash Proposed Tender Offer by Novartis

January 26, 2018 Advanced Accelerator Applications/Novartis Announces US FDA Approval for Lutathera® for US Market (Already approved in Europe/UK/NZ)

Prostate cancer imaging with PSMA-ligands

- PSMA: prostate-specific membrane antigen
- cell surface protein with overexpression in prostate cancer
- transmembraneous localization including large extracellular part
- promising target for prostate cancer specific imaging and therapy
- recently: development of various PSMA-ligands for PET imaging
- e.g. ^{68}Ga-PSMA: Glu-NH-CO-NH-Lys-(Ahx)-[^{68}Ga(HBED-CC)] (only for ^{68}Ga) and
  PSMA I&T (TUM/Scintomics), suitable for M^{3+} labeling (^{68,67}Ga, ^{177}Lu, ^{90}Y, ^{111}In...)



Rajasekaran A et al. Am J Physiol Cell Physiol 2005

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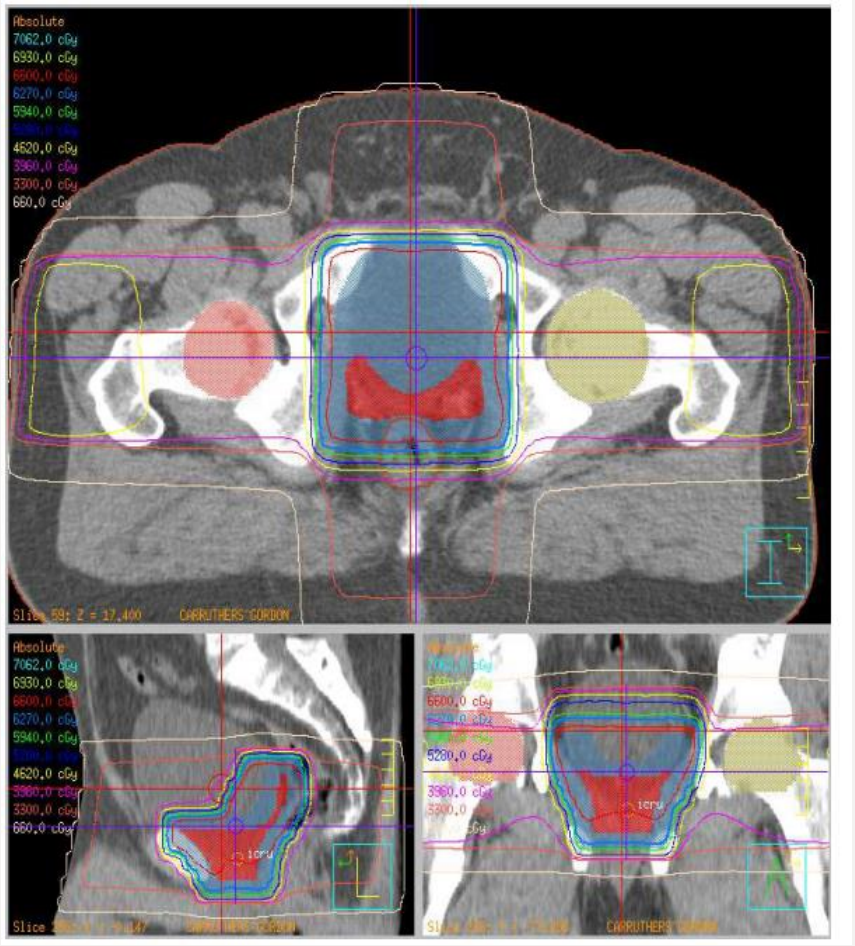

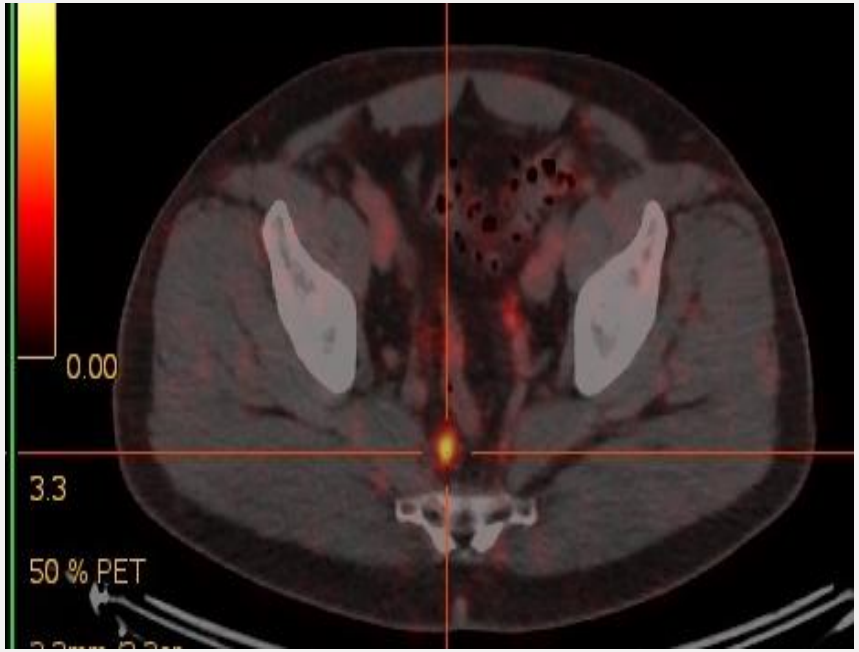

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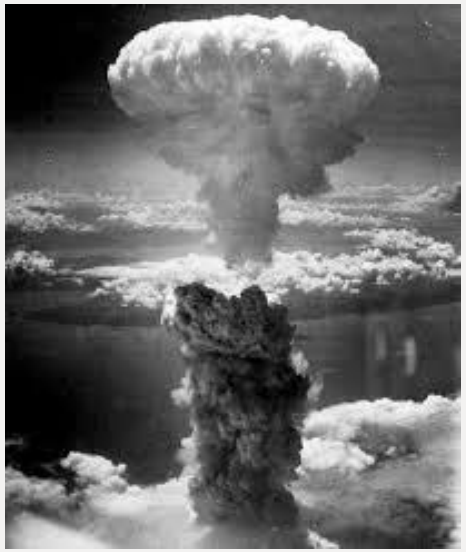
Why the explosion?

- Prostate cancer
  - Worldwide problem - approx. 20 000 cases diagnosed annually in Australia; more than 300 000 new cases annually in Europe
  - Approx. 1.4 million men die worldwide yearly; 4th most common cause of cancer death worldwide
  - Most common cancer diagnosis in Australia (more than breast, lung and melanoma)
  - *1/3 will show biochemical relapse (PSA) within 10 years*
  - More men die per year from prostate cancer (>3000) in Australia than women die from breast cancer
  - No major advance in therapeutic options in last 15 yrs
    - Surgery/brachytherapy/radiotherapy
    - ADT/pelvic irradiation
    - 2nd line ADT/Docetaxel/2nd line chemo (cabazitaxel)
    - Radium (palliation)
    - Overall survival benefit of 2nd line therapies modest at best



Status of PCa treatments –EJNM 2015

Table 1 Compounds approved for the treatment of CRPC: overall survival benefits versus control arms in phase III clinical studies

Reference	Investigational compound	Control arm	Hazard ratio for death (95 % CI)	Overall survival benefit (months)	*P* value
[3]	Docetaxel	Mitoxantrone	0.80 (0.67 – 0.94)	1.9	0.02
[4]	Docetaxel	Mitoxantrone	0.76 (0.64 – 0.94)	2.4	0.009
[5]	Cabazitaxel after docetaxel	Mitoxantrone	0.70 (0.59 – 0.83)	2.1	0.001
[6]	Abiraterone after docetaxel	Placebo	0.65 (0.54 – 0.77)	3.9	0.001
[7]	Abiraterone before docetaxel	Placebo	0.75 (0.61 – 0.93)	5.2	0.0097
[8]	Enzalutamide after docetaxel	Placebo	0.63 (0.53 – 0.75)	4.8	0.001
[9]	Enzalutamide before docetaxel	Placebo	0.71 (0.60 – 0.84)	1.8	0.001
[10]	^{223}Ra	Placebo	0.70 (0.56 – 0.83)	3.6	0.00007

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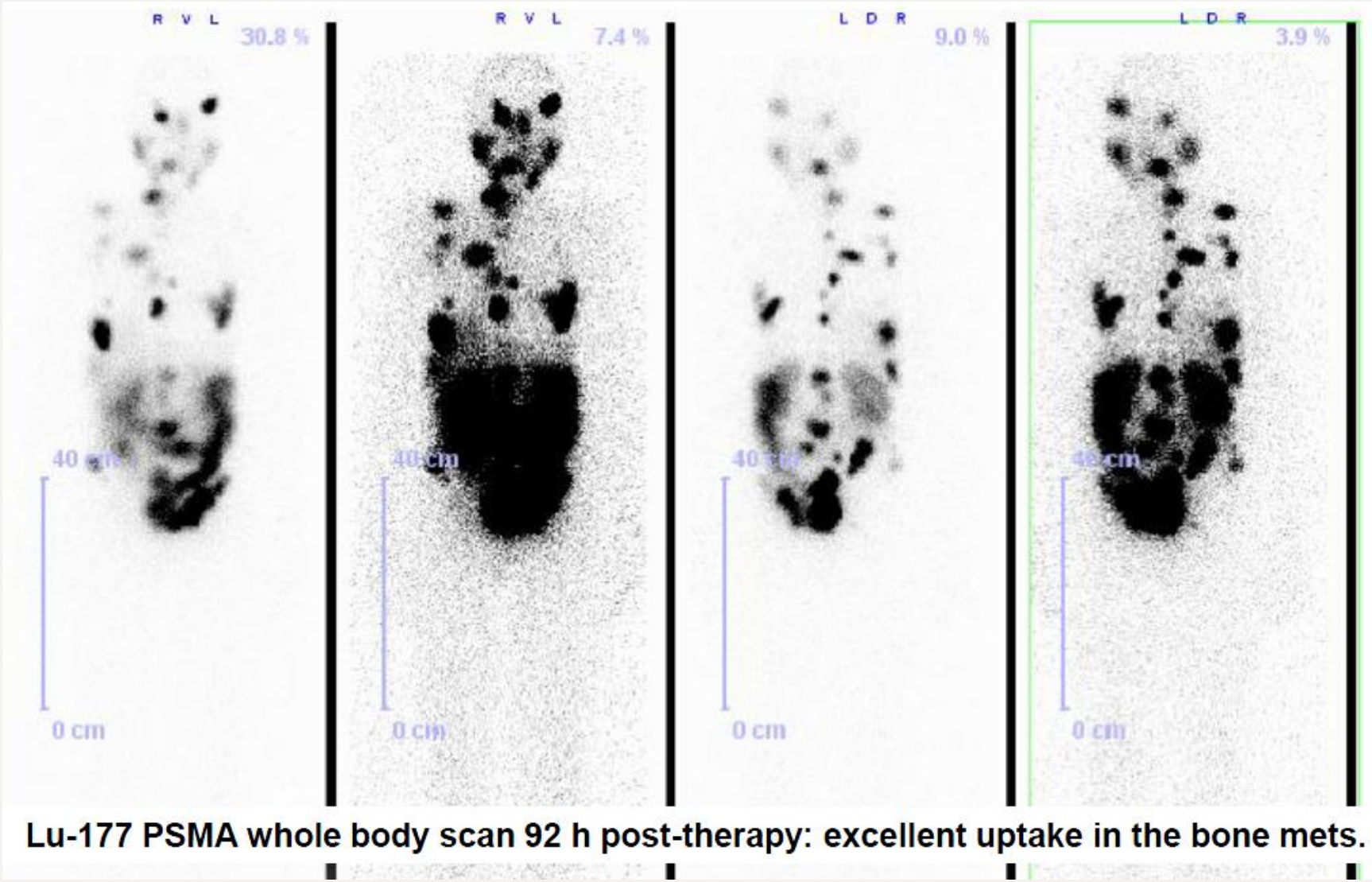
Lutetium-177 PSMA



Lu-177 PSMA whole body scan 92 h post-therapy: excellent uptake in the bone mets.

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Systemic radioligand therapy with 177Lu-PSMA-I&T in patients with metastatic castration-resistant prostate cancer. H. Wester & M. Schwaiger Munich March 2016

Material and Methods

22 mCRPC patients treatment failure with both chemotherapy and novel androgen-receptor targeted therapy treated 8-weekly with up to 4 cycles of 177Lu-PSMA-I&T.

Results

First 3 patients treated with a lower activity of 3.7 GBq in their first cycle. Due to a favourable safety profile the activity was increased to 7.4 GBq in 19 subsequent patients who completed a total of 40 cycles.

With higher activity no grade 3/4 toxicities were observed. Main non-hematologic and hematologic grade 1/2 toxicities were dry mouth in 7 (37%), anemia in 6 (32%) and thrombopenia in 5 (25%) patients.

Proportion of patients achieving a maximum PSA-decline of ≥ 30%, ≥ 50% and ≥ 90% was **56%, 33%** and 11%, respectively. Combined assessment of bone and soft-tissue metastases showed a **complete remission in 5%, stable disease in 63%** and progressive disease in 32% of patients.

ECOG performance status improved or was stable in 74% of patients. Of men with bone pain, 58% achieved complete resolution or reduced pain.

Conclusion

Radioligand therapy with 177Lu-PSMA-I&T appears to be safe and active in heavily pretreated mCRPC patients.

GenesisCare

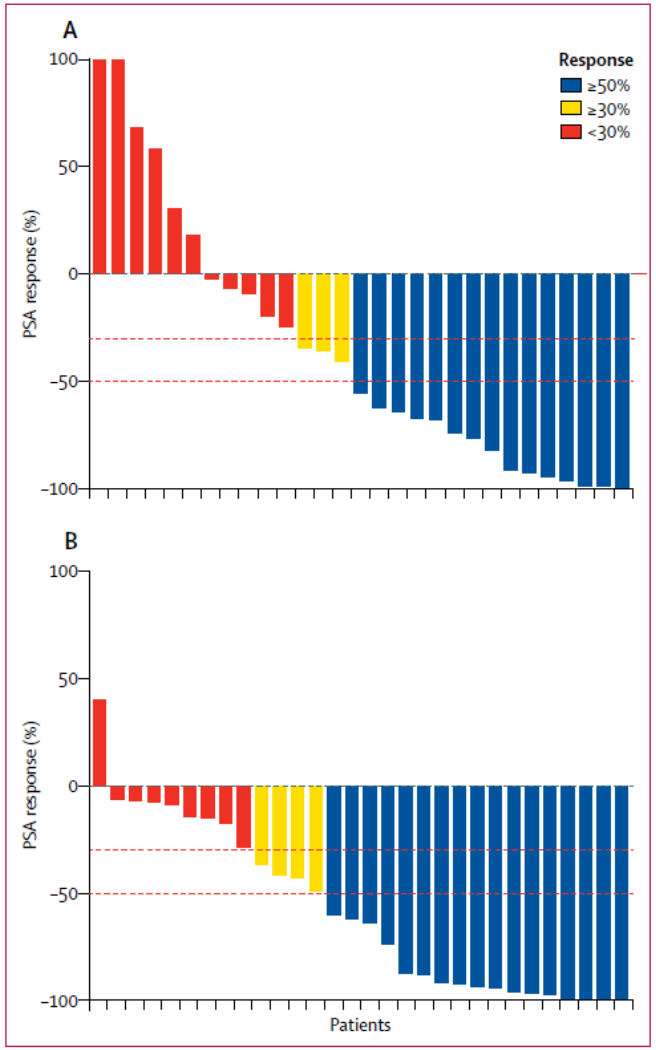
Lu-177 PSMA in Treatment

[(177)Lu]-PSMA-617 radionuclide treatment in patients with metastatic castration-resistant prostate cancer (LuPSMA trial): a single-centre, single-arm, phase 2 study.

Hofman MS, Violet J, Hicks RJ, Ferdinandus J, Ping Thang S, Akhurst T, Iravani A, Kong G, Ravi Kumar A, Murphy DG, Eu P, Jackson P, Scalzo M, Williams SG, Sandhu S.

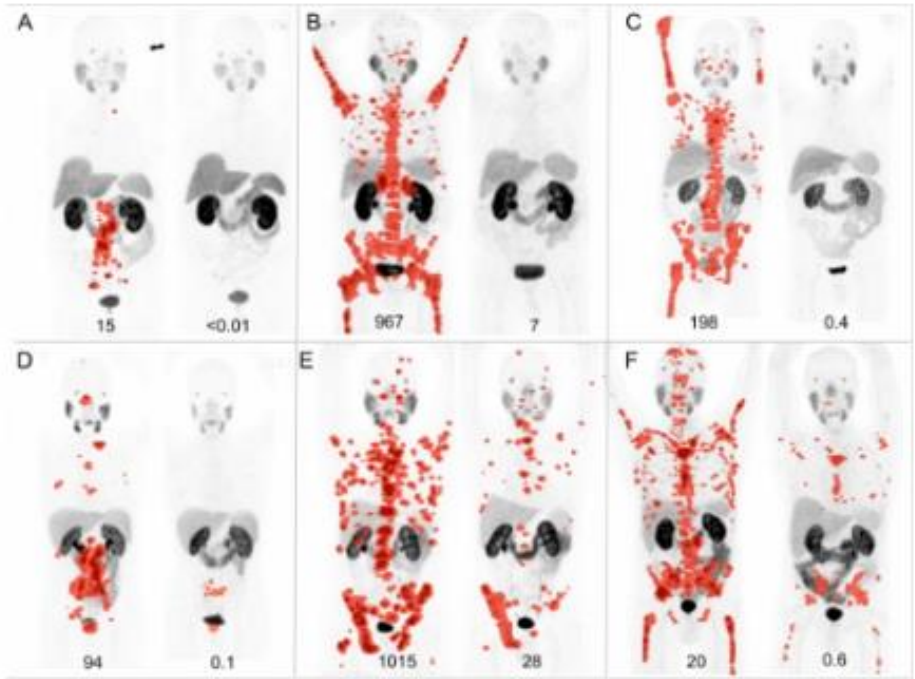
Lancet Oncol. 2018 May 7.

Proof of Concept study shows PSA response in 29 out of 30 patients



Hofman et al, Lancet, 2018, June Vol 19, p 825-833

SNMMI Image of the Year: 68Ga-PSMA-11 PET maximum intensity projection (MIP) images at baseline and three months after 177Lu-PSMA-617 in eight patients with PSA decline > 98 percent.



Reduced cancer activity observed in six men involved in Peter Mac's proof-of-concept trial who recorded post-treatment PSA level declines of >96%. Red dots indicates sites of prostate cancer before (left side) and after (right side) treatment with LuPSMA.

Source: Endocyte Inc

GenesisCare

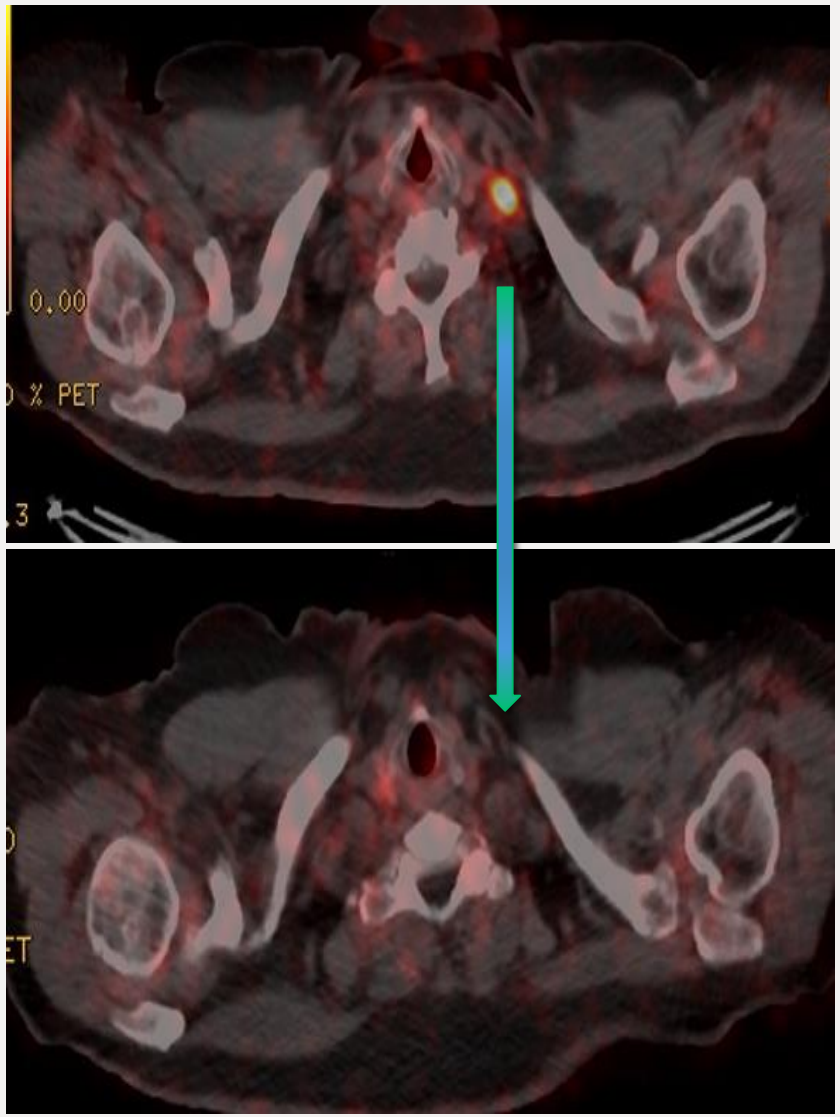
Lu-177 PSMA in Treatment

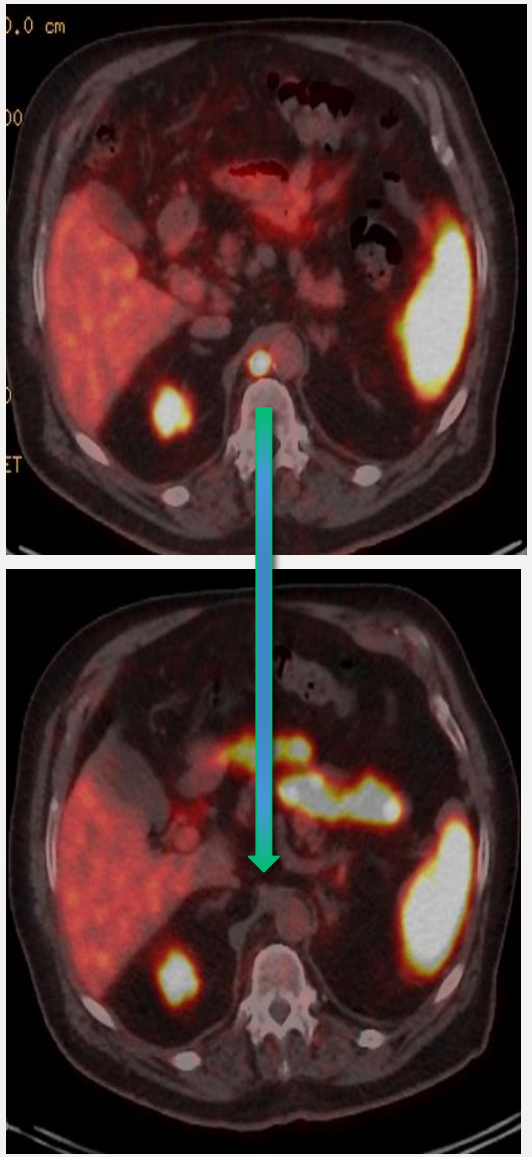
- 177Lu-PSMA has been used safely in advanced metastatic prostate cancer patients (>3000 worldwide – mostly Germany) with promising results.
- Theranostics Australia – Hollywood Private Hospital and Macquarie University Hospital Sydney. ~200 patients treated. Currently treat approx. **5-10 patients a week.** Compassionate basis under TGA SAS.
- Number of studies now published: largest >500 patients in castrate resistant metastatic prostate cancer who have failed ALL treatment options. **After 3-4 cycles Lu-177 PSMA:**
  - **40% show >50% reduction in PSA**
  - **30% show 0-50% reduction in PSA**
  - **30% show progression despite treatment**
  - **Progression free survival of 6-21 months**
  - **Overall survival benefit of 6-14 months**

Lu-177 PSMA Side Effects

- 10-15% nausea
- 10-15% bone "flare"
- Transient mouth dryness
- Tiredness
- Bone marrow dysfunction – usually self limiting
- Financial toxicity!

Mr J – 3 cycles: 17 GBq





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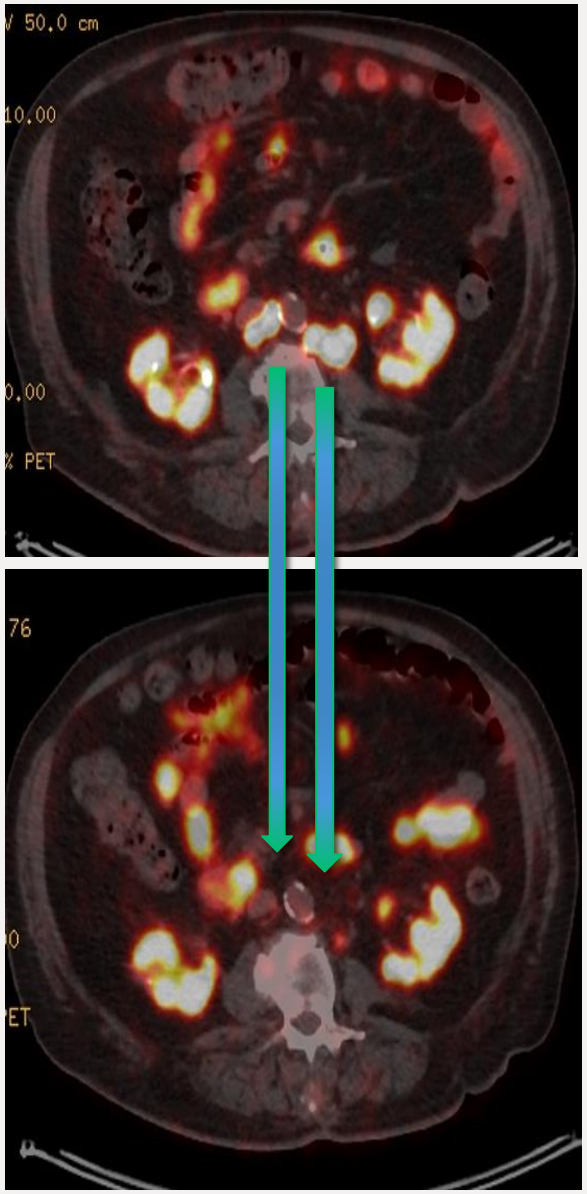
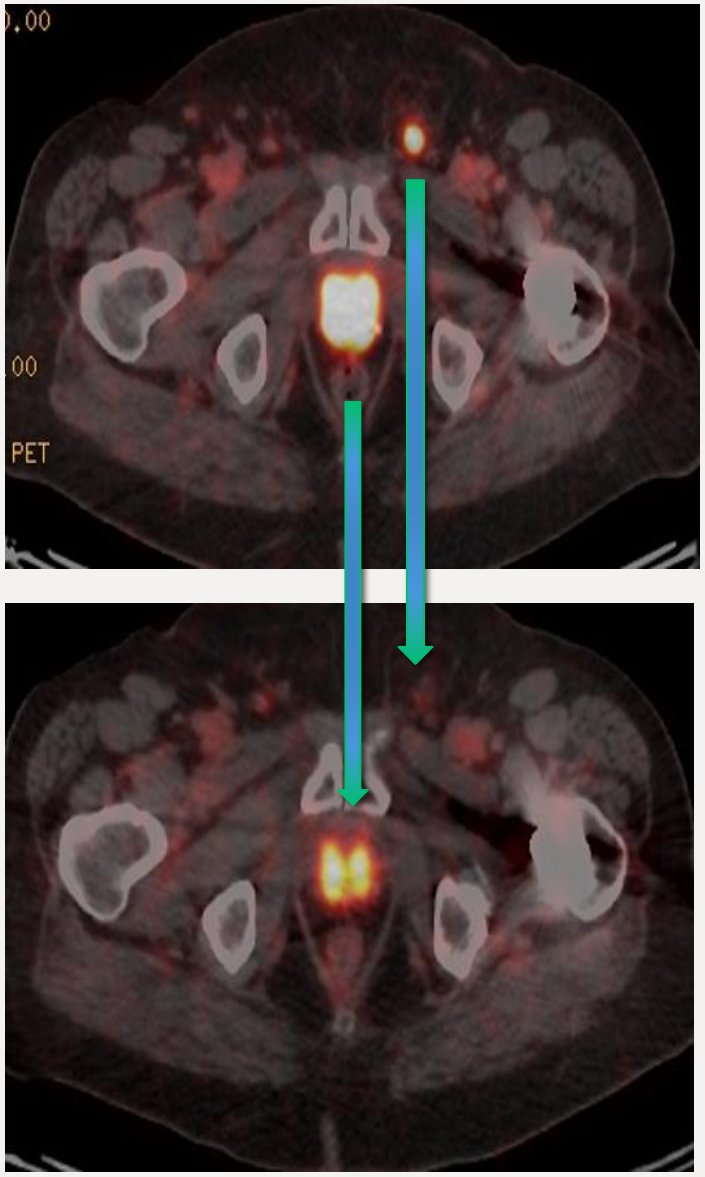
Mr J – 3 cycles: 17 GBq





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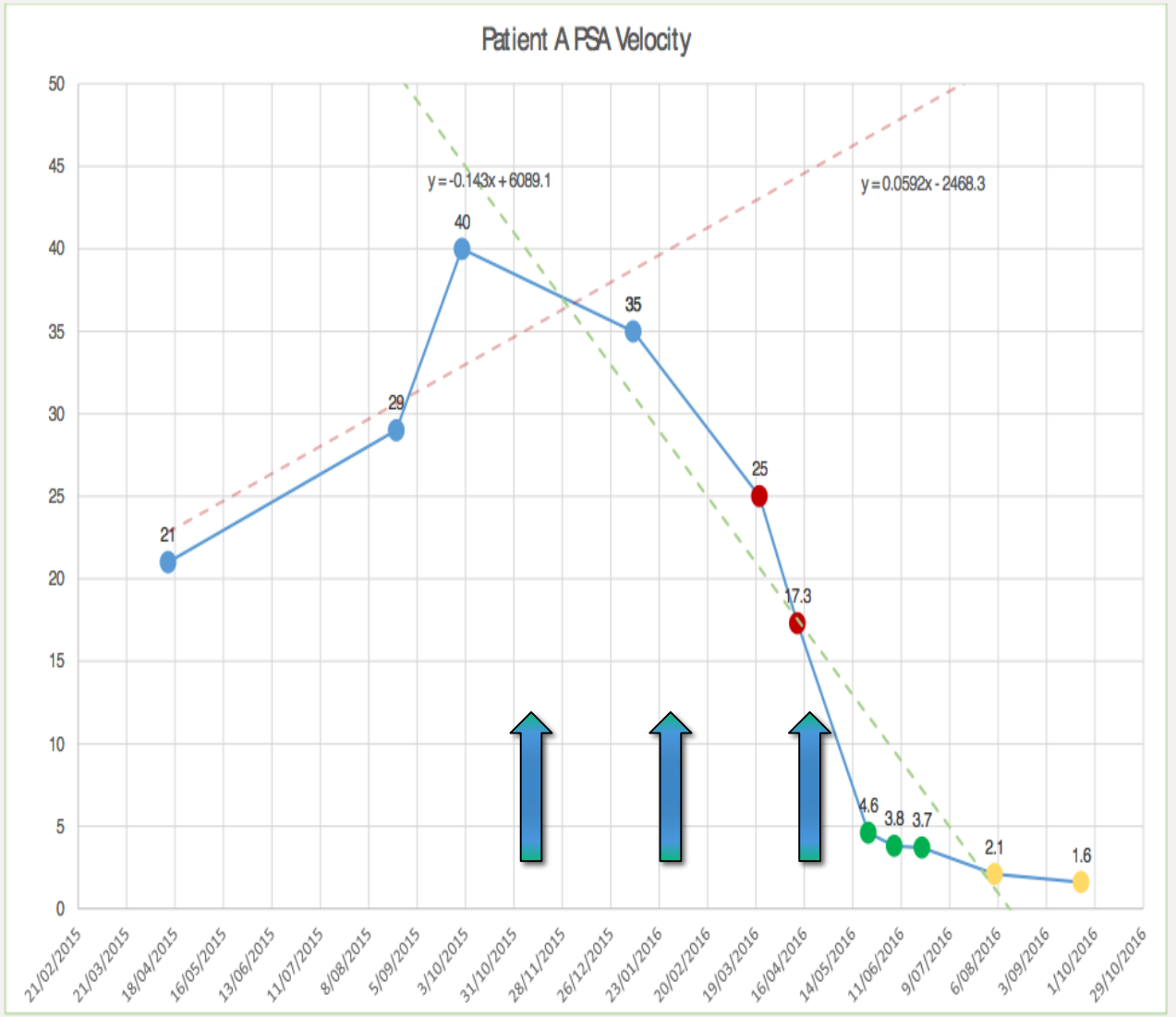
Mr J – 3 cycles: 17 GBq



Lenzo, Meyrick and Turner. Diagnostics. 2018 Feb 11;8(1).

GenesisCare

- VIDEO 1
- VIDEO 2

GenesisCare

THERANOSTICS

GenesisCare

February 06, 2017 | *First U.S. Multi-center Investigational Clinical Trial of 177 Lu PSMA-617 Targeted Radioligand Therapy in Metastatic Castration Resistant Prostate Cancer Receives FDA Clearance* ***Source:*** *RadioMedix Inc.*

November 2017 / Endocyte Announces Exclusive Worldwide License of Phase 3 Ready PSMA-Targeted Radioligand Therapy for Development in Prostate Cancer

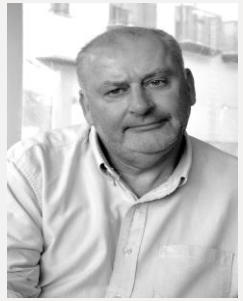
January 2018 / ANZUP Australian TheraP Trial: A Randomised Phase 2 Trial of 177Lu-PSMA617 Theranostic Versus Cabazitaxel in Progressive Metastatic Castration Resistant Prostate Cancer (ANZUP Protocol 1603)
http://www.anzup.org.au/content.aspx?page=lutetiumprostatecancertrial

Sept 2018 / GenesisCare (Oncology) to commence phase III trial of Radiotherapy +/- 177Lu-PSMA in metastatic pelvic nodal recurrent disease

Oct 2018 / Novartis announce buy out of Endocyte for $2.1 billion USD

GenesisCare

The GenesisCare Theranostics Team



Bernard Phelan
General Manager
Theranostics

Assoc. Prof Nat Lenzo
Nuclear Medicine Physician
Clinical Director

Dr. Danielle Meyrick
Radiochemist
Chief Scientist

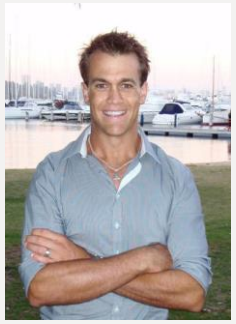
David Macfarlane
Nuclear Medicine Physician

Julie Crouch
Operations Manager
Theranostics

Alex Feetham
Business Development
Collaborations & New Ventures

Sophie Mepham
National Research Manager
Oncology

Assoc. Prof. Louise Emmett
Nuclear Medicine Physician



Dr. Jerome Barley
Business Development
Research and Innovation

Krish Jayatilleke
Clinical Research Coordinator
Theranostics

GenesisCare

Theranostics Strategy – become the leading private provider of theranostics treatments and as a respected clinical research partner

Lead the way in providing treatment to patients in need

Clinical Trials revenue support funding of GC services

GC supports new agents coming to market through research network

Develop a national & international network of Theranostics services

Sites footprint to develop a national and international translational research network

Partner with industry to commercialise IP

RCT evidence supports regulatory approval, reimbursement and services and

IP opportunity supports stakeholder investment in clinical trials

GenesisCare

Established partnerships supporting bringing theranostics agents to market

ITG – Passion for Precision

ANSTO

Telix Pharmaceuticals

CSIRO

AMMI – Advanced Nuclear Medicine Ingredients

Centre for Innovation in Biomedical Imaging Technology
Queensland University

Clarity Pharmaceuticals

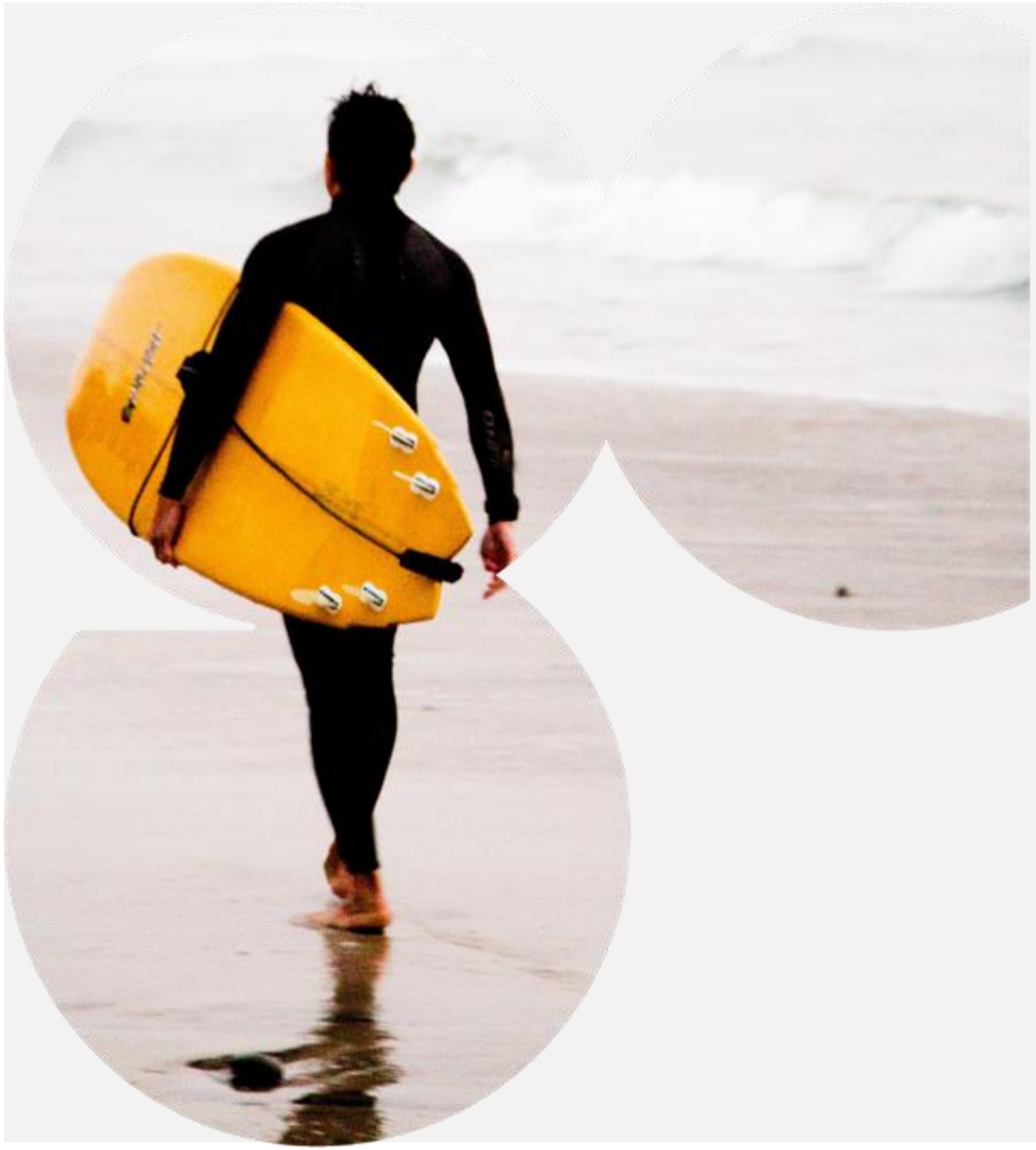
IPSEN – Innovation for patient care

OncoBeta – epidermal radioisotope therapy

The University of Western Australia

VARIAN medical systems

GenesisCare



Theranostics Clinical Trials at Genesis Care

- **Ipsen OPS201 –** Lu-OPS201 in somatostatin receptor positive neuroendocrine tumours
- **TARGET –** A GC sponsored and funded RCT. External Beam Radiation Therapy (EBRT) Alone versus EBRT in Combination with ^{177}Lu-PSMA in Patients with Biochemically Recurrent Prostate Cancer *(late protocol review stage)*
- **Clarity** imaging and therapy trials (*details confidential*)
- **Telix** imaging and therapy trials (*details confidential*)
- **^{68}Ga-PSMA-PET/CT vs [^{18}F]FET-PET/CT –** CSIRO funded in recurrent glioblastoma
- **Activate Trial** - phase 2 study of ^{225}Actinium PSMA in (mCRPC) with clinical progression on ^{177}LuPSMA. *(study concept stage)*
- **Global prostate registry** - ^{177}LuPSMA – WARMTH/ NIGHTCAP study *(concept stage)*

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NETTER-1 RCT ^{177}Lu-OCT PRRT PROGRESSIVE MID-GUT NET

	n	CR %	PR %	SD %	PD %	PFS (m)
1 Control	113	0	3	42	68	8.4
1 PRRT	116	1	17	75	23	NR (@ 20)
2 PRRT	94	1	30	53	10	24
3 PRRT/ CAP/TEM	15	13	13	67	7	31

1. Strosberg J et al. N Engl J Med 2017:376;125-135
2. Brabander T, Kwekkeboom DJ. Clin Cancer Res 2017
3. Claringbold PG, Turner JH. Cancer Biother Radipharm 2002:27;561-569

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COMBINATION PRRT-CHEMOTHERAPY PROGRESSIVE PANCREATIC NETS ^{177}Lu-OCT-CAPECITABINE-TEMOZOLOMIDE

	n	CR %	PR %	SD %	PD %	PFS (m)
1 PRRT	66	3	55	23	15	31
2 PRRT CAP/TEM	30	13	67	20	0	48

1. Brabander T, Kwekkeboom DJ. Clin Cancer Res 2017
2. Claringbold PG, Turner JH. Cancer Biother Radipharm 2002:27;561-569

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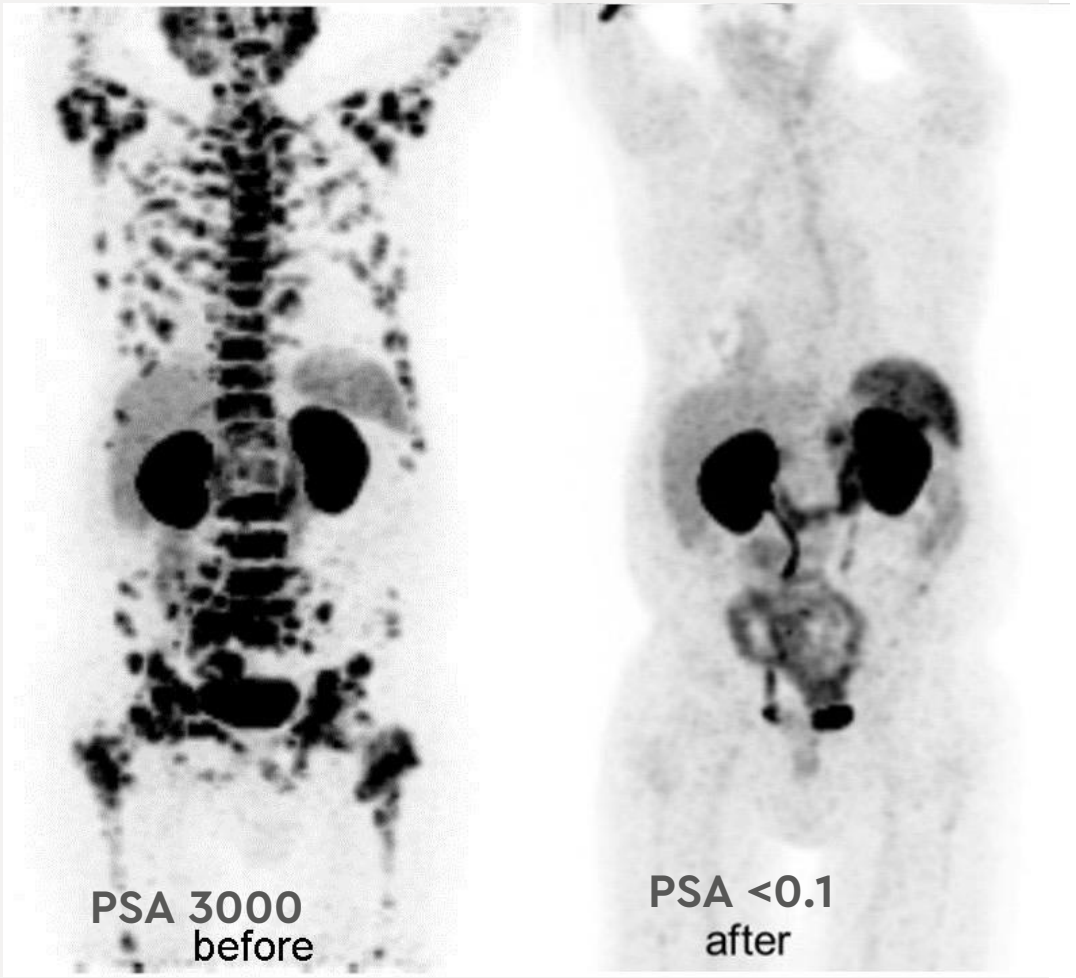
The Future of Theranostics

- No longer a 'cottage industry'
- New molecules with multiple-tumour indications developed by multinational companies
- Registered and reimbursed products coming on line
- Comprehensive clinical trials programs supported by high quality real-world data
- Theranostics treatments upstream in cancer management
- Monotherapy and combination therapies (e.g. radiosensitizers) advancing efficacy and improving patient outcomes

Actinium-225 PSMA

Lu-177 PSMA failure



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Thank you