Telix Pharmaceuticals Limited

ASX:TLX

Detailed Program Update
January, 2019

TELIX PHARMACEUTICALS

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TELIX PHARMACEUTICALS

Presentation Contents

TELIX PHARMACEUTICALS

Executive Summary

- Founders : Dr. Chris Behrenbruch and Dr. Andreas Kluge, experienced nuclear medicine executives
- Board : Kevin McCann (ex-Chairman, Macquarie Bank), Mark Nelson (Caledonia), Jann Skinner (ex-PwC Partner) and Oliver Buck (ITM Group)
- Melbourne (Australia) HQ with operations in USA, Europe and Japan

Telix develops diagnostic and therapeutic radiopharmaceuticals for:

- Metastatic prostate cancer : Diagnostic (pre-NDA), Therapeutic (Ph III)
- Renal (kidney) cell cancer : Diagnostic (Ph III), Therapeutic (Ph II)
- Brain cancer (glioblastoma) : Therapeutic (Ph I/II)

Multiple commercial partnerships with leading global healthcare companies

CardinalHealth™ CYCLOTEK nihon medi+physics GenesisCare ISOLOGIC Innovative Radiopharmaceuticals ENDOCYTE JFE

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Market Metrics

ASX **$0.65**

(3rd January 2019)

Mkt. Cap: A$145m (USD$105m)

Disease Focus	Oncology
Clinical Stage	Phase I - III
Shares on Issue	218.4m
Options on Issue	11.1m
Cash on Hand	~AUD $30m
ASX Ticker	TLX

- Nov 2017 – Initial Public Offering on the Australian Securities Exchange (ASX). Raised AUD $50m
- Predominantly institutional shareholder base : Fidelity, Acorn Capital, UV Cap
- Balance sheet : AUD $30m, AUD $55m development tax grant, runway to mid-2020
- Early revenue generation from prostate cancer imaging product (US market)

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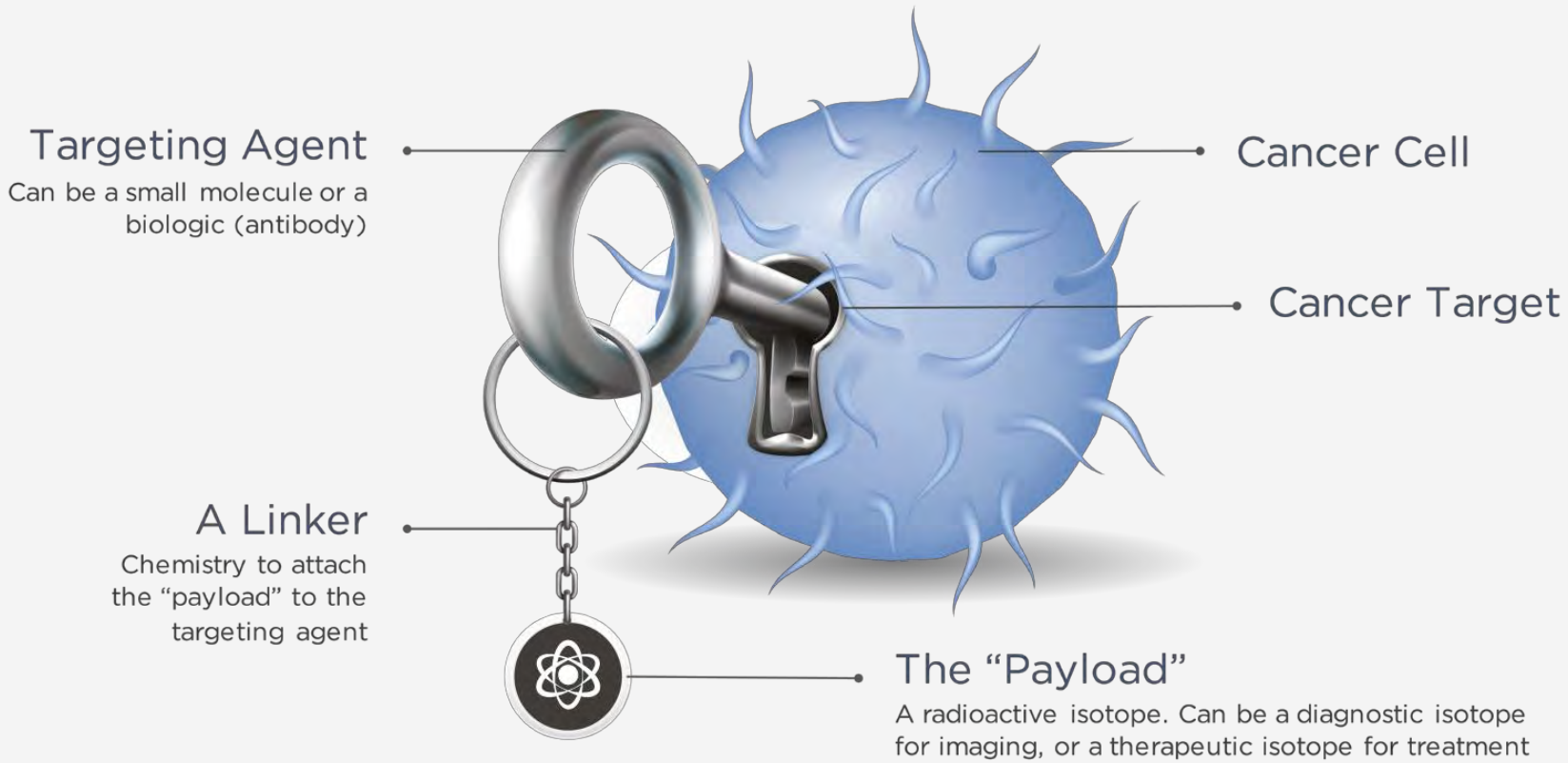
Our Approach : Molecularly-Targeted Radiation (MTR)



MTR works by chemically "linking" radioactive isotopes to targeting molecules that are very specific for cancer cells. At low doses, this enables the location of the cancer cells to be pinpointed using PET imaging. At high doses the patient is very effectively treated

We distinguish the term MTR because there are many "radiopharmaceuticals" that are not targeted. Telix is targeting agent agnostic – we use both antibody and small-molecule approaches

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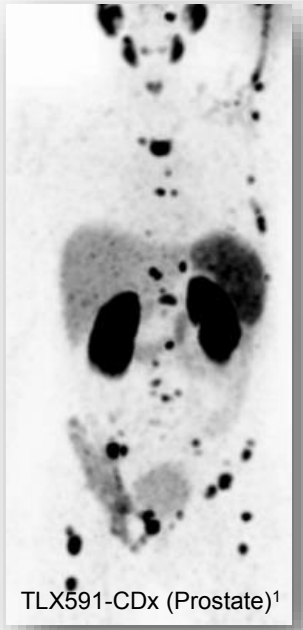
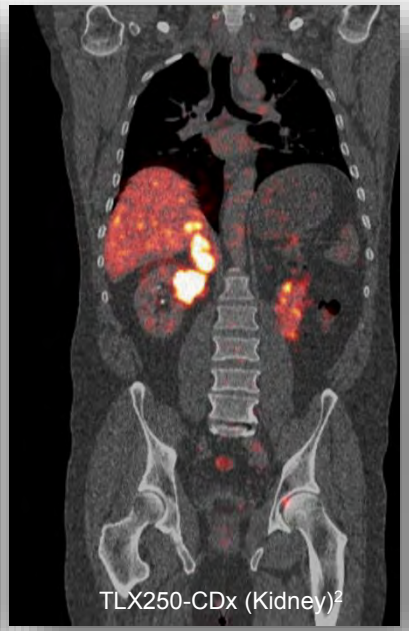
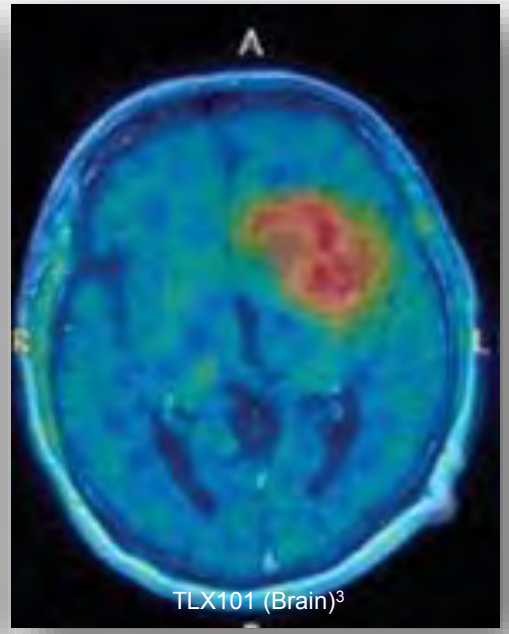
See it, Treat it…

- Telix develops drugs that deliver targeted radiation directly to cancer. At low doses (or using diagnostic nuclides), the patient can be **imaged**

The use of molecular imaging with PET enables a precision medicine approach to treatment through better patient selection and personalized dose optimization


TLX591-CDx (Prostate)[1]


TLX250-CDx (Kidney)[2]


TLX101 (Brain)[3]

- At high doses (with therapeutic nuclides) the patient is **treated**

Positron Emission Tomography – "PET"

[1] Courtesy of Dubai Nuclear Medicine & Molecular Imaging Center, UAE
[2] Courtesy of Radboud University Medical Centre, Netherlands
[3] Courtesy of ZentralKlinik Bad Berka, Germany

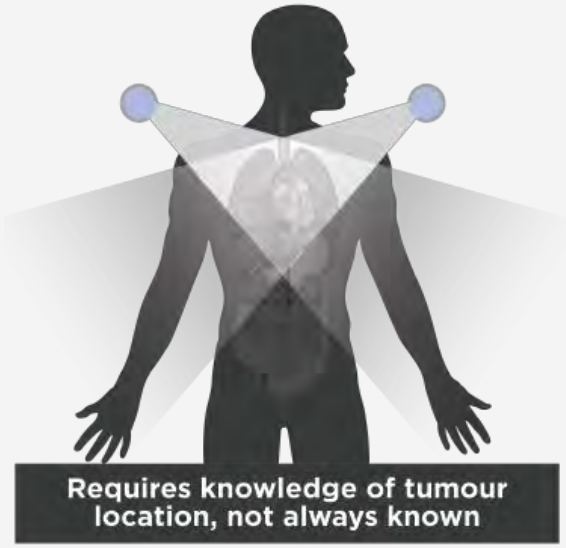
A Better Weapon Against Cancer

varian XRT

External

External Radiotherapy (XRT)

- A fundamental part of cancer treatment
- "Externally Targeted" from a machine (a linear accelerator)
- ~Multi-$Bn global market. Decent procedure growth, but linear accelerator growth is low. Leading companies are in M&A mode

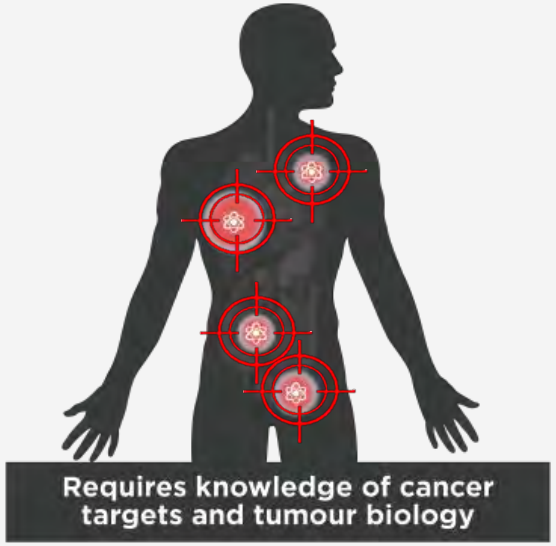


TELIX PHARMACEUTICALS MTR

Internal

Molecularly-Targeted Radiation (MTR)

- Deliver radiation only to areas where disease target is expressed
- Injected, "Molecularly Targeted"
- Able to hit very small tumors not able to be localized with standard imaging and therapy systems
- Far less collateral damage to healthy tissue. Well tolerated by patients



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Telix's Clinical Pipeline

	Isotope	Target	Agent	Phase I	Phase II	Phase III	Clinical Trial
Renal Cancer	^{177}Lu	CA-IX	mAb	TLX250 (Girentuximab)	Therapy		In manufacturing
	^{89}Zr	CA-IX	mAb	TLX250-CDx (Girentuximab)		Imaging	ZIR-DOSE / ZIRCON
Prostate Cancer	^{177}Lu	PSMA	mAb	TLX591 (huJ591)		Therapy	In manufacturing
	^{68}Ga	PSMA	Small Molecule	TLX591-CDx (PSMA-11)		Imaging	Pre-NDA (US)
GBM	^{131}I	LAT-1	Small Molecule	TLX101	Therapy		IPAX-1
	^{124}I	LAT-1	Small Molecule	TLX101-CDx	Imaging		Research Use Only

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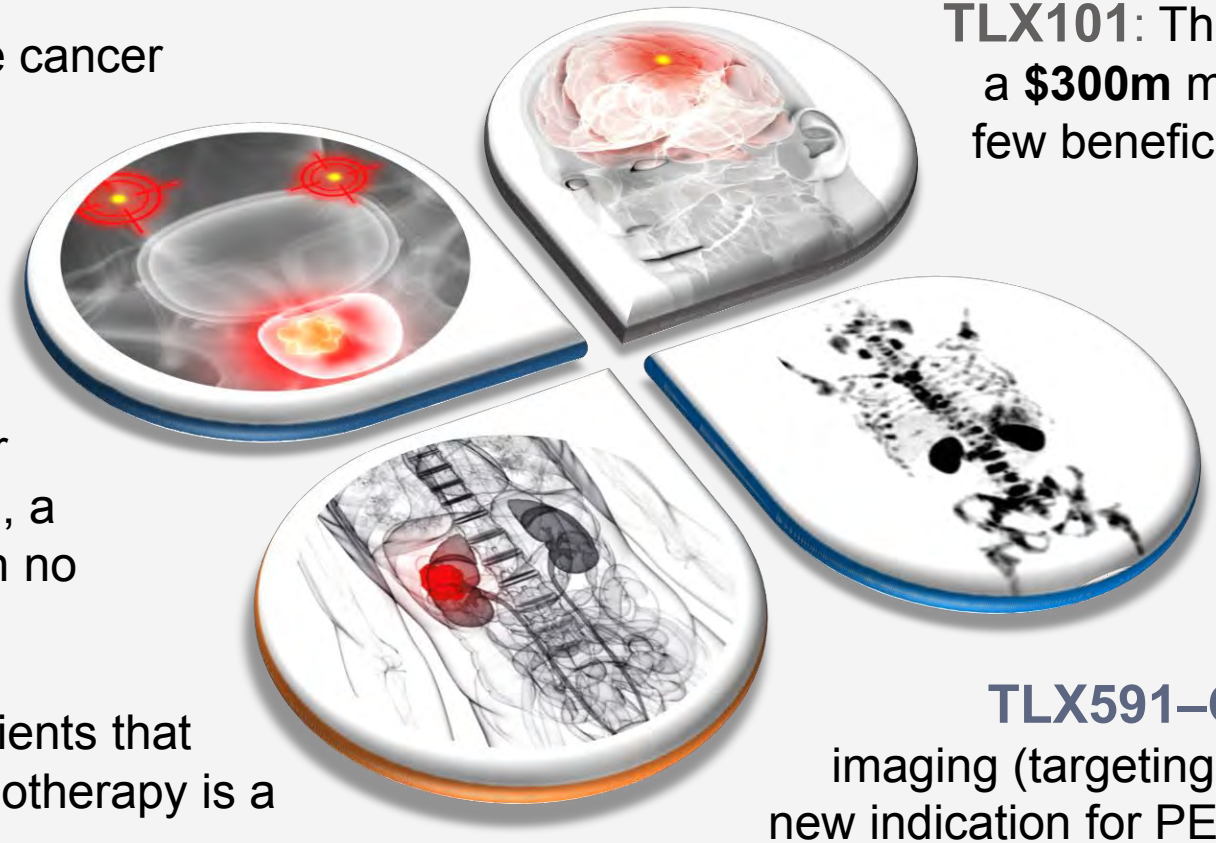
CDx = Companion Diagnostic
GBM = Glioblastoma Multiforme

Telix's Pipeline is a Multi-$Bn Opportunity

TLX591: Metastatic prostate cancer radionuclide therapy is **$2Bn** opportunity in late-stage disease alone

TLX250-CDx: Renal cancer patients are often mis-staged, a niche **$250m** opportunity with no real competition

TLX250: Our therapy for patients that have progressed from immunotherapy is a **$400-500m** opportunity



TLX101: The treatment of GBM is a **$300m** market opportunity with few beneficial options for patients

TLX591–CDx: Prostate cancer imaging (targeting PSMA) is the biggest new indication for PET/CT in radiology and represents a **$500m** opportunity in the US alone

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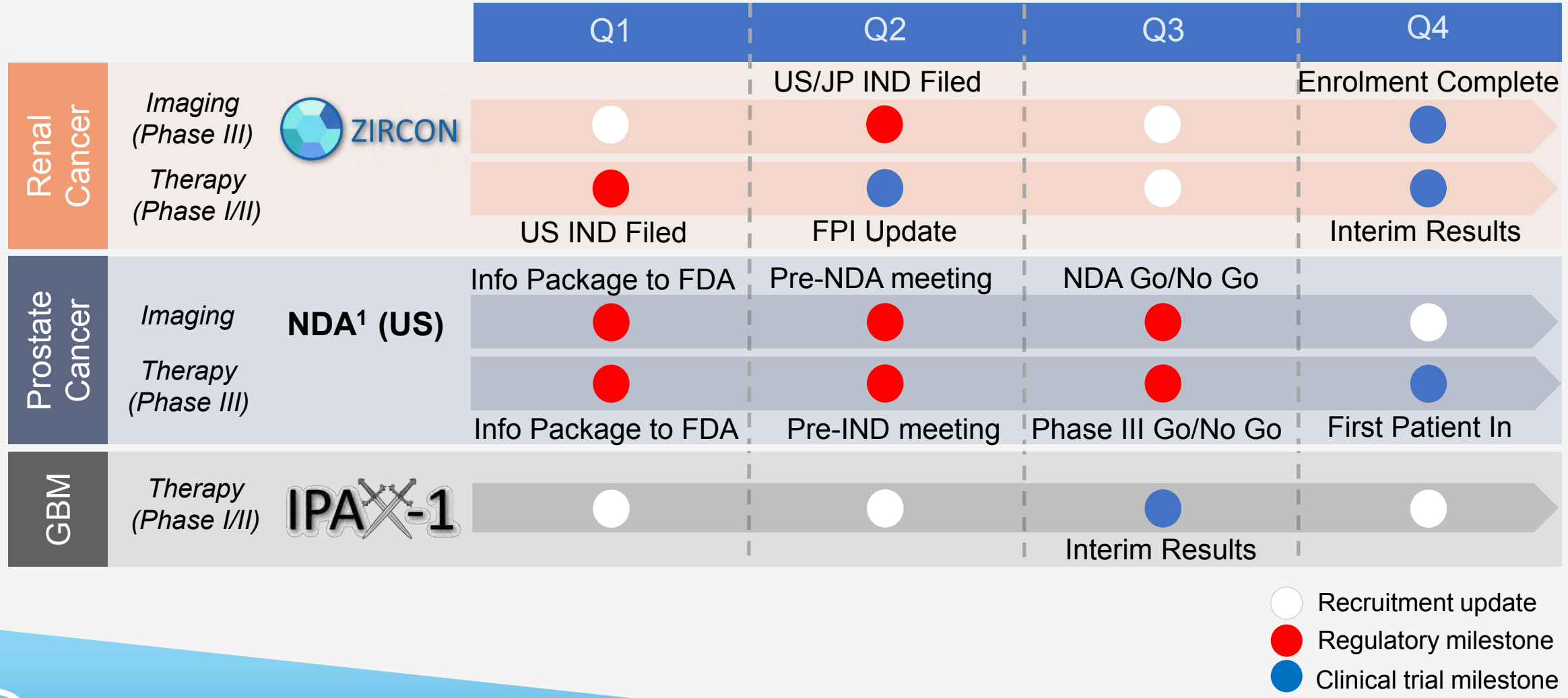
Company estimates, in US dollars

Multiple Milestones and Readouts Coming in 2019



[1] New Drug Application, subject to regulatory approval

Active Clinical Studies : Summary

Renal Cancer

ZIR-DOSE (Zirconium Dosimetry) :
EudraCT 2017-004769-28

10 patient, single site (RUMC, Netherlands) bridging study (Phase I) to formally measure the change in radiation dose to the patient when ^{124}I (legacy) is replaced with ^{89}Zr for imaging kidney cancer for TLX250-CDx, dose optimization (Recruitment Complete)

ZIRCON (^{89}Zr Imaging for Renal Cancer Oncology) :
EudraCT 2018-002773-21

252 patient confirmatory international multi-centre Phase III trial of TLX250-CDx in at least 15 sites in EU/AUS/US. Primary end-point is sensitivity / specificity compared with histology (for ccRCC) in surgical resection patients (Recruiting)

Glioblastoma

IPAX-1 (IPA+XRT) :
EudraCT 2018-002262-39

44 patient multi-centre Phase I/II trial to evaluate preliminary safety and efficacy of TLX101 in patients with recurrent glioblastoma (7 sites in EU/AUS). Open label in conjunction with standard care (Recruiting)

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Clinical Activity – By Country

Country	TLX250 (Renal Cancer Therapy)	TLX250-CDx (Renal Cancer Imaging)	TLX591 (Prostate Cancer Therapy)	TLX591-CDx (Prostate Cancer Imaging)	TLX101 (Glioblastoma Therapy)
Australia	Phase I/II (2019)	ZIRCON	Phase III (2019)	SAS	IPAX-1
Austria					IPAX-1 / SAS
Belgium		ZIRCON		IMPD* / SAS	IPAX-1
Canada		ZIRCON		DMF	
Czech Rep				IMPD*	
Denmark				IMPD* / SAS	
France		ZIRCON		IMPD*	
Germany				IMPD* / SAS	
Italy				IMPD*	
Japan		ZIRCON (Bridging)			
Netherlands		ZIR-DOSE / ZIRCON		IMPD*	IPAX-1
Portugal				IMPD*	
Spain		ZIRCON			
Sweden				IMPD	
UK		ZIRCON		IMPD* / SAS	
USA	Phase I/II (2019)	ZIRCON	Phase III (2019)	DMF*	

In preparation
Filed / under review
Clinical trial approved

DMF = Drug Master File
SAS = Special Access Scheme (compassionate use)
IMPD = Investigational Medical Product Dossier (DMF equivalent in EU)
*Dossier is referenced by a third party clinical trials (i.e. Endocyte/Novartis)

M&A Activity – 2018

M&A is an important facet of Telix's corporate activity as we continue to build a leading pipeline of radiopharmaceutical products and technologies

ATLAB PHARMA

- **Origin:** Spin-out from Centre Hospitalier Universitaire (CHU) de Nantes (France), a leading European nuclear medicine cluster
- **Consideration:** $USD 10m in scrip
- **Purpose:** access to clinical data and patent portfolio in relation to huJ591 anti-PSMA mAb, particularly for combination therapy with anti-androgens and image-based patient selection

AMI
Advanced Nuclear Medicine Ingredients

- **Origin:** Liège (Belgium)-based nuclear medicine start-up
- **Consideration:** €5.1m in cash / scrip + earn-out
- **Purpose:** EU/RoW rights to PSMA imaging technology and access to an early-stage pipeline of "kit" technologies for other oncology application areas, talent acquisition

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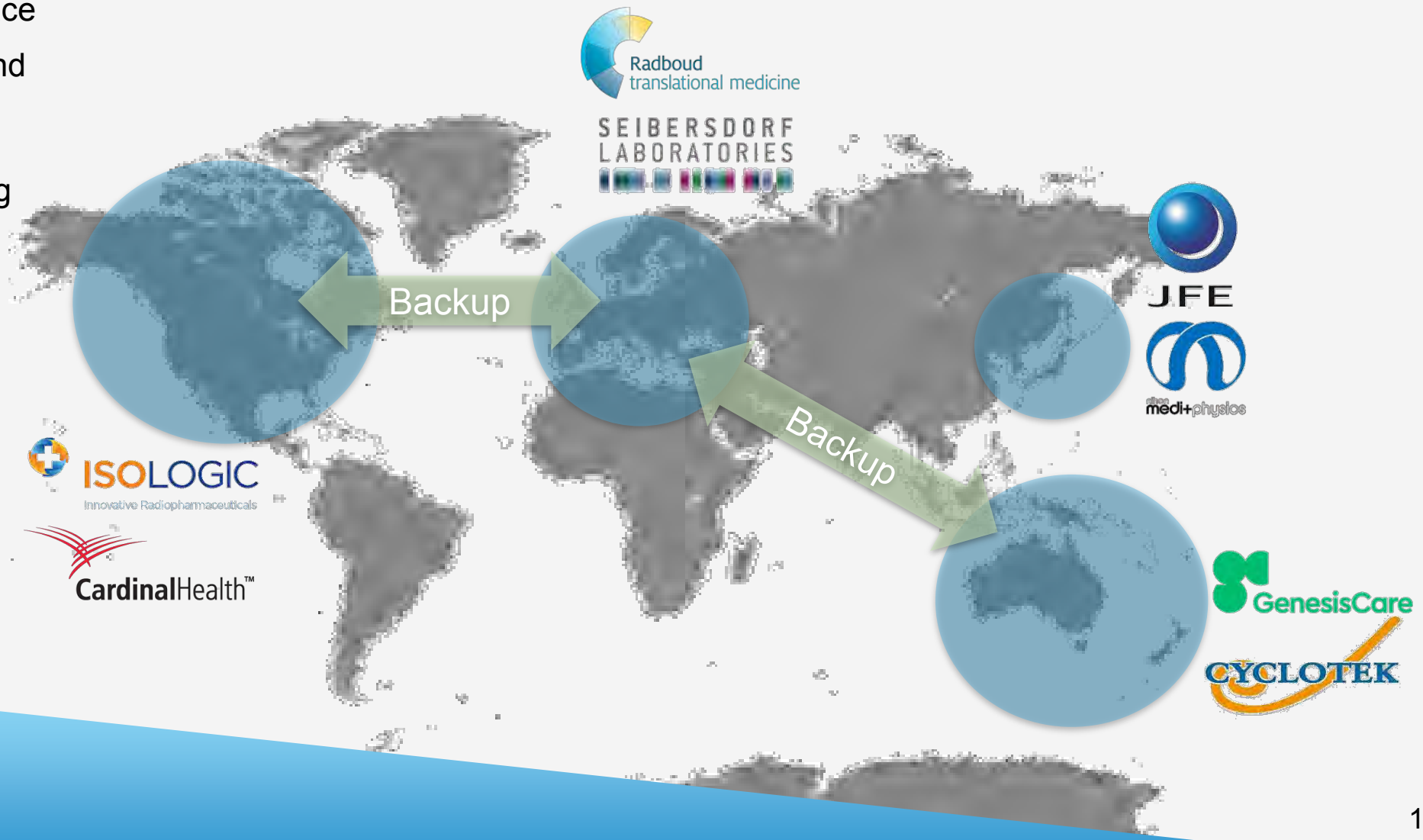
Supply Chain and Production Network Established

- ✓ Key partners in place
- ✓ For clinical trials and early commercial product roll-out
- ✓ Discussion ongoing with partners for MENA, Asia and LATAM



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Management Team

Dr. Christian Behrenbruch (Co-Founder, MD and CEO)

Chris has 20 years of healthcare executive experience as CEO, Mirada Solutions, CTI Molecular Imaging (now Siemens Healthcare), Fibron Technologies and ImaginAb, Inc., former Director of Momentum Biosciences LLC, Siemens Molecular Imaging Ltd, Radius Health Ltd (now Adaptix) and was the former Chairman of Cell Therapies P/L.. He is currently a non-executive director of Factor Therapeutics (ASX:FTT). Christian holds a D.Phil (PhD) in biomedical engineering from the University of Oxford, an executive MBA (TRIUM Program) and a Juris Doctor (Law) from the University of Melbourne.

Dr. Andreas Kluge (Co-Founder and Chief Medical Advisor)

Andreas has 20 years of clinical research and development experience, including as Founder, General Manager and Medical Director for ABX-CRO GmbH, a full service CRO based in Dresden, Germany. Andreas is a physician and holds a doctorate in Medicine from the Free University of Berlin.

Mr. Douglas Cubbin (CFO)

Doug has spent the last eleven years in CFO, COO, commercial and business development roles in companies in the nuclear medicine sector. Prior to that Doug, was the Group CFO of DHL (Australia-Pacific). From 2013 to 2016, Doug was the Chairman of Australian Nuclear Science and Technology Organisation (ANSTO) and the General Manager of Business Development at ANSTO. Doug is a fellow of the Australian Society of CPAs and a Graduate of the Institute of Company Directors

Dr. Jyoti Arora (Director of Operations)

Jyoti has extensive experience in project management, operations and GMP manufacturing. Prior to joining Telix, Jyoti was a Senior Project Manager at Cell Therapies Pty Ltd, with responsibility for overseeing product development of several advanced cell and gene therapy technologies. She holds a PhD in Medical Science and Radiopharmaceutical Chemistry from RMIT University

Dr. Michael Wheatcroft (Director of R&D)

After completing a PhD in the Department of Biochemistry, Cambridge University, Mike worked at Cambridge Antibody Technology (now Medimmune). After moving to Melbourne in 2010, Mike oversaw the pre-clinical development of several engineered antibody drug conjugates at AviPep P/L. Mike has worked in senior development roles at Medicines Development Limited, Hatchtech Pty Ltd and Starpharma Limited

Dr. Marissa Lim (Director of Global Medical Affairs)

Marisa has held a number of senior and international medical director positions at Ipsen, Vifor and Hospira, BMS and Novartis, before joining Telix. She brings extensive experience in oncology trial design and management, particularly in disease focus areas relevant to Telix. Marissa obtained her medical degree from Monash University.

Ms. Alannah Evans (Director of Quality/Regulatory)

Alannah has 20 years of experience in quality-controlled manufacturing and biological material processing. Prior experience included technical and managerial roles at Nucleus Network, Cell Therapies P/L (Peter MacCallum Cancer Centre), Eastern Health and Gribbles Pathology. Alannah has a bachelor's degree in biomedical sciences from Curtain University and master's degree in biotechnology and business from RMIT.

Dr. Shintaro Nishimura (President, Telix Japan)

Shintaro is a highly-experienced drug development and commercialization professional, with particular emphasis on the use of molecular imaging in drug development. Prior to Telix, Shintaro held senior positions at Eli Lilly, ImaginAb and Astellas, as well as academic appointments at Kyoto Prefecture University of Medicine, the University of Tsukuba and Tokohu University. Dr. Nishimura received his doctorate in organic chemistry from Keio University and was a post-doctoral researcher at the University of Michigan Medical School.

Ms. Odile Jaume (President, Telix Europe)

Odile leads Telix's European commercial activities, based in Brussels. Prior to joining Telix, Ms. Jaume held a variety of senior product management, marketing and commercial roles at Molecubes, Siemens, CTI Molecular Imaging and IBA. Ms. Jaume's qualifications include an M.Sc in material science from the Université Catholique de Louvain (UCL) and an MBA from the University of Chicago, Booth School of Business.

Dr. Bernard Lambert (President, Telix USA)

Bernard was Vice President, CMC and Radiopharmaceutical Development at Zevacor and IBA Molecular, and led the manufacturing of 124I-girentuximab (the predecessor to Telix's TLX250 product) that was studied in the Phase III REDECT trial by Wilex AG. A radiochemist by training, Dr. Lambert has a Ph.D in Chemistry from the University of Liège.

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Board of Directors

Mr. H. Kevin McCann AM

Chairman

Kevin is currently Chairman of Citadel Group and Dixon Hospitality Limited. He is a former Chairman of Macquarie Bank Limited, Origin Energy, Healthscope Limited and ING Management Limited. Kevin practiced as a Commercial Lawyer as a Partner of Allens Arthur Robinson from 1970 to 2004 and was Chairman of Partners from 1995 to 2004. Kevin has a Bachelor of Arts and Law (Honours) from Sydney University and a Master of Law from Harvard University.

Dr. Mark Nelson

Non-executive Director

Mark is the Chairman and Co-founder of The Caledonia Investments Group, a global investment management firm based in Sydney. He is Vice President of the Board of Trustees of the Art Gallery of NSW and serves on the Board of a number of other not for profit enterprises including the Florey Neurosciences Institute. Mark holds a M.Phil in bioscience]from the University of Cambridge and a Ph.D in molecular biology from the University of Melbourne.

Dr. Christian Behrenbruch

Dr. Andreas Kluge

Executive Directors

(see previous slide)

Ms. Jann Skinner

Non-executive Director

Ms. Skinner, B Com, FCA, FAICD has extensive experience in audit, accounting and in insurance. She worked with PricewaterhouseCoopers for almost 30 years, beginning her career with Coopers & Lybrand in 1975, and was a partner of the firm for 17 years before retiring in 2004. Jann was appointed as a non-executive director of QBE in 2014, where she also serves as Chair of the Risk and Capital Committee, Deputy Chair of the Audit Committee and a member of the Remuneration Committee. She serves as a Director of Enstar Australia Group, the Create Foundation Limited, HSBC Bank Australia Limited, and the Tasmanian Public Finance Corporation. Jann is a Fellow of both Chartered Accountants Australia & New Zealand, and the Australian Institute of Company Directors.

Mr. Oliver Buck

Non-executive Director

Oliver is Founder of ITM Group, one of the largest isotope manufacturing and distribution companies in the world. He is an experienced executive and business developer in medical and defence industries. Oliver holds a masters degree in theoretical physics from the Technical University of Munich.

Ms. Melanie Farris

Company Secretary

Melanie is an experienced governance, communications and operations executive. Currently a non-executive director for Synapse Australia Limited, and in governance and operations roles with Factor Therapeutics Limited (ASX:FTT) and Invion Limited (ASX:IVX), previous roles include with HRH The Prince of Wales's Office, Global Asset Management, Imperial Cancer Research Fund, and The Prince's Foundation. Melanie holds a Bachelor of Communication (Public Relations), and a Graduate Diploma in Applied Corporate Governance. She is an Associate of the Governance Institute of Australia and an Associate of the Institute of Chartered Secretaries (UK).

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International Scientific Advisory Board

Dr. Rodney Hicks

Chief of Nuclear Medicine and Radiology, Peter MacCallum Cancer Centre (Melbourne, Australia). One of the world's radio-pharmaceutical clinical thought leaders and strong advocate for the integration of PRRT/RIT into oncology standard care.

Dr. Jean-Francois Chatal

Professor, Univ. of Nantes (Nantes, France). Prof. Chatal pioneered the use of antibody-targeted therapies in nuclear medicine.

Dr. Jason Lewis

Chief of Radiochemistry, Vice-Chair of Radiology at MSKCC (NY, USA). Internationally recognized for innovation in the clinical production of radiopharmaceuticals.

Dr. Klaus Kopka

Head of the Division of Radiopharmaceutical Chemistry of the German Cancer Research Center (DKFZ) Heidelberg, Germany. His research interests focus on Radiopharmaceutical Sciences in combination with Labelling Chemistry and Medicinal Chemistry. A thought leader in PSMA targeting ligands.

Dr. Neil Bander

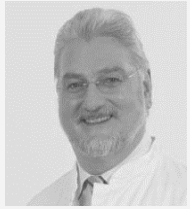
Chair of Urology at Weill Cornell Medical Centre (NY, USA). First led the development of PSMA-targeting radiopharmaceuticals for prostate cancer, discoverer and developer of huJ591 (anti-PSMA mAb) technology.

Dr. Chaitanya Divgi

Retired ex-Columbia / UPenn radiology and nuclear medicine. Experienced regulatory adviser and clinical translation consultant. Led the original clinical development of Girentuximab (TLX250).

Dr. Samuel Samnick

An accomplished radiopharmaceutical researcher stationed at the University of Wurzburg. He is a pioneer in the use of imaging and nuclide therapy targeting LAT1.



Dr. Richard Baum

Professor of Nuclear Medicine, Chairman & Clinical Director, Department of Molecular Radiotherapy at Zentralklinik Bad Berka, Germany. He is a thought-leader in the field of theranostic technology and has been one of the pioneers of peptide radiotherapy.

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Summary of Accomplishments Since IPO (Nov ’17)

- ✓ Clinical trial GMP manufacturing for TLX101 and TLX250 / TLX250-CDx programs
- ✓ Phase III trial launched (confirmatory Ph III) for lead program for imaging kidney cancer (TLX250-CDx) – EU / Australia. US early 2019
- ✓ Phase I/II trial launched for TLX101 (brain cancer) – EU / Australia
- ✓ Successful drug master file filing with the US FDA for prostate imaging product (TLX591-CDx) – first revenues attained in 2018
- ✓ Scale-up (commercial) manufacturing of TLX591-CDx “kit” in place
- ✓ Several excellent commercial partnerships in key markets established for prostate cancer and renal cancer pipeline
- ✓ AUD $55.2m R&D tax “overseas finding” from AusIndustry
- ✓ Significant “big pharma” interest in what we are doing

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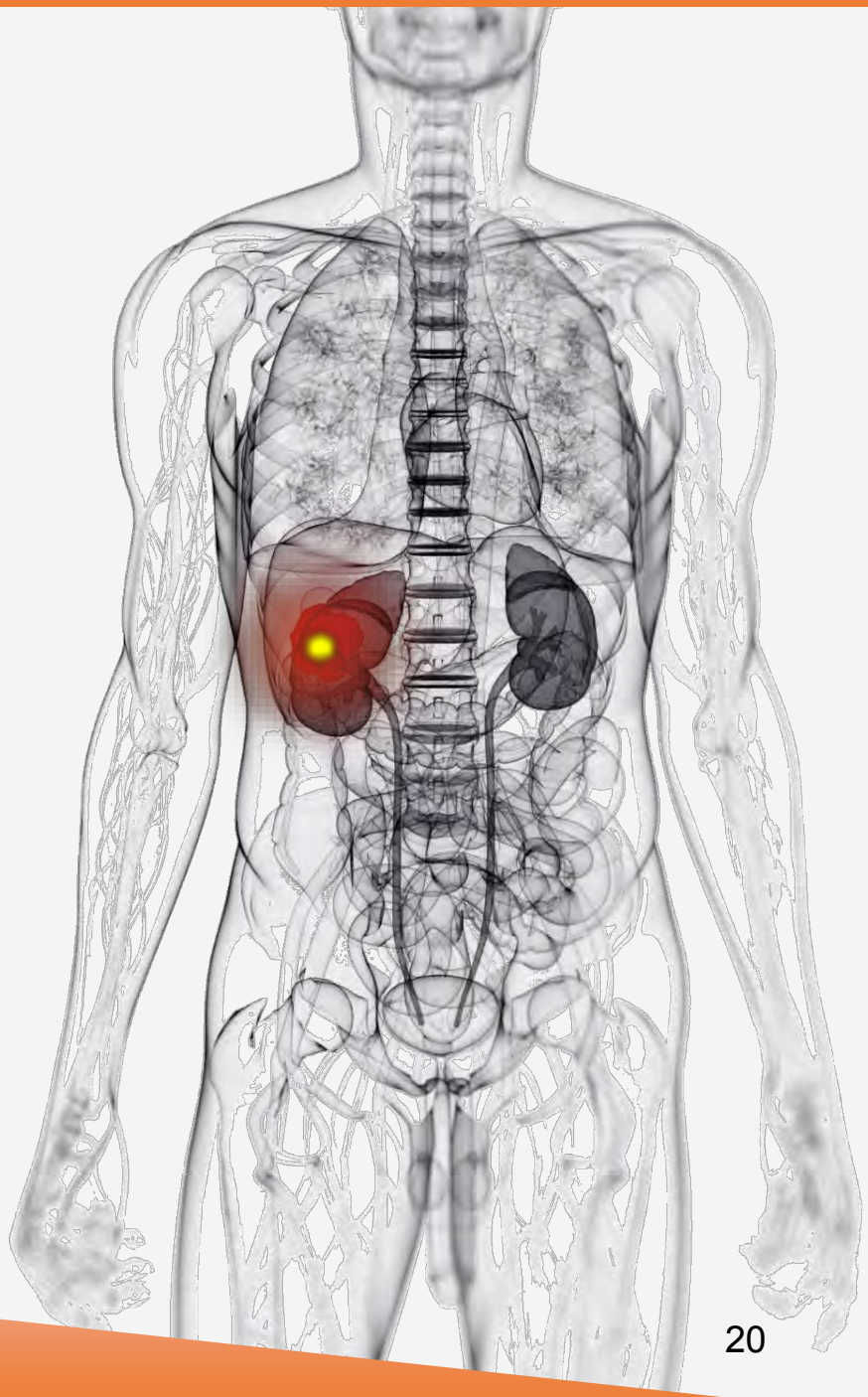
Renal Cancer Imaging

TLX250-CDx
(^{89}Zr-girentuximab)



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TLX250-CDx (Imaging) : Background

- Antibody-based PET imaging agent targeting carbonic anhydrase 9 (CA-IX). CA-IX is a cell-surface antigen that is highly over-expressed in renal cell cancer, particularly the clear cell phenotype
- Previously underwent a Phase III trial (REDECT trial, NCT00606632) with an iodinated (^{124}I) version of the imaging agent (Wilex AG).

REDECT Study:

- Non-invasive evaluation of incidental findings from abdominal CT
- 86% accurate, 95% Positive Predictive Value (PPV) for clear cell renal cell cancer (ccRCC) – comparable to the "gold-standard" of biopsy
- Rejected by FDA as a registration trial as it was insufficiently powered for negative histology.
- Granted a Special Protocol Assessment (SPA) by the FDA for confirmatory Phase III study
- Telix takes over program from Wilex AG

		Histology (REDECT PhIII with ^{124}I-girentuximab)			
		ccRCC	Non-ccRCC	Total	
PET/CT imaging	ccRCC	123	7	130	PPV = 95%
	Non-ccRCC	20	46	66	NPV = 70%
	Total	143	53	196	
		Sensitivity = 86%	Specificity = 87%		Accuracy = 86%

RCC : The Unmet Need

Diagnosis		Intervention (Treatment)	
Incidental findings	150,000 patients in the US from routine abdominal CT	**Biopsy not accurate**	~1/6 biopsies benign. ~30% of kidney are surgeries unnecessary
Standard imaging	MRI and CT have limitations, FDG PET is generally not applicable	**Patients typically detected late**	Even patients that may appear resectable are not (see case study)
Staging	Patients typically mis-staged, including resectable disease	**Relapse rate is high**	Because patients often have small distant metastases
Prognosis	Need imaging biomarkers that show disease aggressiveness	**Existing treatment confer little benefit**	TK/VEGF inhibitors give <1 year of benefit. MTR can potentially exceed
Treatment response	RCC is aggressive, need to know if treatment is working	**Want to move quickly to the next treatment, particularly given new I-O drugs**	Imaging gives a highly accurate picture of treatment efficacy

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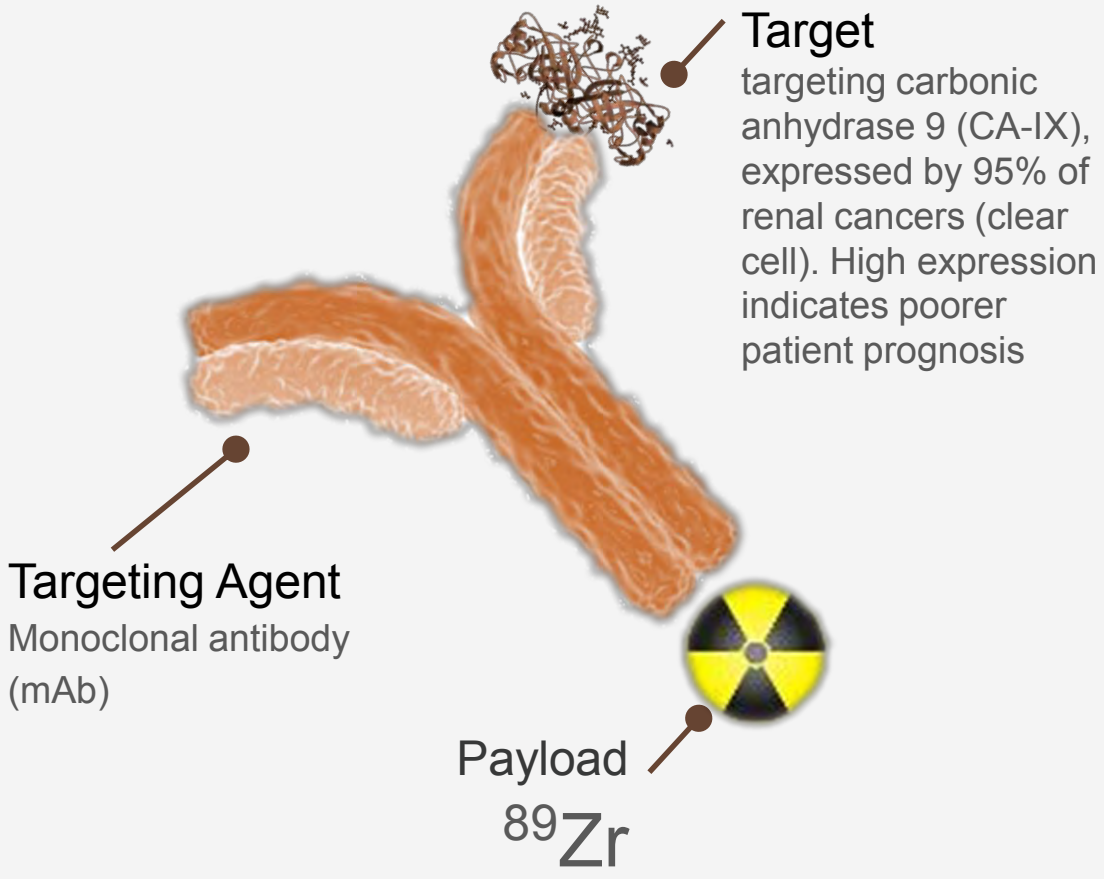
TLX250-CDx : Product Overview



Description:

- Radiolabeled mAb (girentuximab) targeting carbonic anhydrase 9 (CA-IX)
- For the imaging of clear cell renal cell cancer (ccRCC) with PET
- Liver-cleared, kidneys free of background signal for optimal imaging

Technology Origin:

- Ludwig Inst / MSKCC via Wilex AG (license)

Clinical Status:

- Phase III (ZIRCON study)

Unmet Need:

- ✓ Better / more cost-effective management of incidental findings
- ✓ Patients are often incorrectly staged
- ✓ Partial nephrectomy guidance
- ✓ Rapid treatment response assessment

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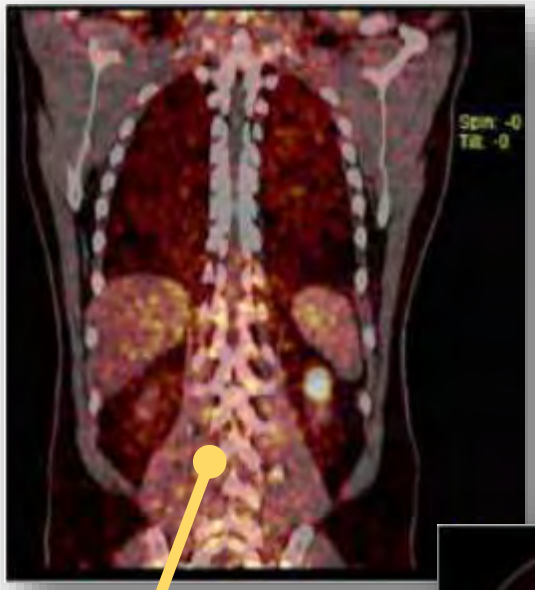
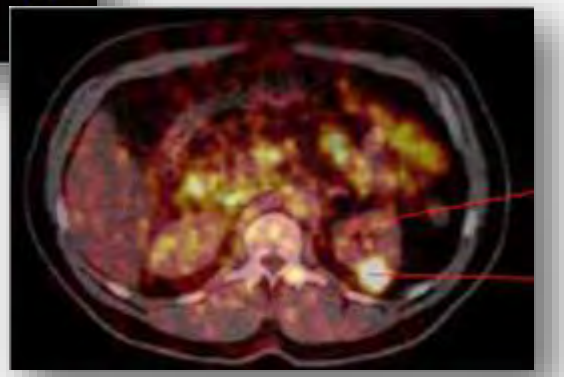
Telix Program Improvement : Replace ^{124}I with ^{89}Zr

^{124}I (Old - Wilex)



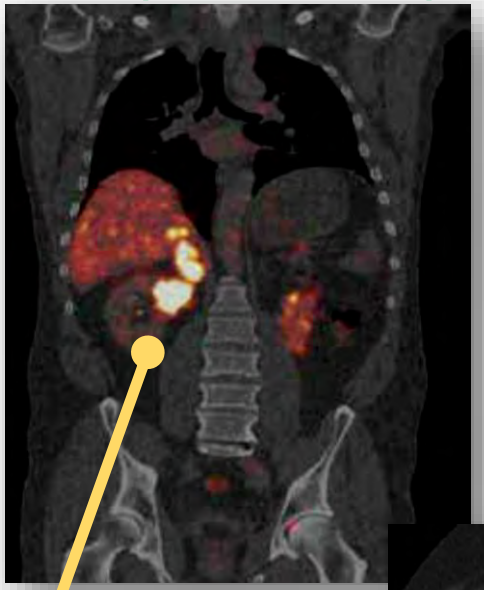


Iodine (^{124}I) images are noisy and so small tumors are harder to see

Benefits:

- ✓ Use of ^{89}Zr instead of ^{124}I gives better imaging sensitivity because radiometal is internalized / trapped
- ✓ Cleaner images due to use of radiometal (iodine is noisy), greatly improved image contrast
- ✓ No thyroid blocking = better clinical ease of use
- ✓ Lower radiation dose
- ✓ Superior production economics

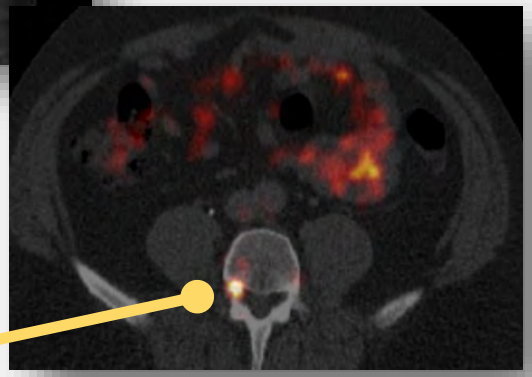
^{89}Zr (New - Telix)



Tumours have superior contrast with ^{89}Zr

Clear background enables small lesions to be seen (images unretouched)

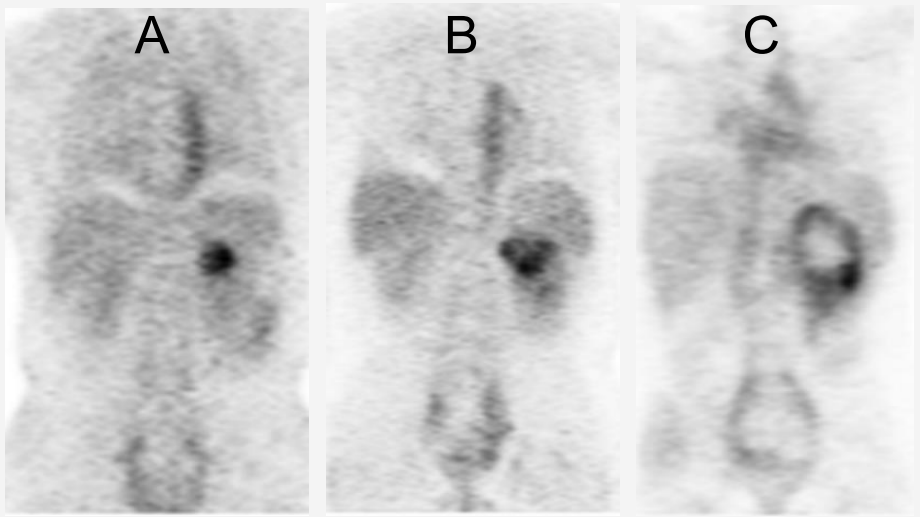
Very small lesions can be seen with ^{89}Zr – like this spinal metastasis



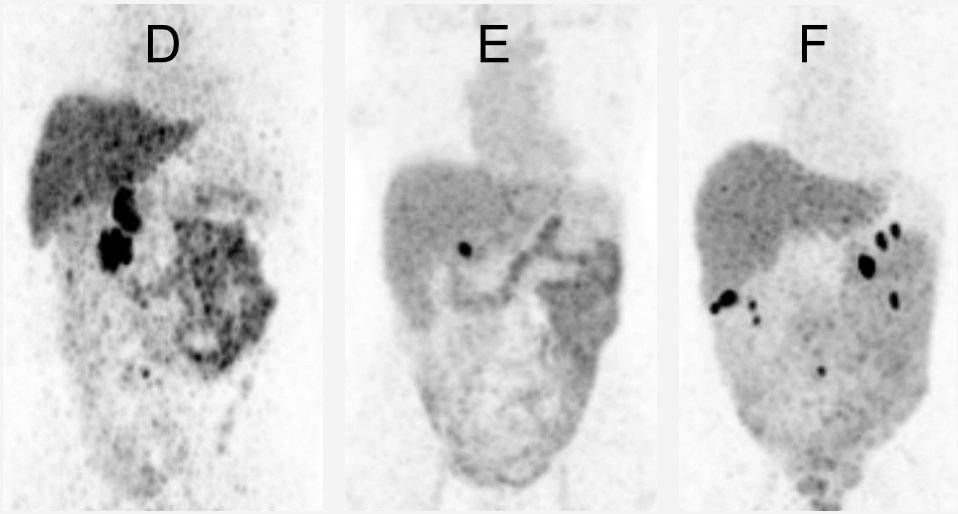
TELIX PHARMACEUTICALS

Dosimetry Comparison (ZIR-DOSE)

^{124}I (Wilex)



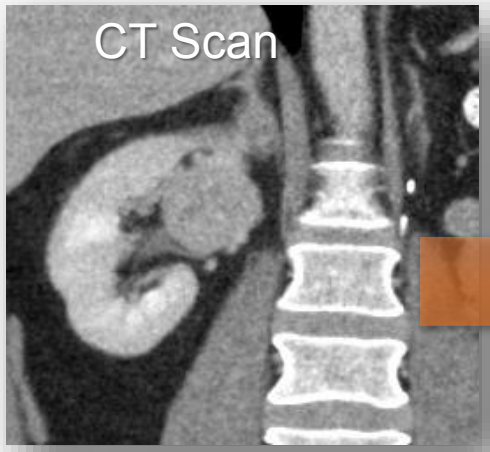
^{89}Zr (Telix)



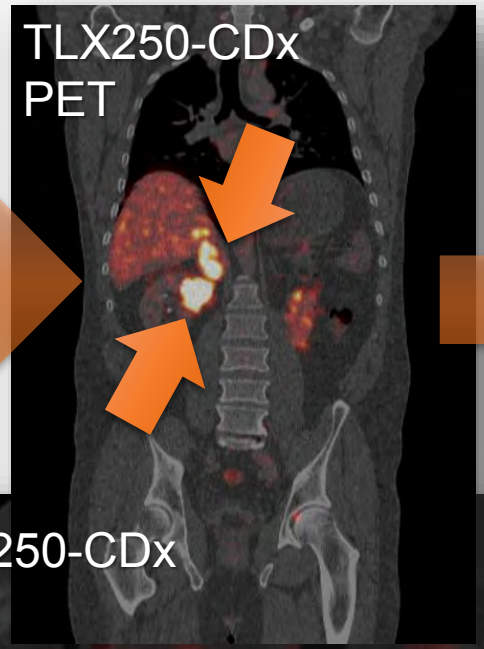
- A – C : 185 MBq (5 mCi) ^{124}I-Girentuximab (radiographically positive cases - REDECT Ph III study)
- D – F : 37 MBq (1 mCi) ^{89}Zr-Girentuximab (courtesy of RUMC, NL)
  - Higher image contrast of ^{89}Zr-Girentuximab, no noisy background
  - Superior detectability of small lesions
  - 1 mCi ^{89}Zr dose results in a **25-30% lower patient dose** than with ^{124}I with **superior image quality**

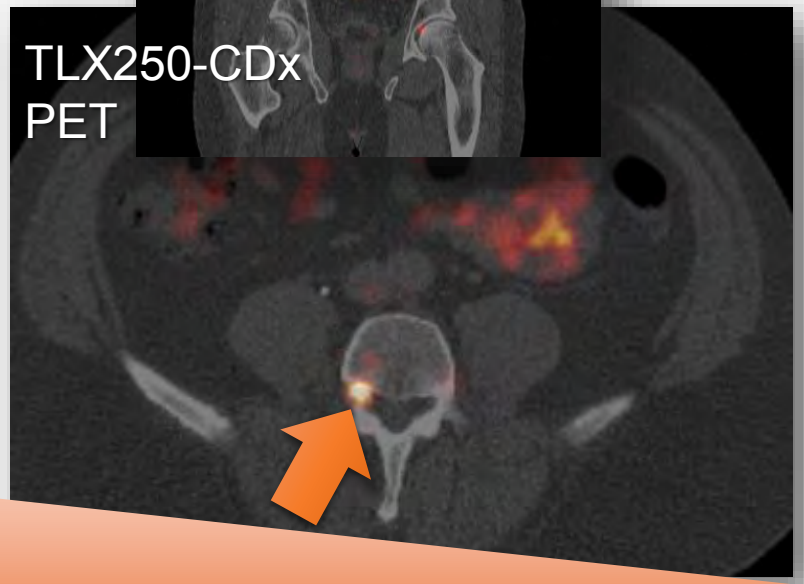
TELIX PHARMACEUTICALS

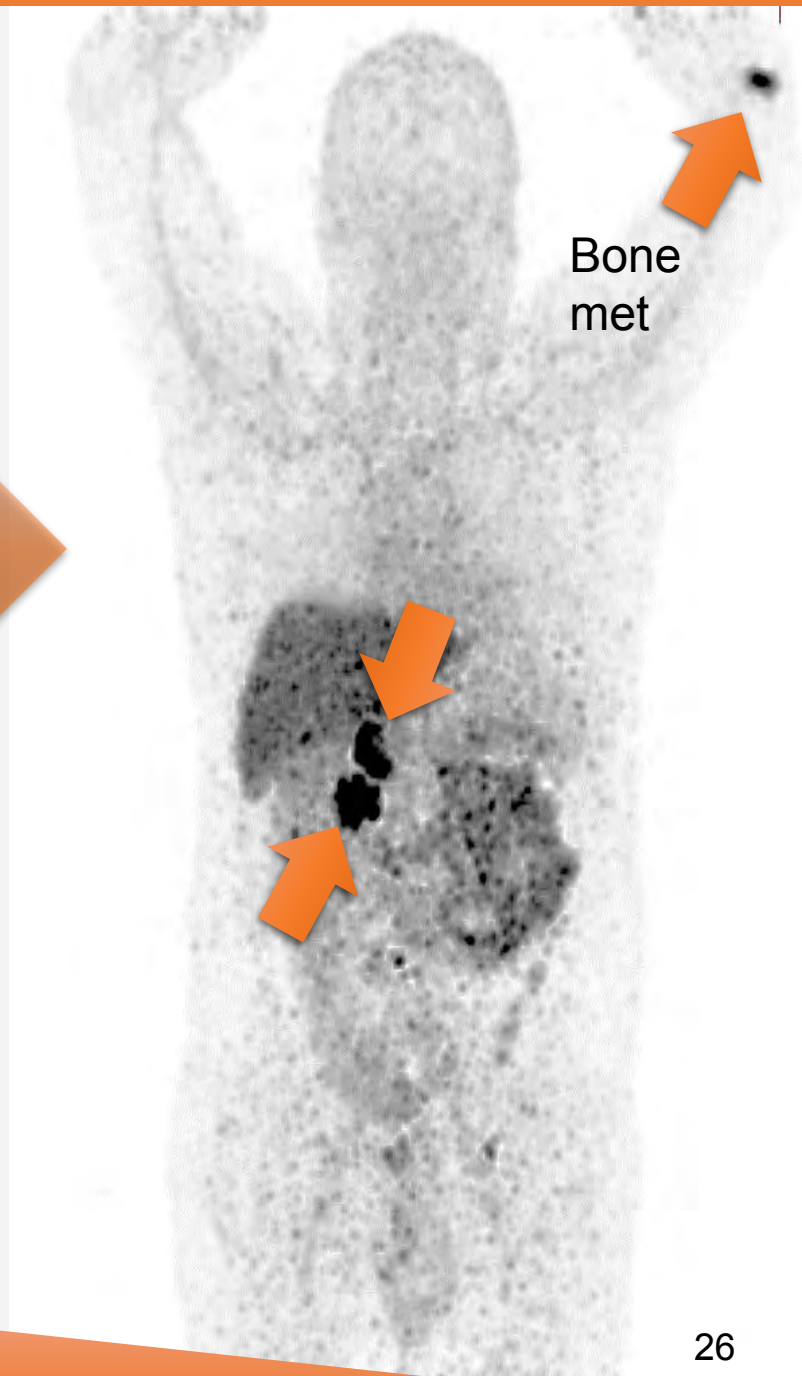
TLX250-CDx : Correctly Staging Renal Cancer



TLX250
PET Scan







Case study:[1]

- 50 year old male
- Only local lesions seen in kidney with CT scan
- TLX250-CDx scan not only showed extent of kidney disease but also distant bone mets
- Patient re-staged, systemic therapy

TELIX PHARMACEUTICALS

[1] Courtesy of Radboud University Medical Centre, Netherlands

Additional Indication #1 : Guiding Surgical Decision-Making

Partial resection of kidney lesions is a growing area of surgical interest and one of the fastest growing robotic surgery procedures

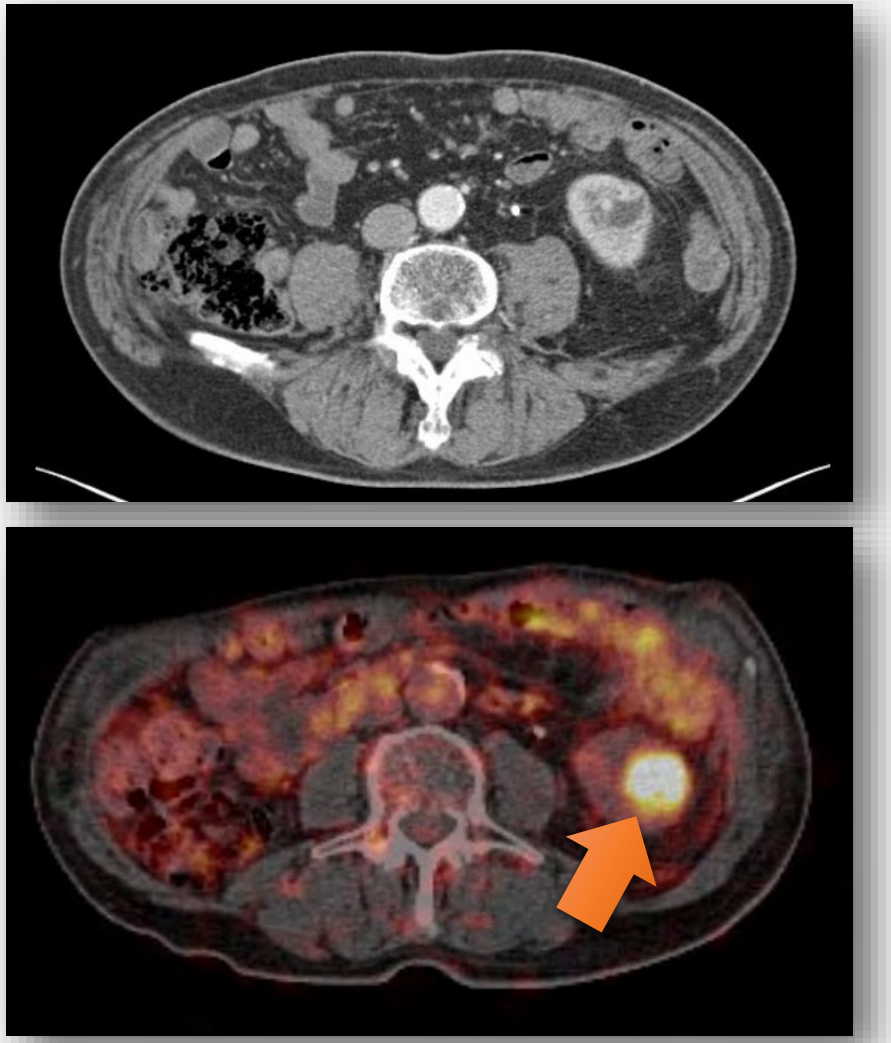
Case Study:[1]

Male, 76 years old

Medical history:

- 1992 Pyelum tumor → Nephro-ureterectomy : urothelial carcinoma
- **January 2016** → Bosniak 3 cystic lesion (27mm)

^{89}Zr-girentuximab PET/CT highly avid → Partial Nephrectomy, confirmed ccRCC



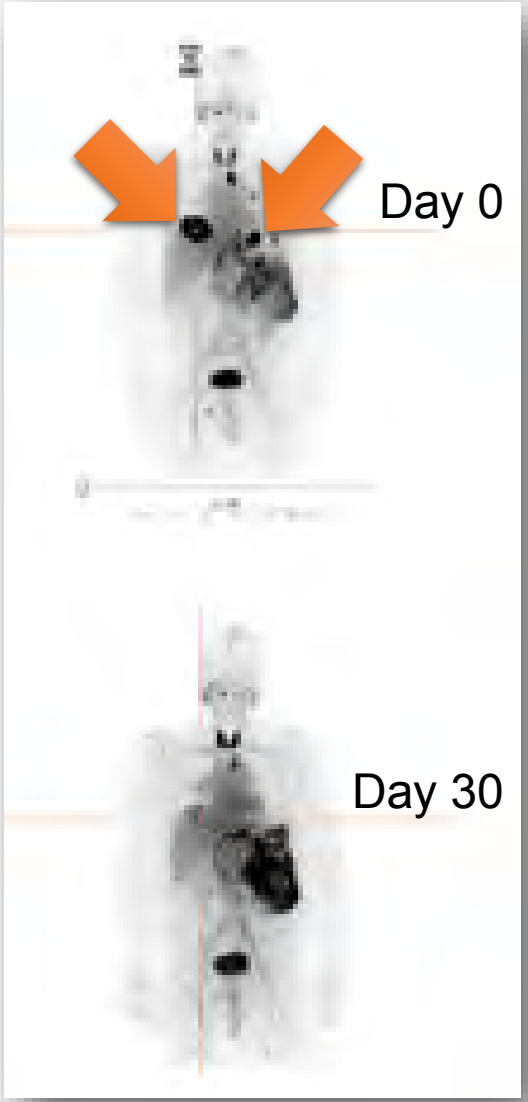
[1] Courtesy of Radboud University Medical Centre, Netherlands

Additional Indication #2 : Treatment Response

- Renal cancer treatment is complex and many first-line treatments have extensive toxicity and poor response rate

- A major clinical goal is to detect non-responders quickly and move onto second-line therapy (i.e. immunotherapy)
  - ➢ “preserve” the patient’s capacity for future treatment
  - ➢ Avoid wasting time, clinical resource, $

- Responders typically improve after 3-4 months of treatment
  - ➢ TLX250-CDx imaging can quantitatively detect response to therapy in as little as 30 days
  - ➢ Two trials running in collaboration with Radboud and MSKCC to explore the potential of this application (NCT02228954, NCT01582204)



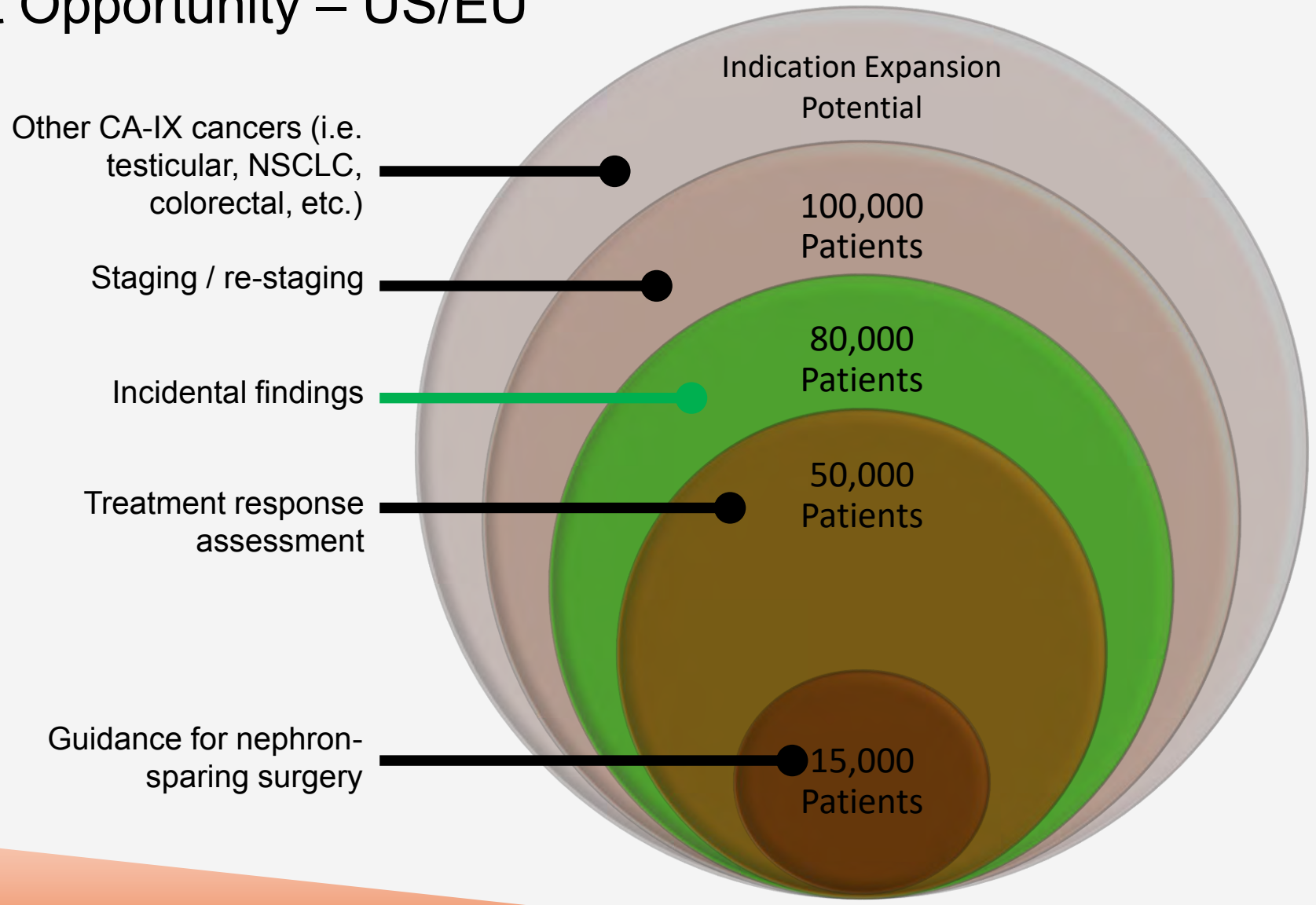
Before/After images of a patient treated with a TK inhibitor. Girentuximab-based imaging has proven to be very sensitive at detecting early patient response to therapy. Courtesy MSKCC

TELIX PHARMACEUTICALS

TLX250-CDx Market Opportunity – US/EU

There are over 1m patients with kidney cancer in the US/EU[1]. Our initial target indication will be incidental findings but TLX250-CDx will have utility in many parts of the RCC treatment journey

Cost-benefit analysis and recent price benchmarks support a unit dose price of ~$USD 3,000+ with a USD $200-250m addressable market for this product



[1] SEER / FDA guidance

TLX250-CDx (Imaging) : 2019 Goals

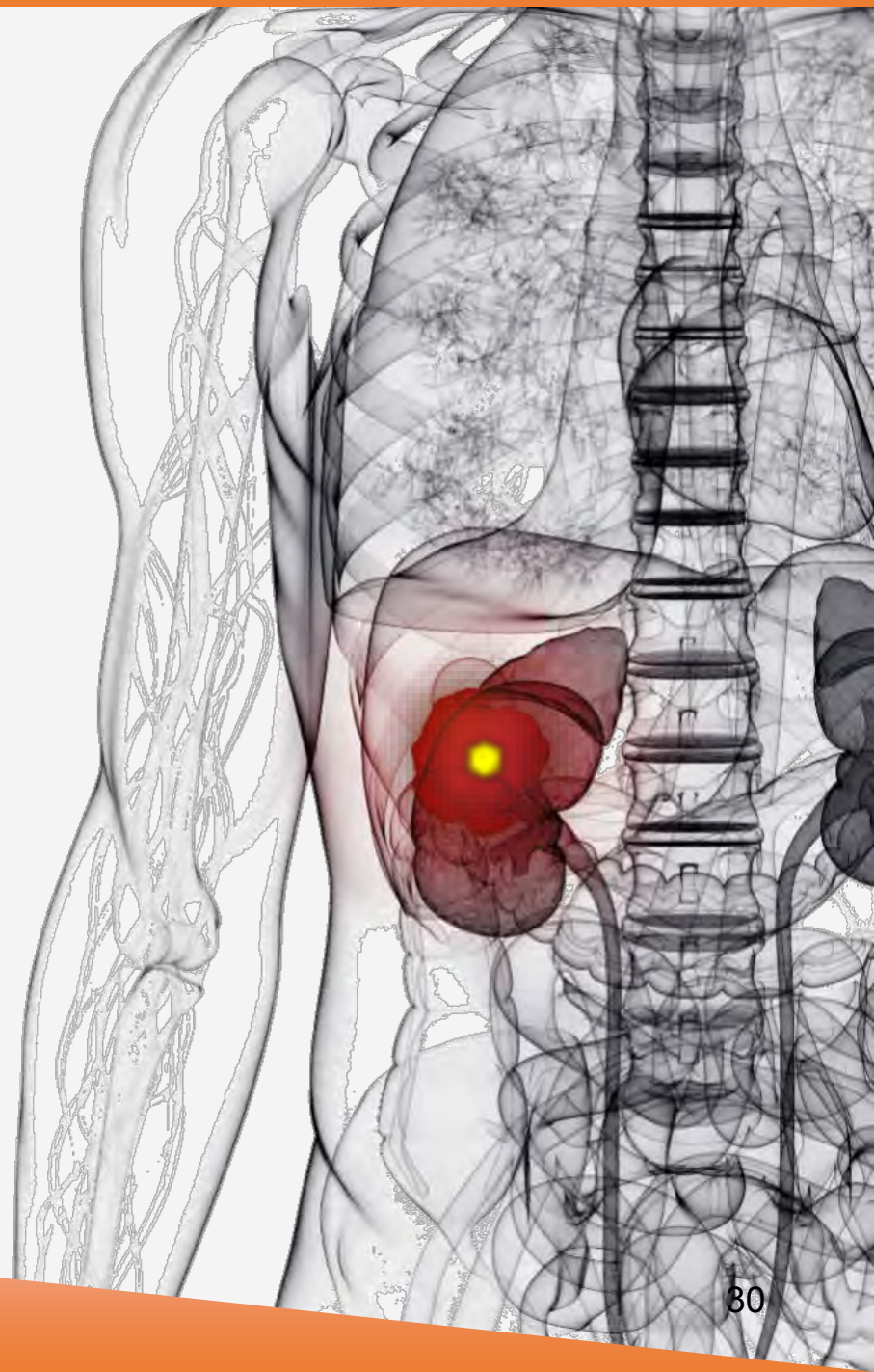
1. Completion of enrolment of ZIRCON Phase III trial by calendar Q4 ‘19

ZIRCON

2. Preparation of manufacturing/CMC package for BLA[1] submission readiness, including FDA consultation for bioprocess improvements planned for Q3 ‘19

3. Further clinical experience in the pre-/post-treatment response setting with key academic collaborators in the US and EU

4. Preliminary evaluation of the role of imaging CA-IX expression in testicular and colorectal cancer

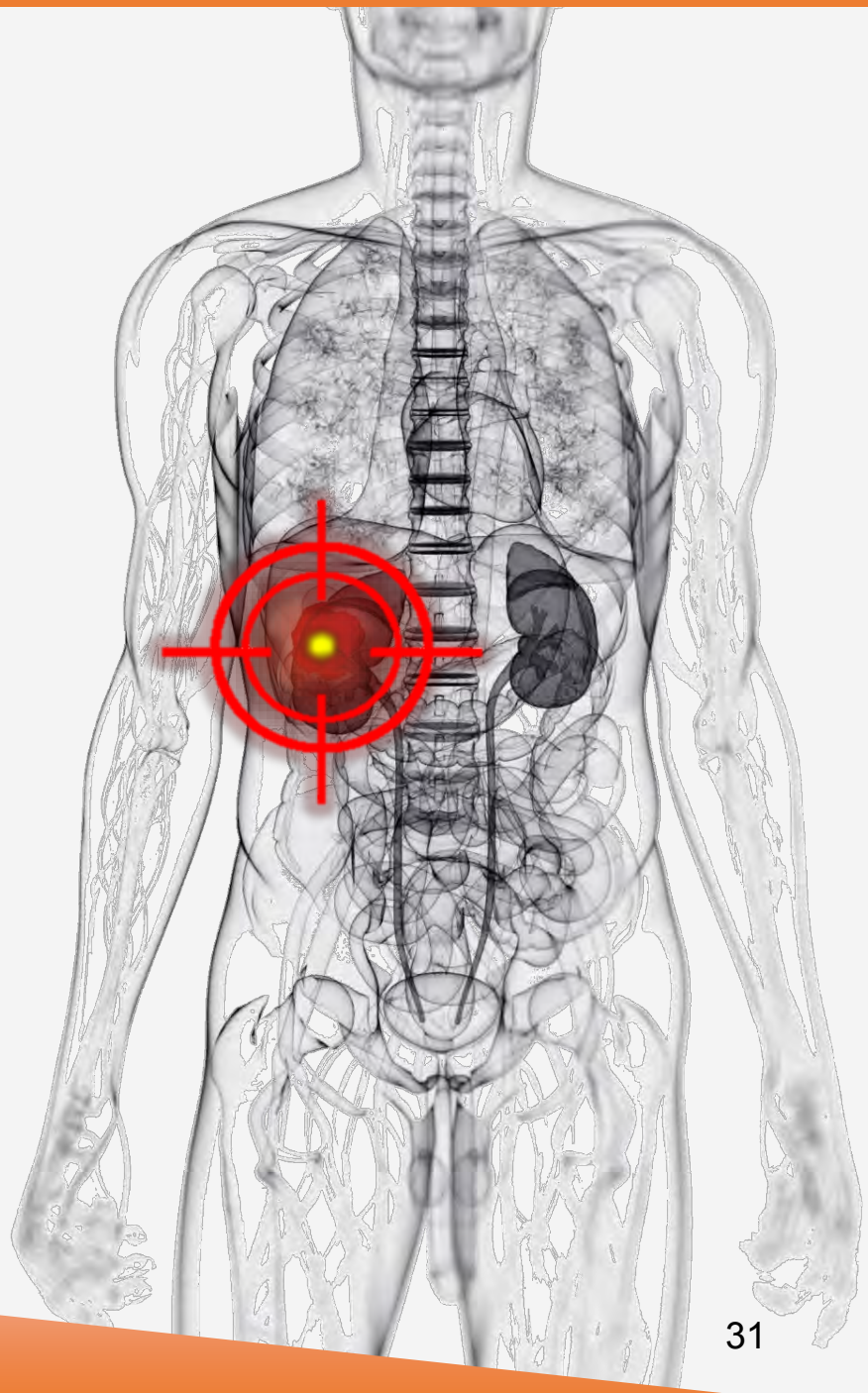


TELIX PHARMACEUTICALS

[1] Biologics License Application

Renal Cancer Therapy

TLX250
(^{177}Lu-girentuximab)

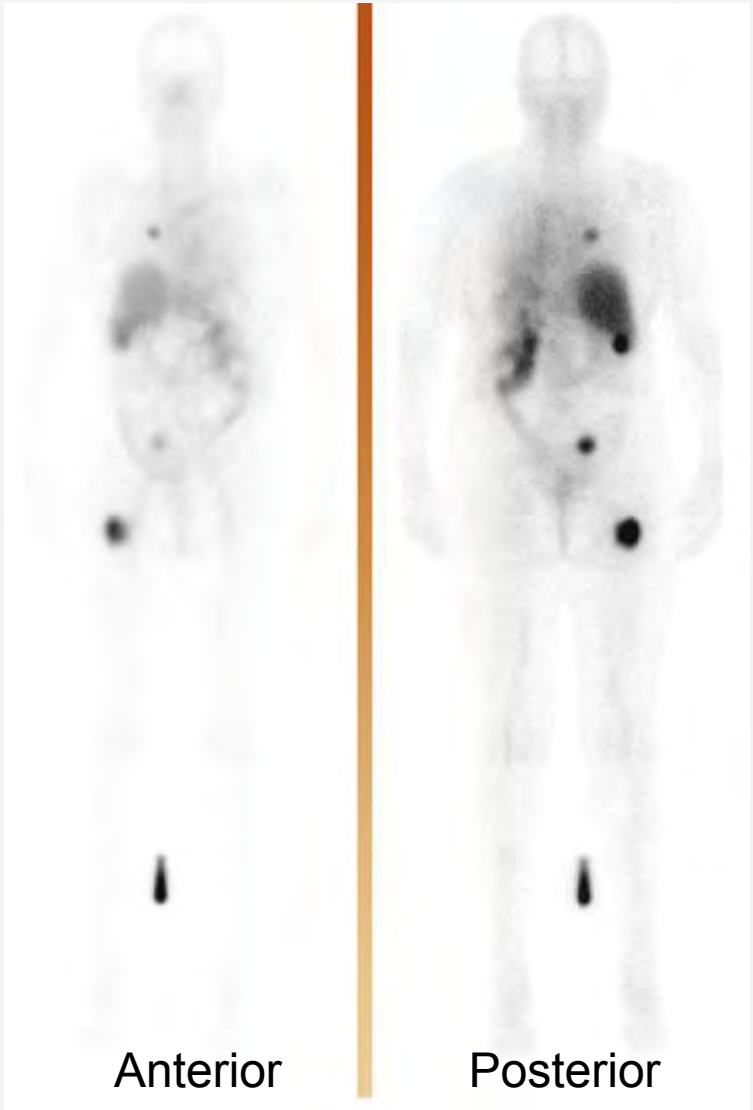


TELIX PHARMACEUTICALS

TLX250 (Therapy) : Background

- The therapeutic radiopharmaceutical applications of girentuximab build on the extensive experience with the antibody in over 1500 patients with various doses and payloads (including the “naked” antibody)
- As a targeting agent, girentuximab is safe and well-tolerated
- Combined with ^{177}Lu (lutetium), a beta-emitting therapeutic radionuclide, girentuximab has shown potent anti-tumor effect[1]
- TLX250 (^{177}Lu-girentuximab) has been studied in metastatic ccRCC salvage patients in academic studies (Phase I/II)

  - ✓ Median PFS of 10+ months in “salvage” patients
  - ✓ Stabilization of disease including some very durable responses in late-stage metastatic patients

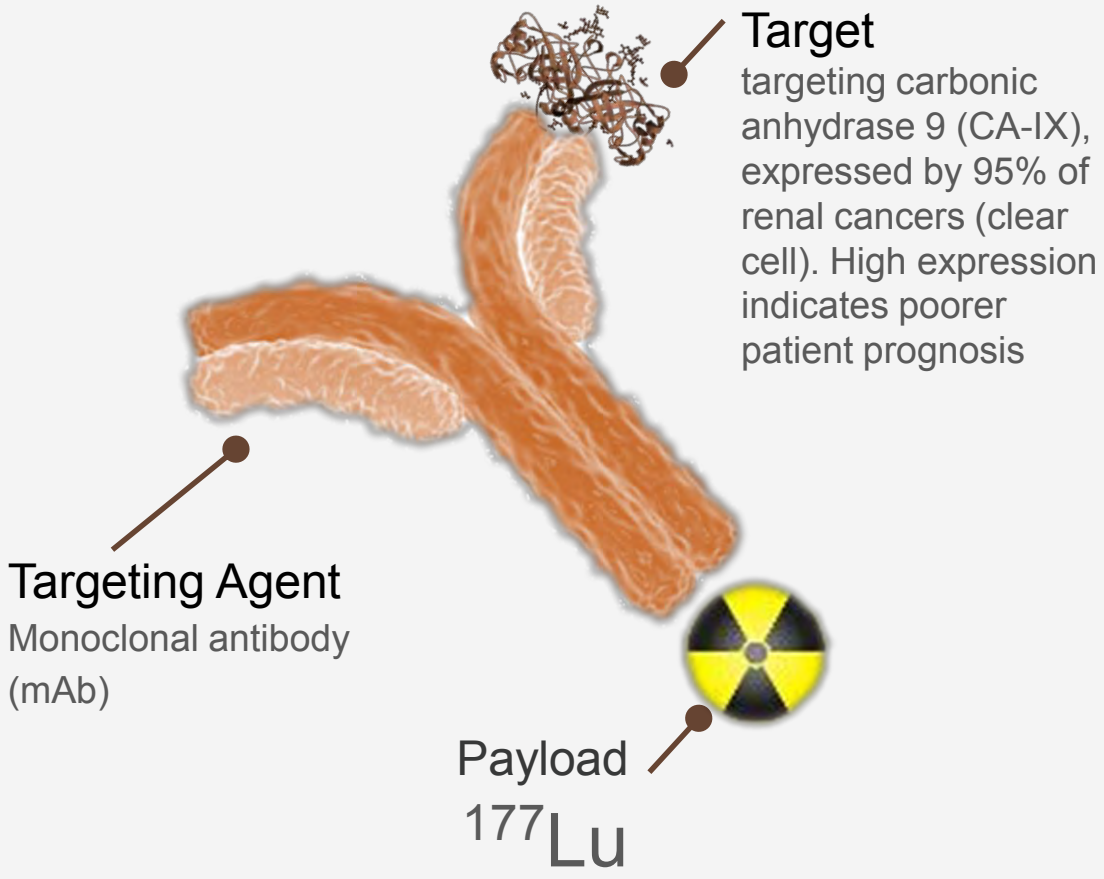


^{177}Lu-girentuximab scintigraphy - targeting of ccRCC metastases 6 days post-injection[1]

TELIX PHARMACEUTICALS

[1] Stillebroer et al, *European Urology*, 2013

TLX250 : Product Overview



Description:

- Radiolabeled mAb (girentuximab) targeting carbonic anhydrase 9 (CA-IX)
- For the treatment of metastatic clear cell renal cell cancer (ccRCC)

Technology Origin:

- Ludwig Inst / MSKCC via Wilex AG (license)
- ^{177}Lu use developed by Radboud Univ (NL)

Clinical Status:

- Phase II

Unmet Need:

- ✓ Patients progressing from immunotherapy have few treatment options
- ✓ Potential combination with immunotherapy (i.e. checkpoint inhibitors) to sensitize a larger proportion to immuno-oncology strategies

TELIX PHARMACEUTICALS

Clinical Experience to Date

- 37 patients (Ph I/II) – salvage patients, progressive disease
- TLX250 radiotherapy significantly slowed progression
  - ➢ Average tumor increase (RECIST) in the 3 months prior to treatment was 40.4%
  - ➢ In the 3 months after treatment it was 5.5%
- Response was not dose-dependent. Some of the best responders received relatively low doses, highly suggestive of a radiation-induced immune response
- Several durable responses with controlled tumor volume progression, in a patient population generally considered to be radiation resistant
- PFS (without patient selection via imaging) ~10 months

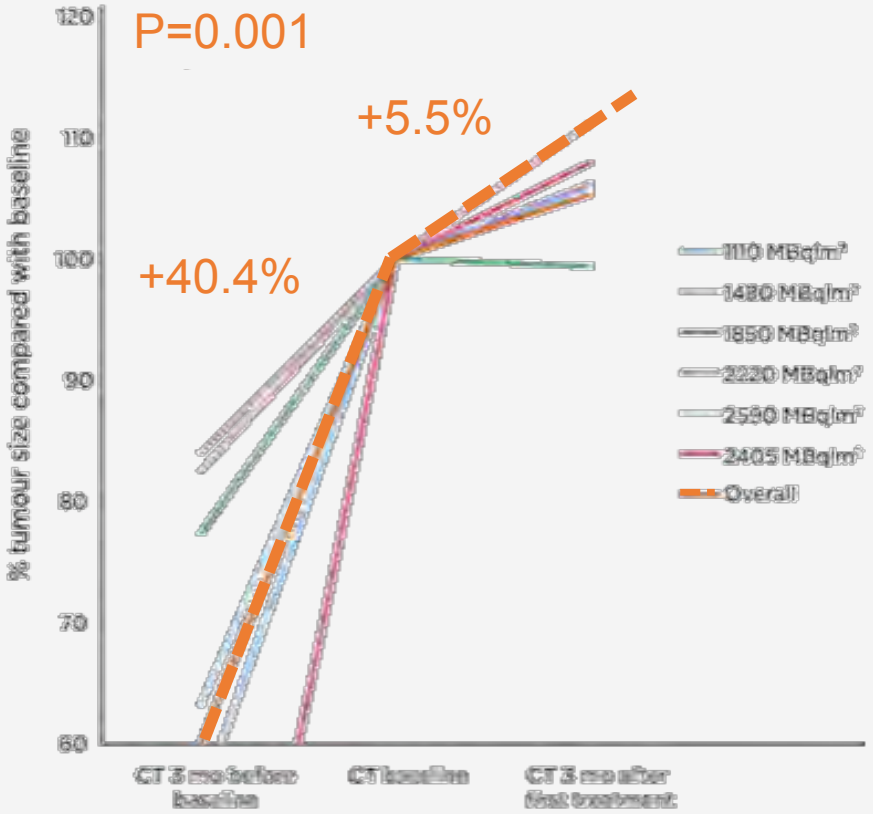


Illustration of the rapid impact on tumor radiographic progression (CT) following TLX250 therapy[1]

[1] Stillebroer et al, *European Urology*, 2013

Fractionation (Repeat-Dosing) Response Profile (Phase I[1])

23 Patients (1st Cycle)

- 17 patients did not progress (i.e. tumor growth stopped)
- 2 patients with ADA[2] response, 3 patients myelotoxicity

12 Patients (eligible for 2nd cycle)

- 7 patients still have stable disease (i.e. tumor growth stopped)
- 1 patient progressed, 1 patient with myelotoxicity

4 patients (3rd cycle)

- 2 patients had extensive stabilization of disease for 2 years and 6 years

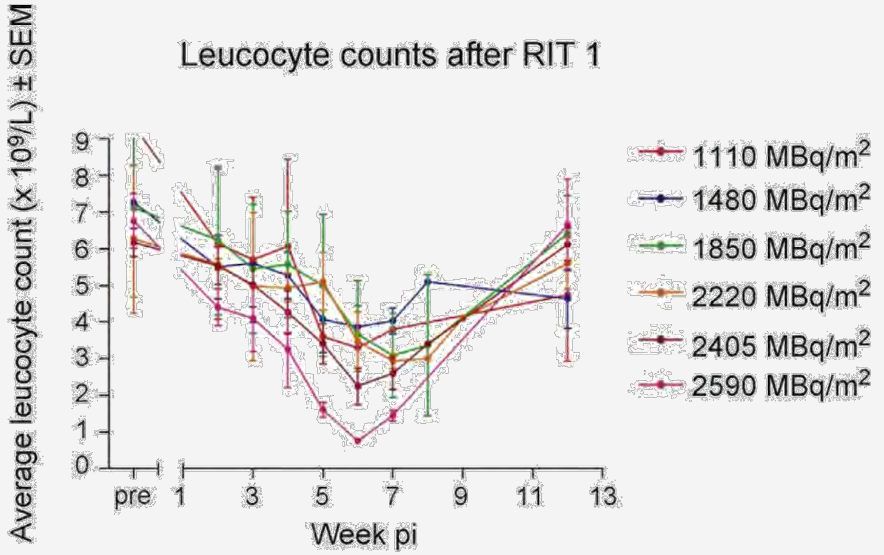
The key to durable response and management of toxicity is to optimize fractionation (repeat dosing)

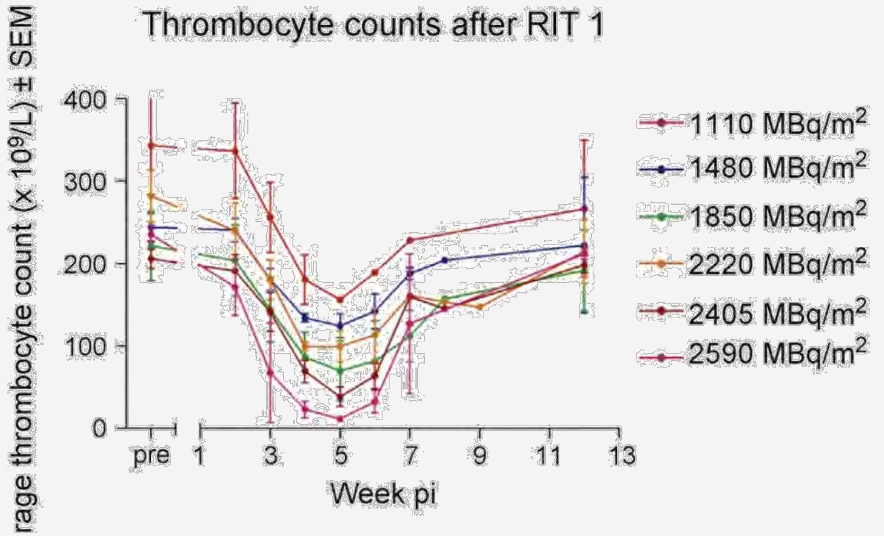
TELIX PHARMACEUTICALS

[1] Stillebroer et al, *European Urology*, 2013
[2] ADA – Anti-Drug Antibody

Safety Profile

- Generally well-tolerated
- Toxicity profile very comparable to other antibody-based radioimmunotherapies (i.e. huJ591)
- Toxicity, particularly myelotoxicity, is likely to be dependent on how patients are previously treated (i.e. VEGF TKIs) – needs further investigation
- Main toxicity is hematologic toxicity and is dose-limiting
  - ~2,400 MBq/m^2 MTD (single dose)
  - All hematologic toxicity was transient, reversible (right)
- Fractionation (dosing) will need to be optimized to minimize transient toxicity in patients that receive multiple cycles of therapy. Our experience with huJ591 (TLX591) is highly informative in this respect



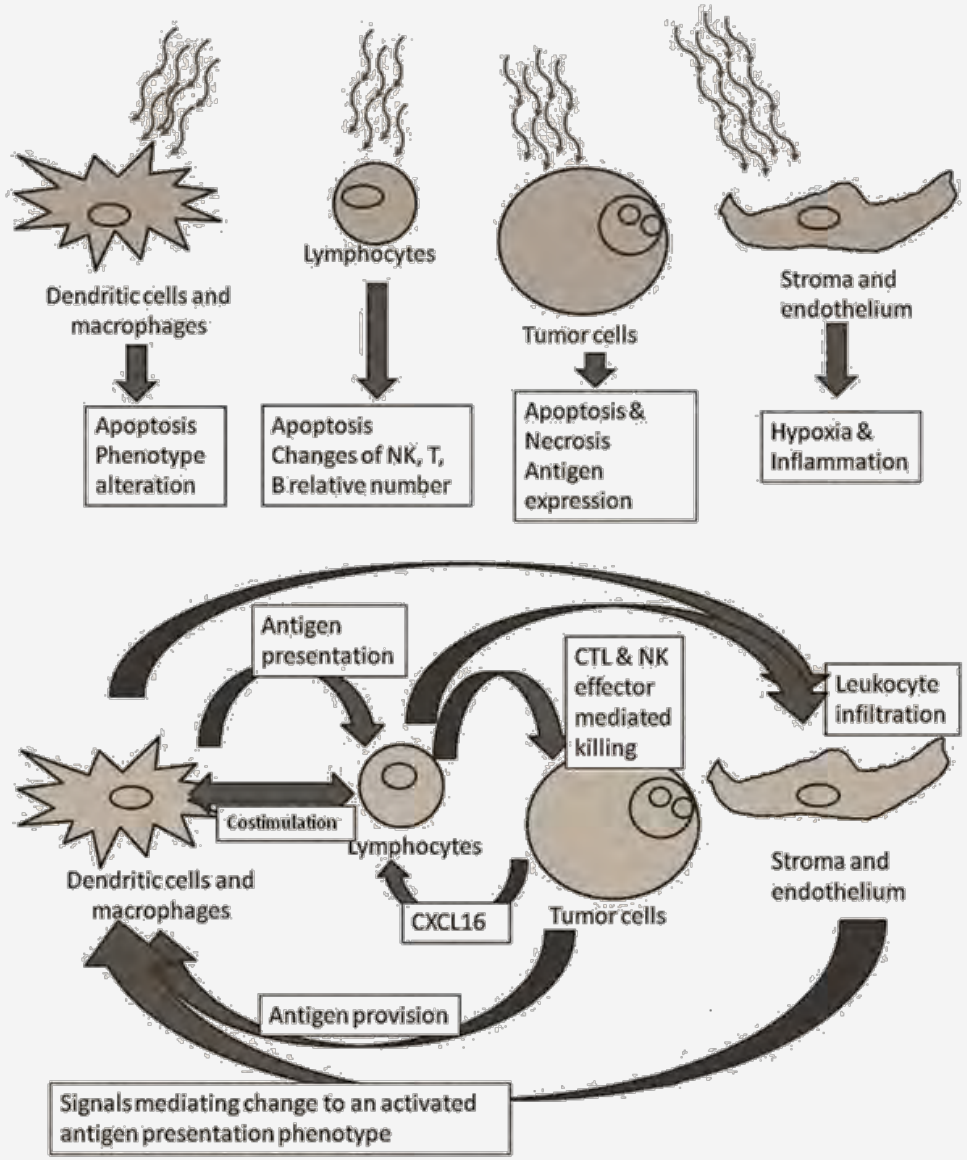


[1] Stillebroer et al, *European Urology*, 2013

TLX250 + Immuno-Oncology

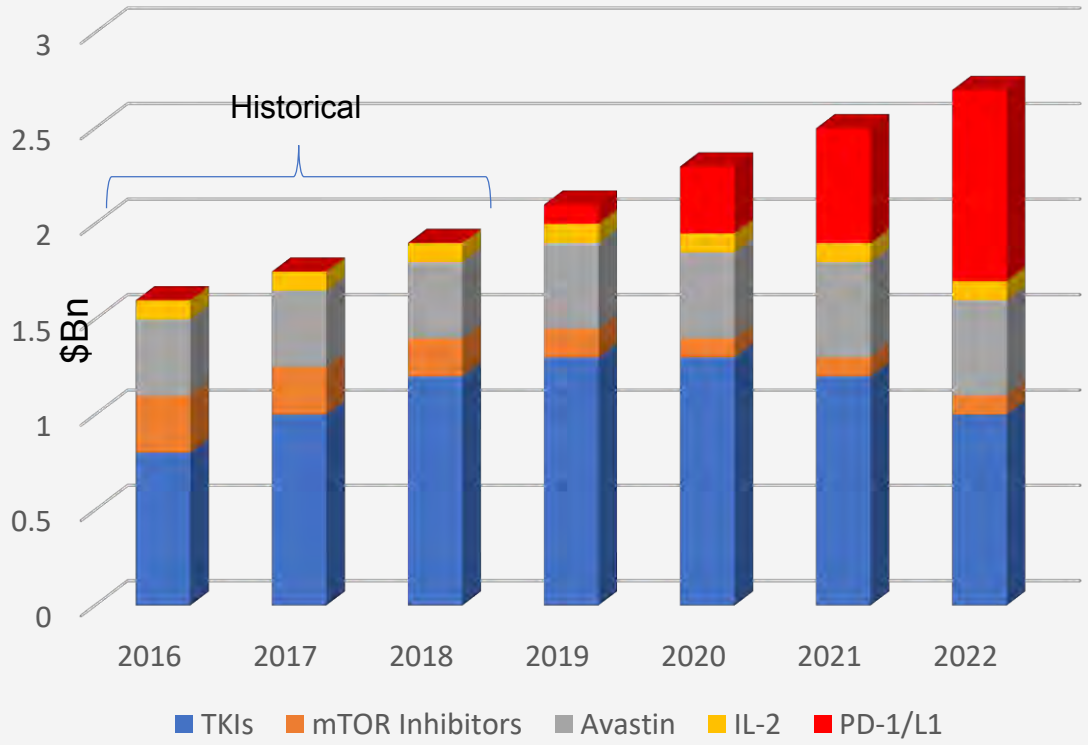
Radiation sets the "groundwork" for immuno-therapies – likely to be particularly relevant to TLX250

- Radiation increases mutations / DNA damage
- Radiation increases antigen presentation / release ⇔ dendritic cell maturation
- Counteracts the immune suppression through MHC class I expression
- Radiation increases expression of proinflammatory cytokines
- Down-regulates Fas ligand expression
- Irradiates the stromal fraction – highly immunogenic (activated T cell recruitment)
- Radiation remodels tumor micro-circulation, alters vascular fraction



TLX250 Market Opportunity – US/EU

- 30% of RCC patients are metastatic at diagnosis
- PD-1 / PD-L1 immunotherapies are fundamentally changing the landscape for kidney cancer
- In major markets (i.e. US), there is momentum to transition as rapidly as possible to immunotherapy - will impact the use of VEGF/TKI therapies
- TLX250 has two opportunities:
  - ➢ Improving the low response rate (20-30%) of immunotherapies – USD $200-300m opportunity
  - ➢ As a salvage therapy for the rapidly growing base of patients that have progressed on immunotherapy with few treatment options - USD $300-400m opportunity

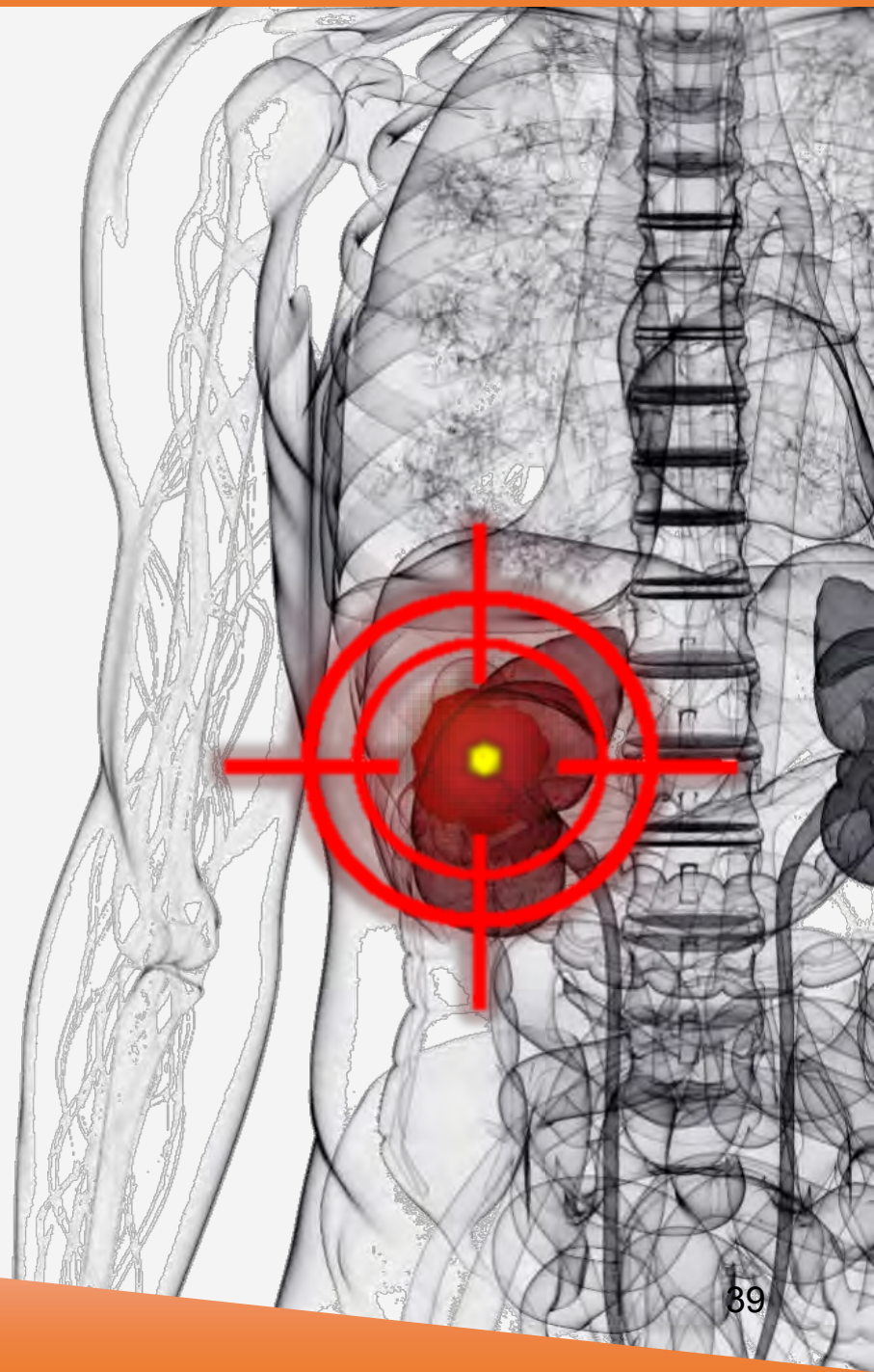


Company predication of how PD-1/L1 (checkpoint inhibitor) immunotherapies, including combinations, will impact traditional RCC treatment modalities

TELIX PHARMACEUTICALS

TLX250 (Therapy) : 2019 Goals

1. Treatment of metastatic renal cancer is a rapidly evolving field. Telix is planning a mid-2019 launch of two US studies to evaluate:
   - Treatment of checkpoint-progressive patients with TLX250 to determine if patients can be re-sensitized to repeat immunotherapy (i.e. Nivolumab)
   - Combination treatment of second-line patients with immunotherapy to evaluate whether concurrent irradiation of metastases improves response rate to immunotherapy (currently ~30%)
2. A commercial collaboration for combination immunotherapy will likely result in sponsored clinical activity in 2019
3. All studies will include TLX250-CDx imaging as a patient selection and treatment response measurement tool

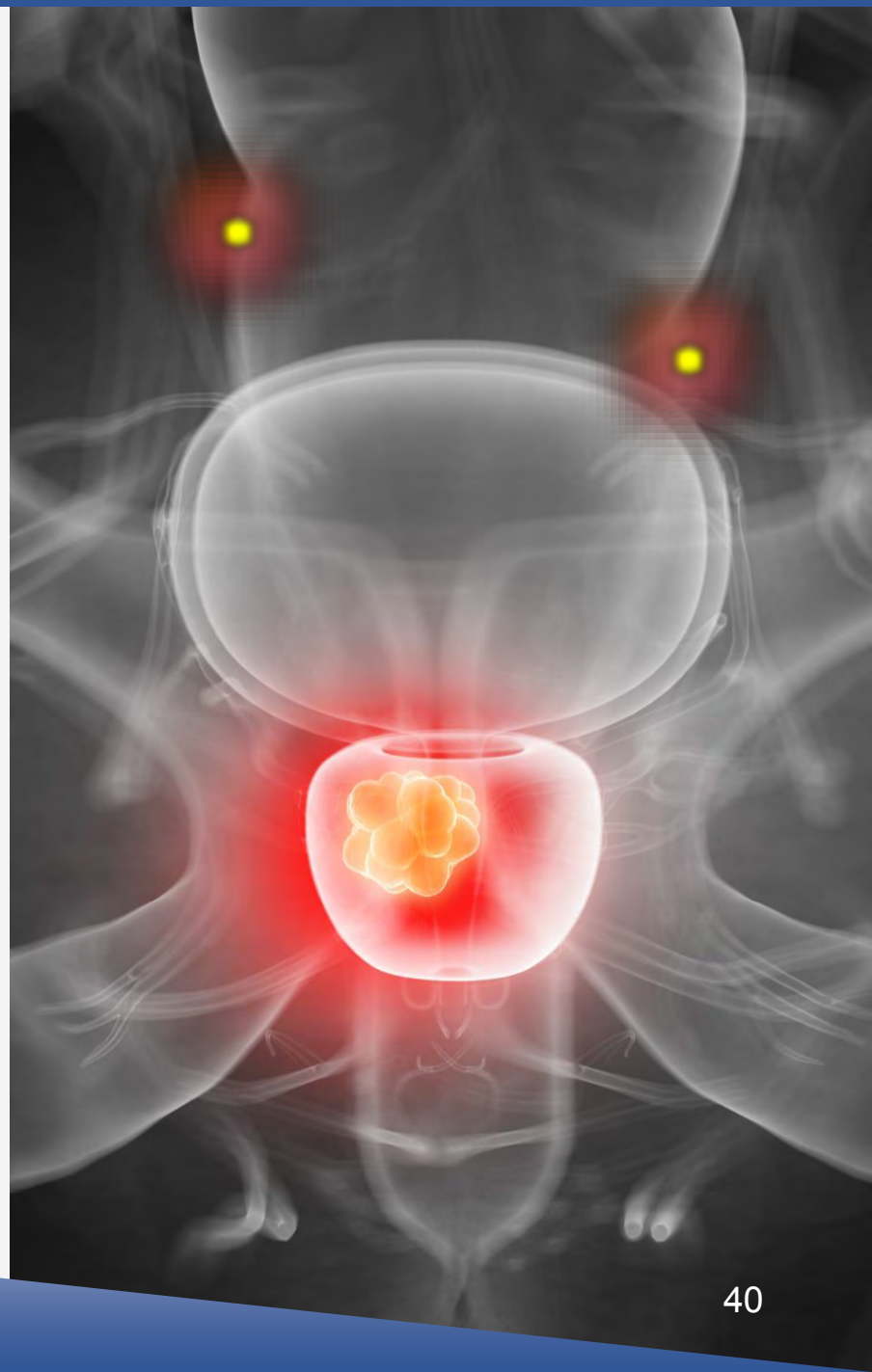


TELIX PHARMACEUTICALS

illumet™
Kit for the preparation of ^{68}Ga-PSMA-11 Injection

Prostate Cancer Imaging

TLX591-CDx
(^{68}Ga-HBED-CC-PSMA-11)



TELIX PHARMACEUTICALS

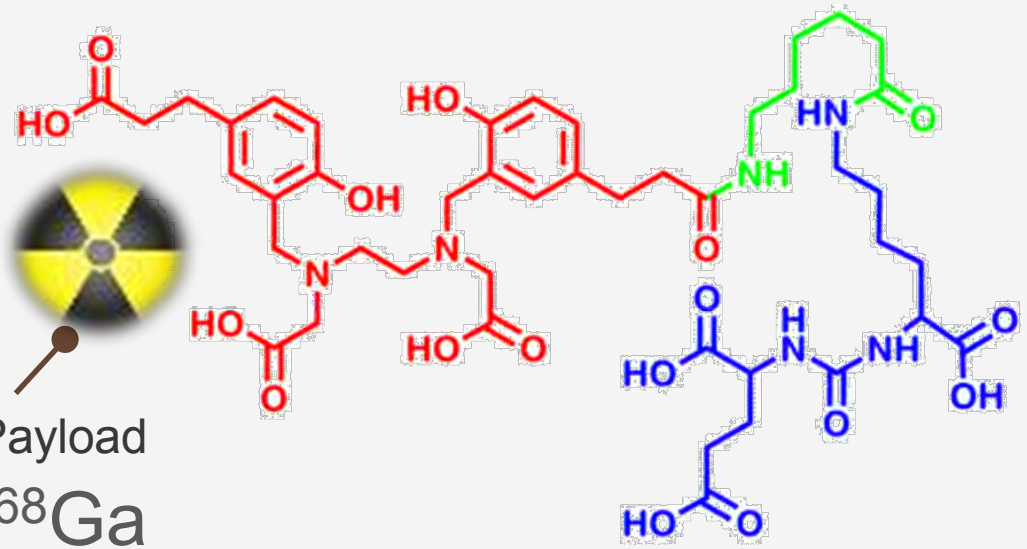
TLX591-CDx (Imaging) : Background

- Telix required a “companion diagnostic” for its TLX591 prostate therapy program – partnering initially identified as optimal solution
- After extensive analysis, Telix elected to focus on ^{68}Ga-PSMA both for companion diagnostic and US market opportunities. ANMI SA selected as the technology partner in October ‘17
- ANMI was acquired by Telix in December ‘18

- **Outcome** : *illumet*^{TM}, a “cold kit” for the rapid, room-temperature preparation of ^{68}Ga-PSMA-11*
- **Outcome** : Enables PET imaging doses to be prepared on-demand, anywhere. Proprietary chemistry enables rapid preparation of a patient-ready dose in under 5 minutes
- **Outcome** : A flexible, *global* strategy for prostate cancer imaging with a rapid pathway to commercialization

*68Ga-PSMA-11 is an investigational product and has not received marketing authorization in the US or EU

TLX591-CDx : Product Overview



Description:

- Radiolabeled small molecule (PSMA-11) targeting Prostate-Specific Membrane Antigen (PSMA)
- For the imaging of prostate cancer with PET
- Rapid targeting / clearing (via kidneys)

Technology Origin:

- German Cancer Research Centre (DKFZ)
- ANMI SA (acquired ‘18) – proprietary formulation

Clinical Status:

- Pre-NDA (USA)
- Phase III (EU)

Unmet Need:

- ✓ Staging of high-risk prostate cancer patients
- ✓ Sensitive detection of metastases in patients with biochemical recurrence
- ✓ Treatment planning / response assessment

Q. Why is imaging so important to prostate cancer management?
A. Plenty of watching and waiting…

Local Disease			Locally Advanced	Lymph Node Mets	Distant Mets
Low Risk	Medium Risk	High Risk			
Active Surveillance	Radical Prostatectomy	Radical Prostatectomy	Radical P'tectomy ++	P'tectomy + Endocrine Tx	Endocrine Tx
Radical Prostatectomy	XRT	XRT + Endocrine Tx	XRT + Endocrine Tx	XRT + Endocrine Tx	Bone Seeking Agents
XRT	XRT + LDR Brachytherapy	XRT + HDR + Endocrine Tx	XRT + HDR + Endocrine Tx	Endocrine Tx	Symptom Oriented Tx
LDR Brachytherapy	XRT + Endocrine Tx	**Watchful Waiting**	**Watchful Waiting**	**Watchful Waiting**	
Watchful Waiting	Active Surveillance				
	Watchful Waiting				

This treatment matrix illustrates "typical" strategies for treating prostate cancer (darker blues illustrate a trend toward systemic therapy)

TELIX PHARMACEUTICALS

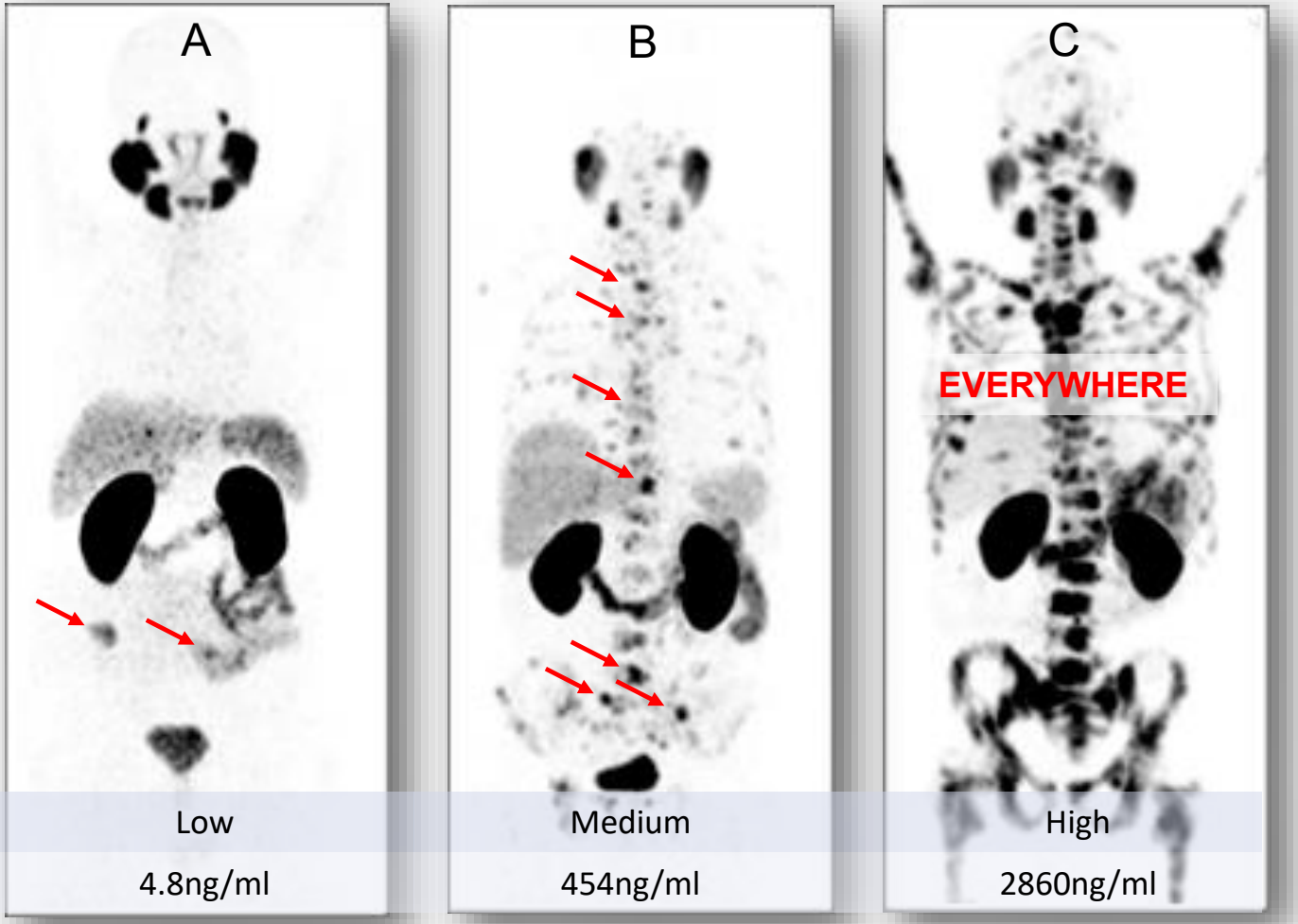
XRT = External Beam Radiation Therapy

PSMA-11 Imaging with PET is Sensitive, Correlates with PSA

It is possible to image disease with PSMA imaging, even at very low PSA levels (= generally lower tumor burden). TLX591-CDx uses the PSMA-11 targeting peptide, one of the most widely studied imaging peptides

The three panels A)-C) illustrate how PSMA-11 imaging avidity changes as a function of PSA level (from low to high PSA). All of these patients are imaged post-prostatectomy[1]

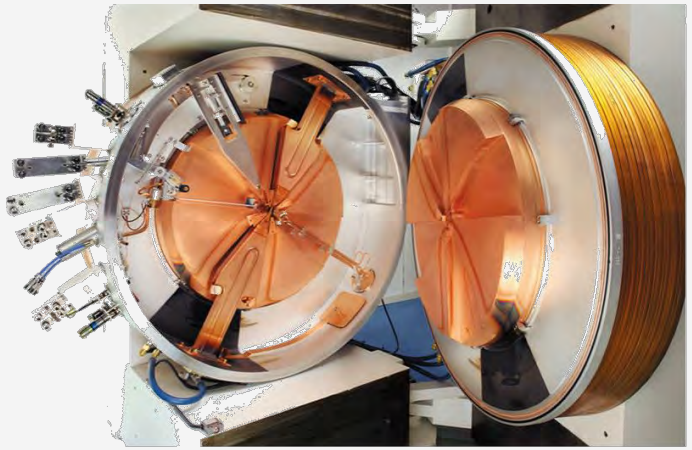
A few highly vivid tumors are marked for noting (red arrows)



	A	B	C
Tumor Load	Low	Medium	High
PSA Level	4.8ng/ml	454ng/ml	2860ng/ml

[1] Adapted from : *Oncotarget*. 2017; 8:55094-55103

Two Ways to Produce PET Agents for Prostate Cancer Imaging



Cyclotrons. ^{18}F is the most commercially used isotope (2 hour half-life). Very high-scale production but also high infrastructure / operating cost, ageing install base. Scheduled production means less patient flexibility and challenging to deliver product to the “last mile”

Generators. $^{68}Ge/^{68}Ga$ (gallium) generators are a portable radiation source that “lives” in the hospital radiopharmacy and is replenished every 6 months or so. Lower throughput but convenient and can be flexibly deployed. ^{68}Ga has a short half-life of 68 minutes which means that a dose needs to be prepared quickly and “on demand”. This is the preferred approach used by Telix (ANMI)

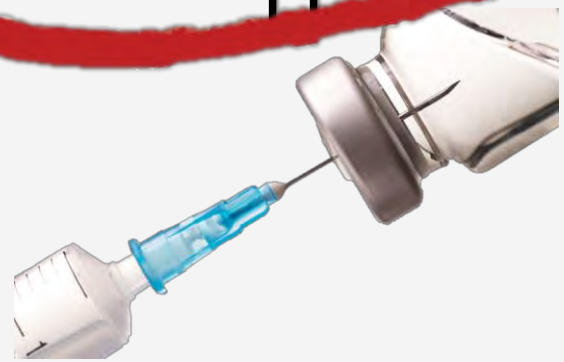
illumet™ : A True “Shake and Shoot” Product

^{68}Ga Generator

The “Kit”

A package containing all the components necessary to attach the radioactivity to a targeting agent (PSMA-11). The kit is used at room temperature (no heating) and takes a few minutes to prepare an injection-ready dose*.

^{68}Ga–PSMA-11



Up to 4 hours stability

TELIX PHARMACEUTICALS

*68Ga-PSMA-11 is an investigational product and has not received marketing authorization in the US or EU

Extensive Validation

- *illumet*^{TM} has been validated with the three leading brands of ^{68}Ga (gallium) generators used in the United States
- Validation data with IRE, E&Z and ITG generators was provided to the FDA in the Drug Master File (DMF) submission for the product*
- Currently validated generators reflect >95% of the install base of ^{68}Ga generators in the United States – **and globally**

- Telix is continuing to validate with other 3rd party generators that are starting to become available in the US (e.g. iThemba)
- Since ^{68}Ga can also be produced via cyclotron, we are also validating the *illumet* product with ^{68}Ga produced from GE and IBA cyclotrons
- We are currently amending our FDA DMF to include support for cyclotron-produced gallium – in progress

*68Ga-PSMA-11 is an investigational product and has not received marketing authorization in the US or EU

The US market opportunity is significant

- Prostate cancer (PCa) is the most common male cancer in the US[1]. 160,000 new cases diagnosed annually in men over 50. Three million men are living with prostate cancer[2]
- Imaging will play a role all the way from staging high-risk patients, through recurrence to monitoring disease in response to therapy
- Localizing metastatic disease early gives more treatment options but existing imaging solutions are inadequate
- A patient who progresses post-prostatectomy will have at least 3 imaging studies over the course of their treatment journey
- Reimbursement benchmarks for PCa imaging agents are in excess of USD $3,000 / dose (i.e. Axumin® / Blue Earth Diagnostics)
- ***PCa imaging is at a USD $500m realizable market opportunity, dominated by imaging Prostate-Specific Membrane Antigen or "PSMA" with Positron Emission Tomography (PET)[3]***

TELIX PHARMACEUTICALS

[1] Excluding skin cancer
[2] Source : American Cancer Society
[3] Jadvar et al. *J Nucl Med* February 1, 2018 vol. 59 no. 2 228-229

Beyond the US Market

- US the initial focus – homogenous regulatory landscape
  - ✓ Including reasonable predicates for product reimbursement (e.g. Axumin® / Blue Earth Diagnostics)
  - ✓ Typically a higher dose price-point than the EU (20-30%)
- EU + RoW > doubles the market opportunity for ^{68}Ga-PSMA
  - ✓ Well accepted in Europe but still a need for a commercially produced product
  - ✓ Growing clinical traction in Asia and Latin America
  - ✓ Will require further clinical development (ongoing in Europe)
- Telix's investment in manufacturing scale-up of the *illumet*™ product can eventually support the international market as well as the US

illumet™ (TLX591-CDx) : 2019 Goals

- US : New Drug Application (NDA)
  - 505(b)(2) path – preparation in progress. Available data:
    - ✓ Information package – summary of clinical experience
    - ✓ Preclinical and animal studies
    - ✓ Toxicology package
    - ✓ Scale-up manufacturing complete early 2019 in the US
    - ✓ 250+ EU patients, 100 additional EU patients for safety
    - ✓ Comparability between synthesizer-produced and kit-produced product (in humans)
- EU : Phase III studies ongoing (ANMI)
- Timeline
  - ➢ Preliminary package will be submitted to FDA early 2019 to initiate NDA discussions

^{68}Ga–PSMA-11

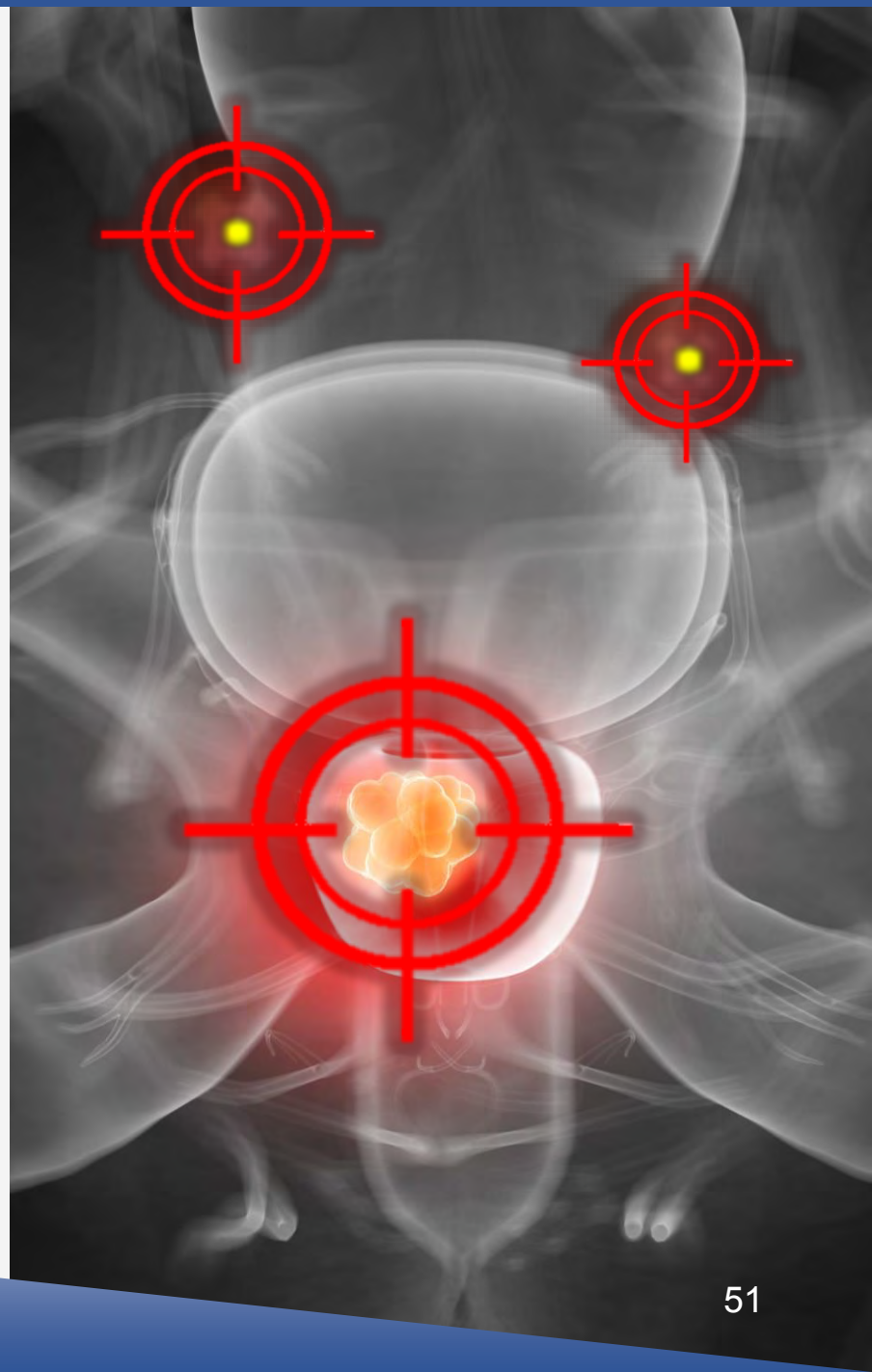
illumet™

Kit for the preparation of ^{68}Ga-PSMA-11 Injection

TELIX PHARMACEUTICALS

Prostate Cancer Therapy

TLX591 (^{177}Lu-huJ591)



TELIX PHARMACEUTICALS

TLX591 (Therapy) : Background

TLX591 (huJ591)

Treatment of late-stage patients with bulky disease

- Developed by Prof. Neil Bander (Cornell)
- Humanized monoclonal antibody (mAb) targeting PSMA
- Extensive clinical experience (200 patients in PhI/II trials)
- Radiotherapy rights obtained through Atlab acquisition
- **Original plan**: engineer huJ591 into a faster-clearing antibody to reduce hematologic toxicity
- **New information**: independent CRO has verified reduced toxicity due to fractionation approach
- **New plan**: Take to Phase III with ^{177}Lu for the treatment of bulky metastatic disease

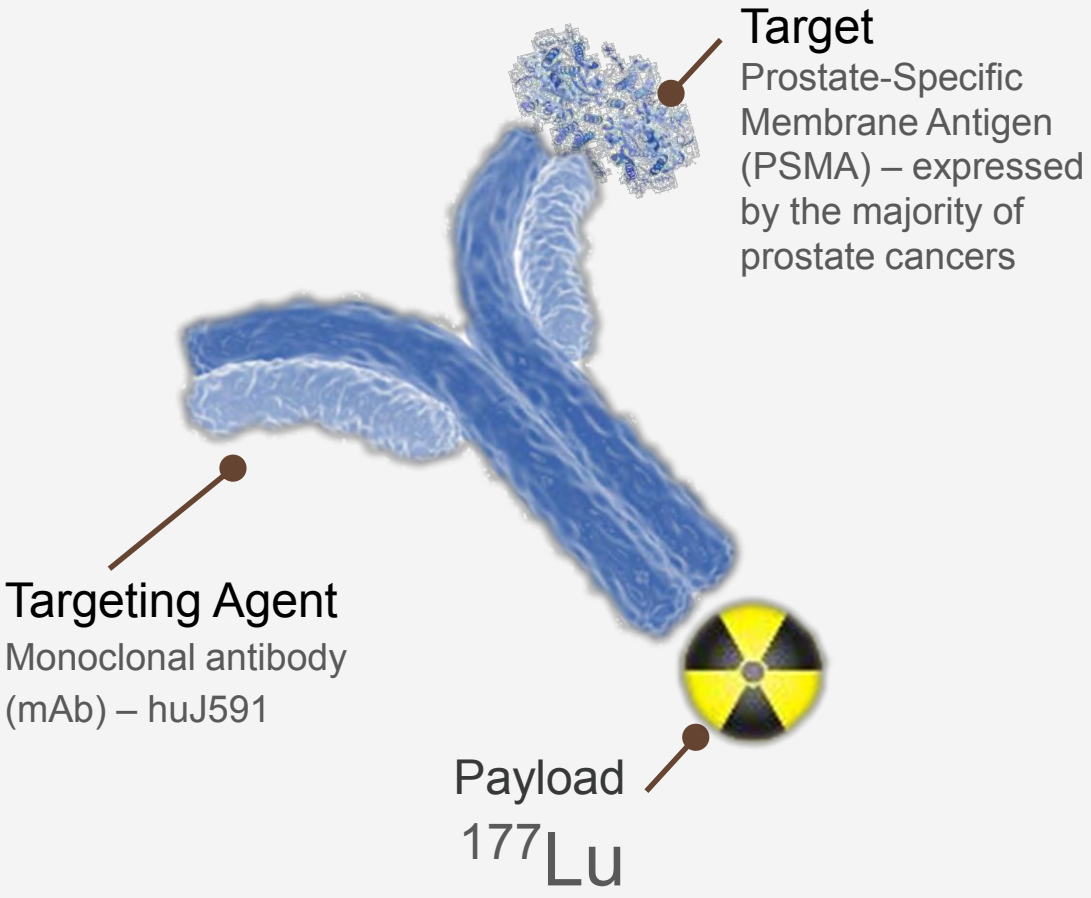
TLX592 (Engineered huJ591)

Treatment of early-stage patients with small metastases

- Developed by Telix, some IP from Abzena
- Pk-engineered mAb for accelerated blood clearance / reduced bone marrow affinity
- **Original plan**: lead Telix program for PCa therapy, rapid clinical pathway to Phase II
- **New information**: 'J591 fractionated data, impressive OS, commercial momentum
- **New plan**: develop as a "2nd generation" product with an alpha-emitter (^{225}Ac) for early-stage patients (small mets)

(See slide 77 – R&D)

TLX591 : Product Overview



Description:

- Radiolabeled monoclonal antibody (huJ591) targeting prostate-specific membrane antigen (PSMA)
- Treatment of metastatic prostate cancer

Technology Origin:

- Weill Cornell Medical Centre (WCMC), NY
- BZL Biologics, LLC
  (via Atlab acquisition - 2018)

Clinical Status:

- Pre-Phase III[1]

Unmet Need:

✓ PSMA-targeted radionuclide therapy is a potentially transformative option for late-stage metastatic castrate-resistant prostate cancer (mCRPC) patients, particularly prior to end-stage chemotherapy

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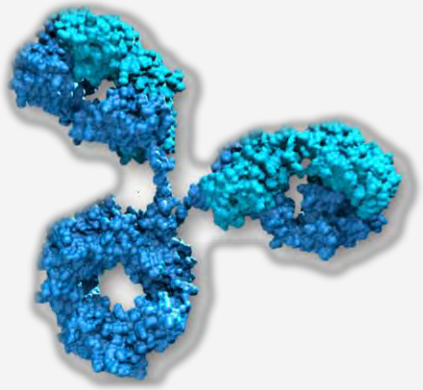
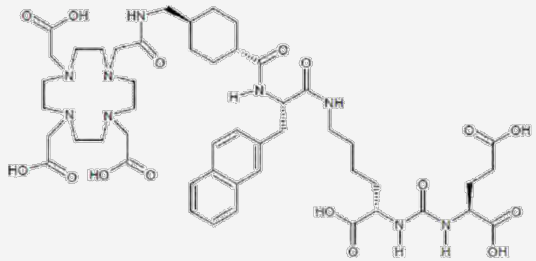
[1] Phase III subject to regulatory approval

Antibodies v Small Molecules

- Several companies are investigating small molecule PSMA therapeutics (radiopharmaceuticals)
  - Early stage : AAA (Novartis), Blue Earth Diagnostics
  - Late stage (Ph III): Endocyte (acquired by Novartis)
- Limitations of small molecule approaches:
  - Because of their size, small molecules are able to reach endogenous PSMA expression (lacrimal/salivary glands, ganglia GI, etc.) causing side-effects that are unpleasant for many patients
  - Complex intellectual property landscape
  - Potential nephrotoxicity (kidney toxicity) risk when used to deliver high-dose ^{177}Lu or alpha-emitting radionuclides



huJ591 – Antibody
Molecular Weight :
150KDa



PSMA-617 (Endocyte)
Molecular Weight :
(1,200 g/mol or ~1.2KDa)

Clinical Experience

- ~200 patients, well-tolerated with significantly reduced toxicity by fractionated delivery (see next slide)
- Impressive survival benefit, no exocrine gland uptake
- A full dose-escalation data set that clearly informs an optimal dose, while demonstrating that fractionated delivery is safe and effective
- 2 doses (instead of 4-6 for PSMA-617) may be enough to deliver better treatment efficacy : Fewer hospital visits a potential advantage
- Pre-chemotherapy : 48 month median overall survival (OS)
- Post-chemotherapy : 28 month OS. Clearly pre-chemotherapy patients are the target:
  - Patients are healthier before chemotherapy – are better responders
  - Tumors lose PSMA expression after chemo – reducing efficacy

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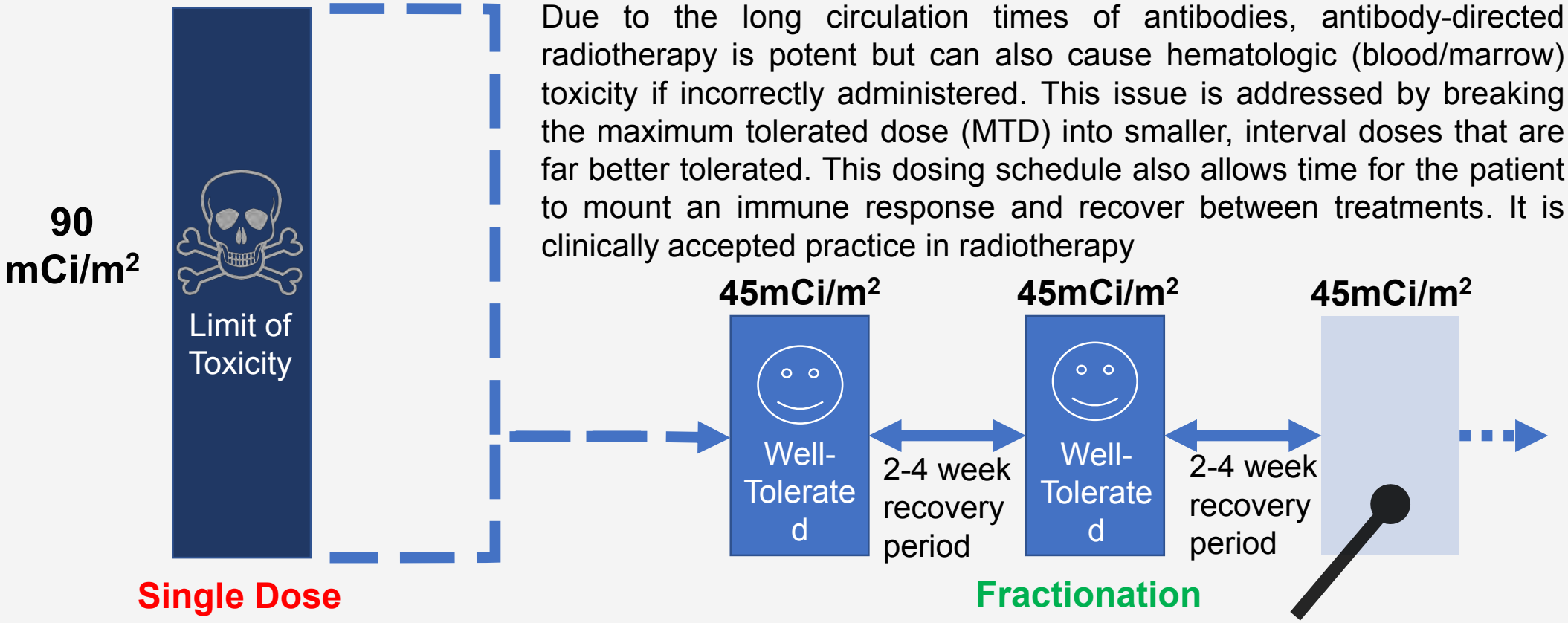
What is Fractionation?



Due to the long circulation times of antibodies, antibody-directed radiotherapy is potent but can also cause hematologic (blood/marrow) toxicity if incorrectly administered. This issue is addressed by breaking the maximum tolerated dose (MTD) into smaller, interval doses that are far better tolerated. This dosing schedule also allows time for the patient to mount an immune response and recover between treatments. It is clinically accepted practice in radiotherapy

Dose fractionation potentially enables a radiation dose greater than MTD to be delivered to the patient = greater durability of response / possibility of maintenance therapy

MTD = Maximum Tolerated Dose

Patient Cohorts - Analysis

huJ591 Radiotherapy Data (Total):

Study	# Patients
^{90}Y Single Dose Phase 1	29
^{177}Lu Single Dose Phase 1	35
^{177}Lu Fractionated (x2) Dose Phase 1	49
^{177}Lu Single Dose Phase 2 (+ Extension)	47
^{177}Lu Fractionated (x2) + Chemo Phase 1	15
^{177}Lu Single Dose + ADT Phase 2	42 (ongoing)
Total	217

Over 200 patients have been treated with huJ591-directed radiotherapy in 6 clinical trials. The observed MTD is 90mCi/m^2 (^{177}Lu)[1] with 65-70mCi/m^2 (single dose) representing a tolerable single-dose limit (in terms of toxicity). Telix has compared this dosing range with the 2x fractionated dosing at 40mCi/m^2 and 45mCi/m^2

Specific Patient Cohorts Used for Analysis

Cohorts (mCi/m^2)	Phase I fractionated	Phase II	Phase II Extension	Total
65		15		15
70		17	15	32
2x40	16			16
2x45	16			16
Total	32	32	15	79

- <u>65 mCi/m2</u>
  Activity of 65mCi/m2 in patients from Phase II
- <u>70 mCi/m2</u>
  Activity of 70mCi/m2 in patients from Phase II
- <u>2x40 mCi/m2 (Fractionated)</u>
  Activity of 2*40 mCi/m2 (two weeks apart)
- <u>2x45 mCi/m2 (Fractionated)</u>
  Activity of 2*45 mCi/m2 (two weeks apart)

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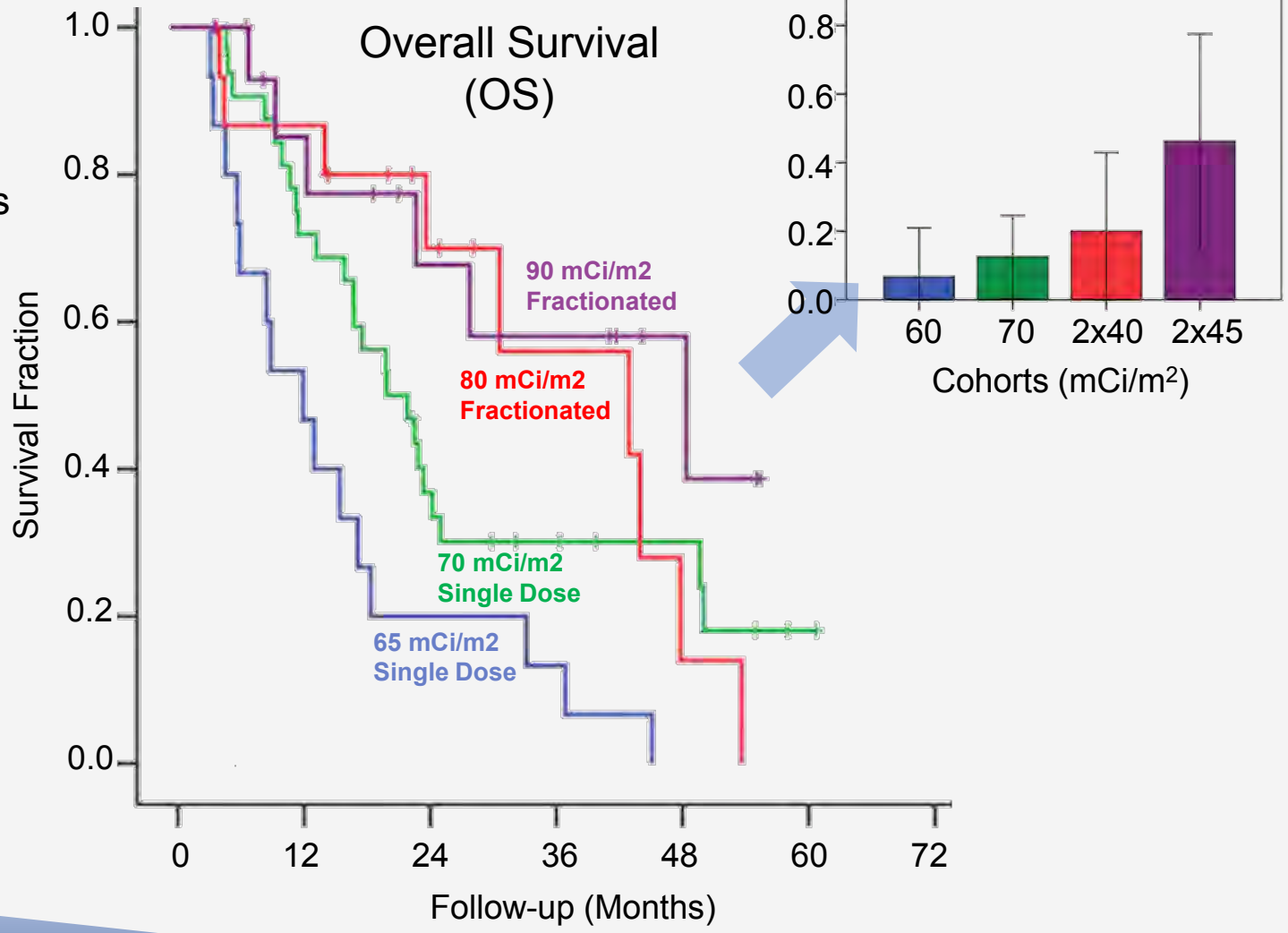
[1] Vallabhajosula et al. *Curr Radiopharm* 2016;9(1):44-53.

Excellent Dose-Response Profile

The fractionated dosing profile is better tolerated than high-activity single dose and delivers a cumulative treatment effect that is significantly more durable both in terms of PSA decline and OS

	Cohorts			
Activity (mCi/m2)	**65**	**70**	**80 F (2x40)**	**90 F (20x45)**
Median OS 95 % CI (months)	11.9 [6-18]	19.9 [13-27]	42.9 [13-73]	48.4 [10-87]
Hazard Ratio (HR)* p-value	1.00 Ref	0.41 p=0.008	0.31 p=0.006	0.19 p=0.001
Corrected HR** p-value	1.00 Ref	0.45 p=0.019	0.39 p=0.037	0.12 p=0.0004

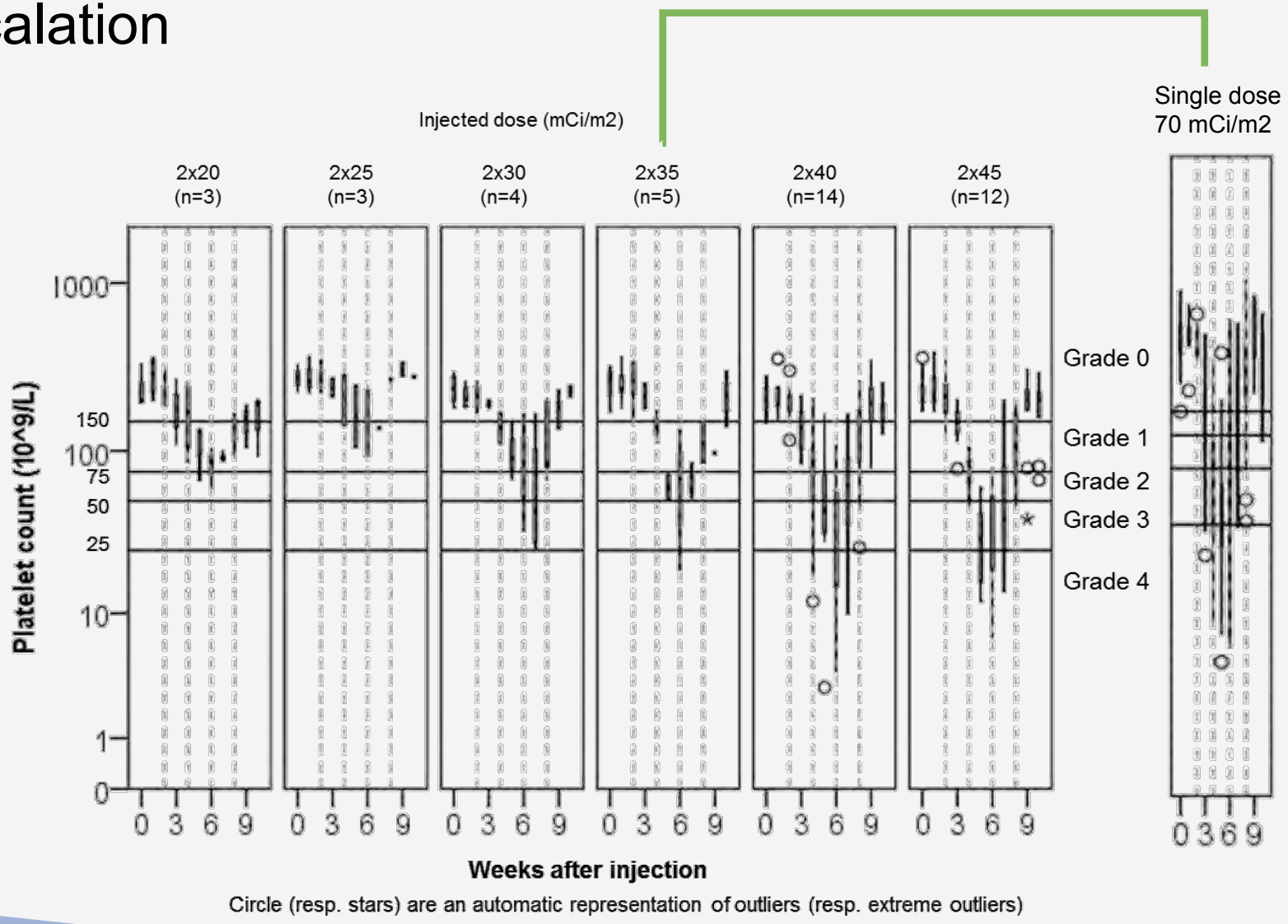


* Cox analysis
** corrected for baseline PSA (log) and previous chemotherapy

Fractionated Dose-Escalation

Traditionally, antibody (mAb)-directed radiotherapies were considered to have an unacceptable hematologic toxicity profile because of the long circulation time

However, fractionated dosing – as is done with small molecules (i.e. PSMA-617) – leads to highly tolerable toxicity profile with potentially superior efficacy

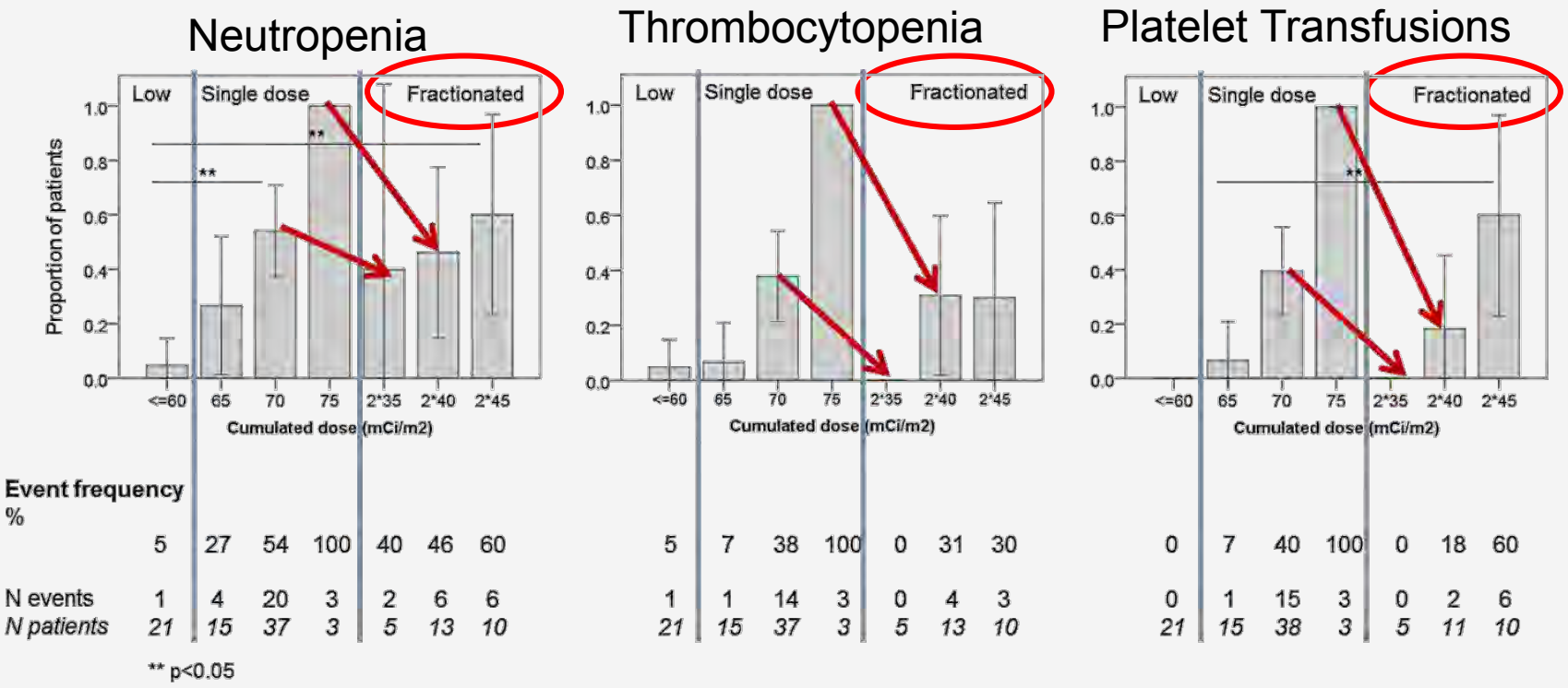


* Note: Cohort rendering excludes a limited number of patients that did not receive a second dose

Fractionation Measurably Addresses Hematologic Toxicity

Fractionation (breaking into smaller repeat doses) is common practice in radiotherapy.

Our data demonstrates a major reduction in toxicity through the use of this approach, supporting the further development of huJ591 (TLX591)



Fractionation data for huJ591 (TLX591) illustrating the excellent reduction in hematologic toxicity (all reversable AEs) achieve through repeat dosing of lower levels of ^{177}Lu activity, while maintaining (and even improving) therapeutic efficacy

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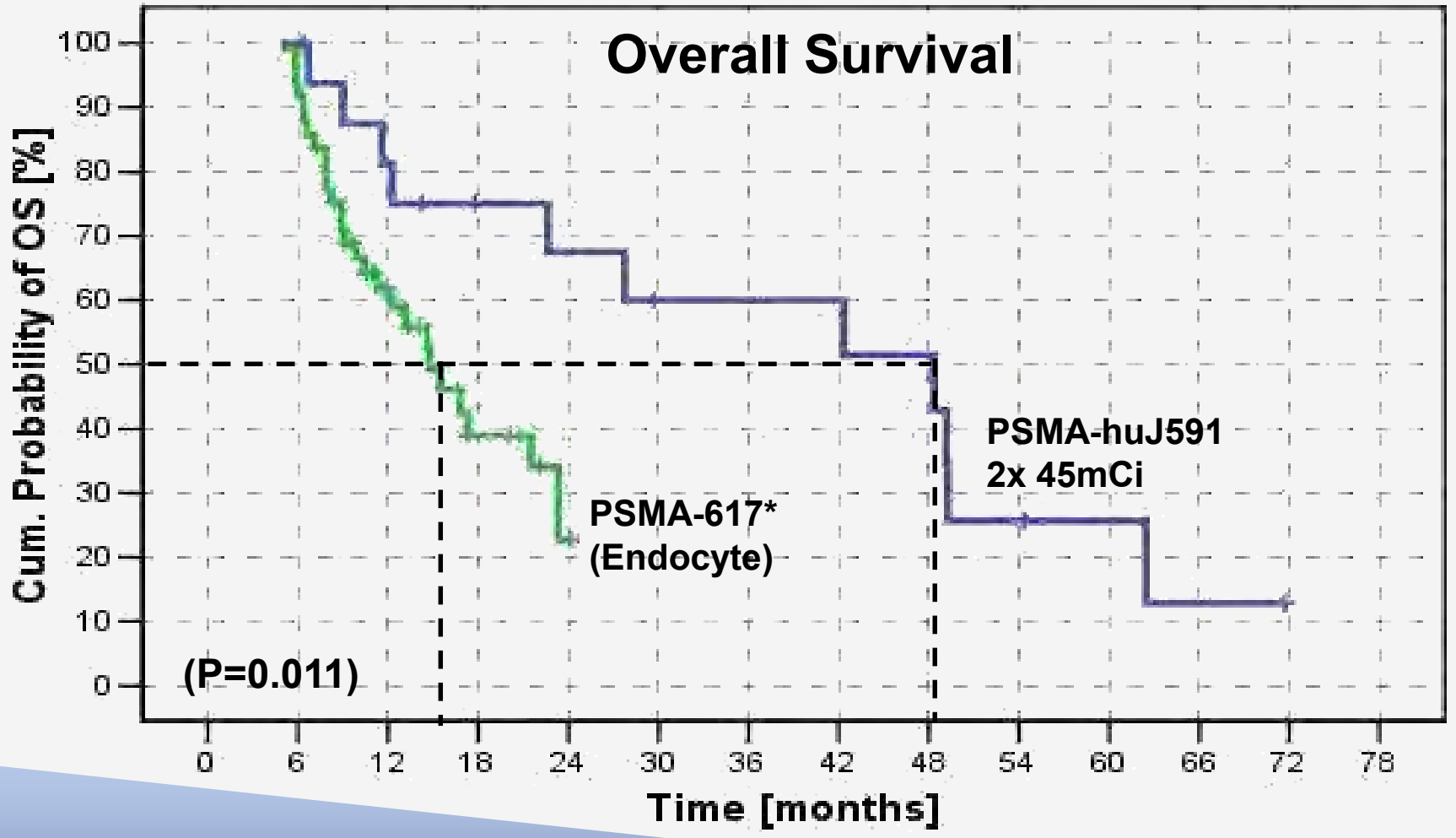
Patient Benefit Compares Favourably to PSMA-617 (Endocyte / Novartis)



Retrospective cross-trial comparison between ^{177}Lu-PSMA-617 and ^{177}Lu-huJ591 (TLX591)

Median overall survival (OS) is >40 months (hu591) vs 15 months (PSMA-617)

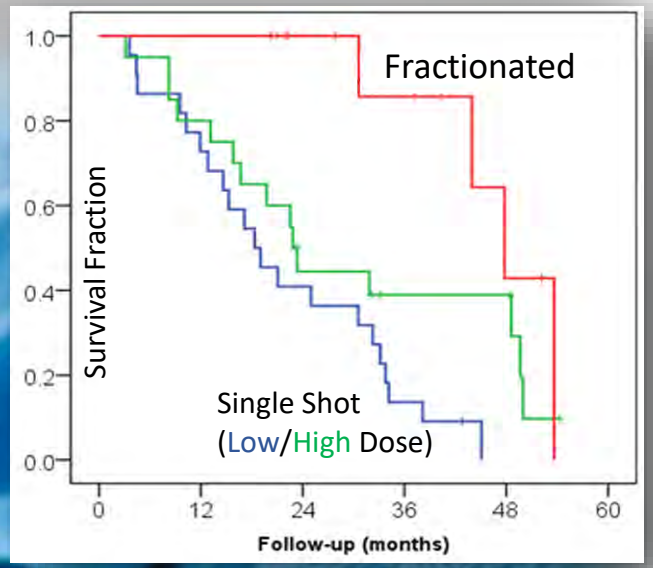
Unpublished data. Analysis performed by ABX CRO. Preliminary data suggests that further clinical development of the antibody-based approach is competitively viable

*Data from the German multi-center trial for PSMA-617 : Rahbar et al. (*JNM* 2017)

TLX591 – Standout Survival in Pre-Chemotherapy Patients

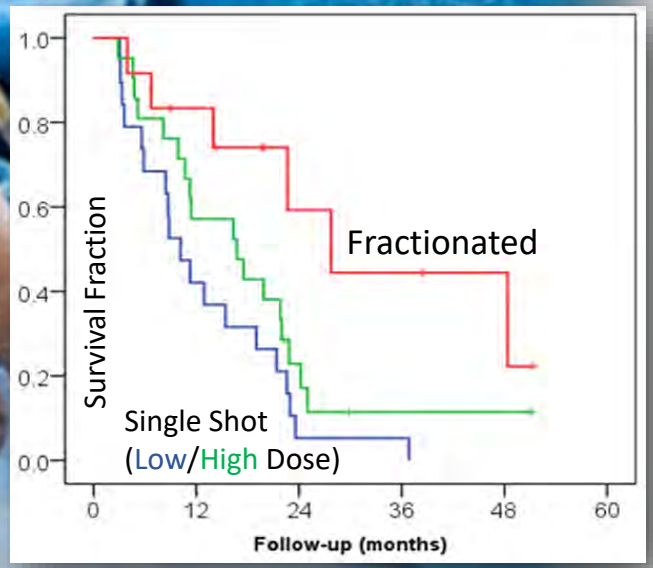
Post-chemotherapy ("salvage") patients have considerably lower PSMA expression, which in turn appears to impact treatment efficacy. Our competition has chosen to run their trials their trials in the salvage patient population

In contrast, a retrospective subset analysis suggests that patients in all dose cohorts respond better prior to chemotherapy. The durability of fractionated response (40+45 mCi/m^2 pooled) appears to be roughly **2x** in pre-chemo patients compared to post-chemotherapy, potentially opening up a much larger ($Bn) market opportunity for TLX591



Pre-Chemo OS= ~48 months

(n=54 patients)



Post-Chemo OS = ~28 months

(n=52 patients)

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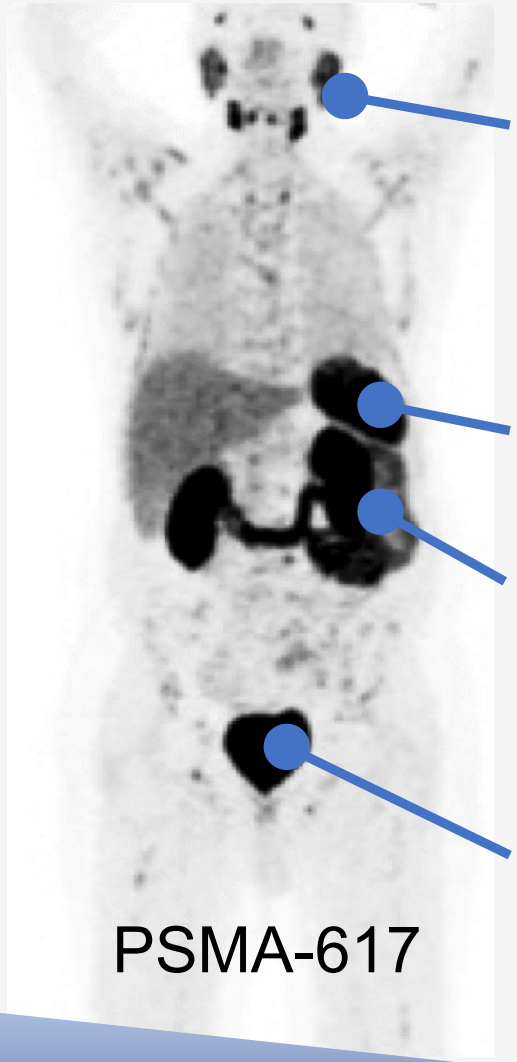
Off-Target Irradiation – Quality of Life Matters

Small molecule-based approaches such as PSMA-617 (Endocyte / Novartis) are able to hit endogenous PSMA expression whereas antibodies are only functionally-specific for tumor-expressed PSMA.

This means that TLX591 does not cause additional unpleasant side-effects like dry eye and salivary gland dysfunction



PSMA-617

Lacrimal, Parotid, Submandibular (salivary) glands

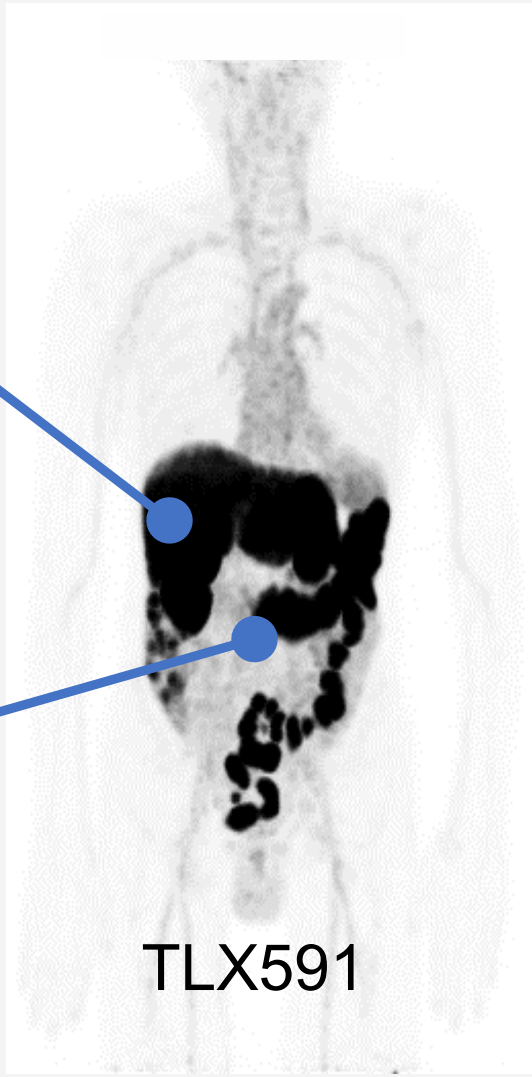
Spleen, Liver

Kidneys, Small bowel

Bladder (urinary excretion)

Liver (preferred clearance organ)

Large bowel (fecal excretion)



TLX591

Data courtesy of Prof. Neil Bander, WCMC

TLX591 (Therapy) : 2019 Goals

- Clinical protocol under development with US/Australian MAB
- Target patient population : chemotherapy naïve patients that have progressed on either enzalutamide (Xtandi®)[1] or abiraterone (Zytiga®)[2]
  - ➢ Approximately trial size : ~500 patients
  - ➢ Initial recruitment focus : US and Australia (Australia likely to start sooner)
- May/June ’19 submission of pre-IND meeting package / request to the FDA for Phase III meeting. Main focus will be clinical protocol
- Clinical material expected to be released by late Q3 / early-Q4 2019 for commencement of Ph III by end-2019
- Preliminary clinical evaluation of ^{255}Ac-TLX592 in parallel

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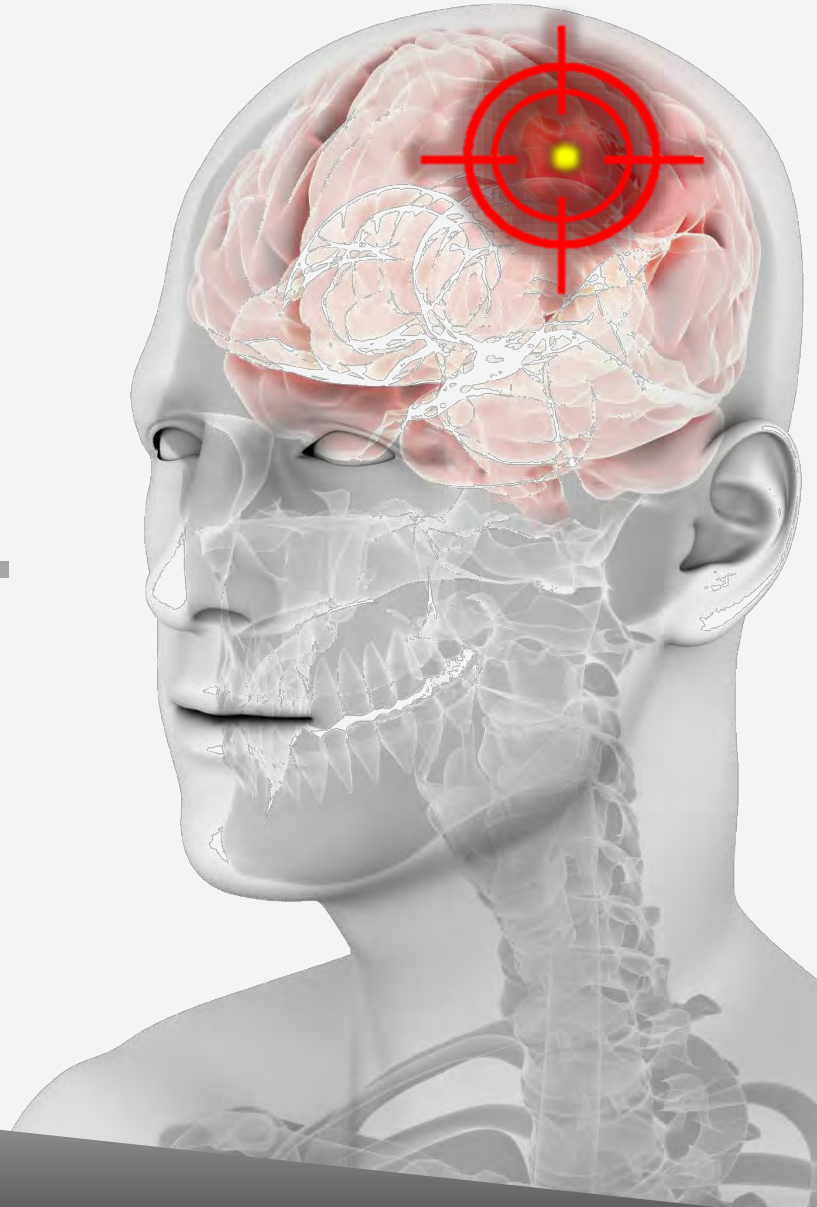
[1] Astellas/Pfizer
[2] Janssen (J&J)

Glioblastoma Therapy

TLX101
(^{131}I-IPA)



TELIX PHARMACEUTICALS

TLX101 (Therapy) : Background

- LAT-1 is a target highly expressed in many cancers, including glioblastoma (GBM), multiple myeloma, NSCLC lung cancer, etc.
- TLX101 is an synthetic amino acid (iodinated phenylalanine or “IPA”) that targets LAT-1 – Telix’s earliest-stage program (Ph I/II)
- Originally developed as an imaging agent and extensively studied in patients with a variety of cancers, including GBM
- Slow wash-out kinetics found to be sub-optimal for imaging but potentially very suitable for therapy
- TLX101 is stably labeled with ^{131}I, an inexpensive and readily available radionuclide – product stability in excess of 5 days
- TLX101 rapidly crosses the blood-brain-barrier (BBB) with very little peripheral dosimetry. Brain is the dose-limiting organ
- Triple mechanism of action (see slide 69)

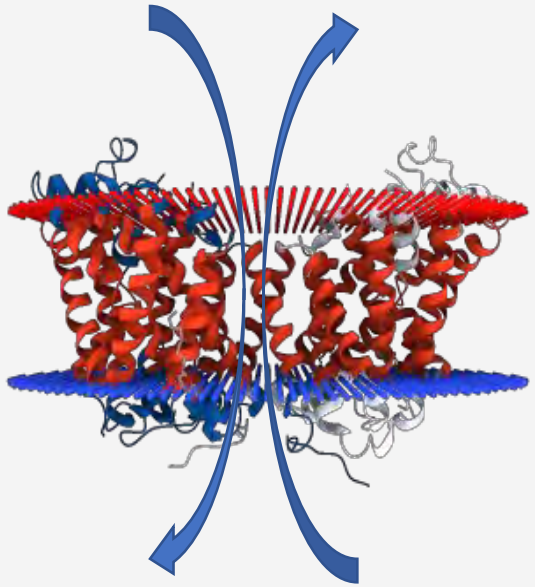
L-Type

Neutral Amino acid

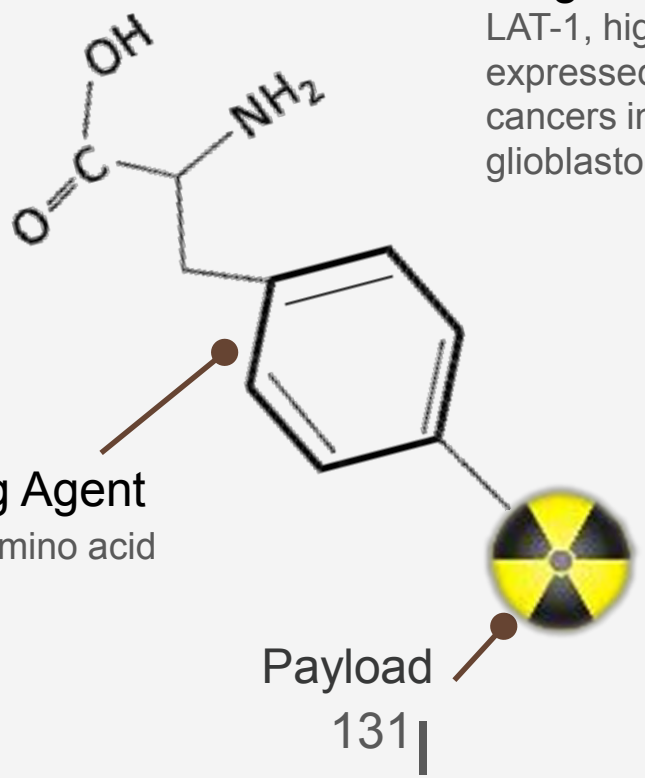
Transporter

1

Leu Phe Tyr Trp (+TLX101)



TLX101 : Product Overview



Description:

- Radiolabeled synthetic amino acid (^{131}I-iodo-L-phenylalanine or ^{131}I-IPA), targeting LAT-1 transporter
- For the treatment of glioblastoma in conjunction with standard care

Technology Origin:

- Saarland University Medical Centre (Homburg)
- Acquisition of Therapeia GmbH (2017)

Clinical Status:

- Phase I/II

Unmet Need:

✓ Very few treatment options exist for recurrent glioblastoma patients

✓ Recurrent patients progress rapidly

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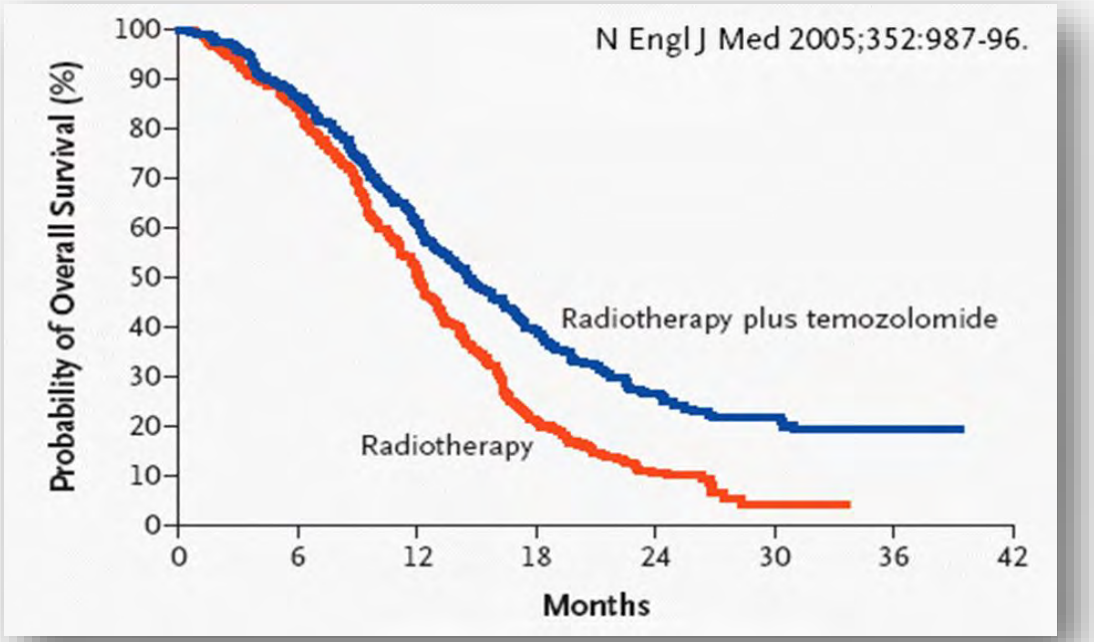
Standard of Care (SoC) Extends Life but is Non-Curative

- SoC = Temozolomide (TMZ) + Radiotherapy (XRT)
- Combination provides a modest life extension
- 60-70% of patients respond
- Virtually 90+% of patients relapse to recurrent Glioblastoma (rGBM) – very few treatment options



TELIX PHARMACEUTICALS

TLX101 : A Unique Triple Mechanism of Action (MoA)

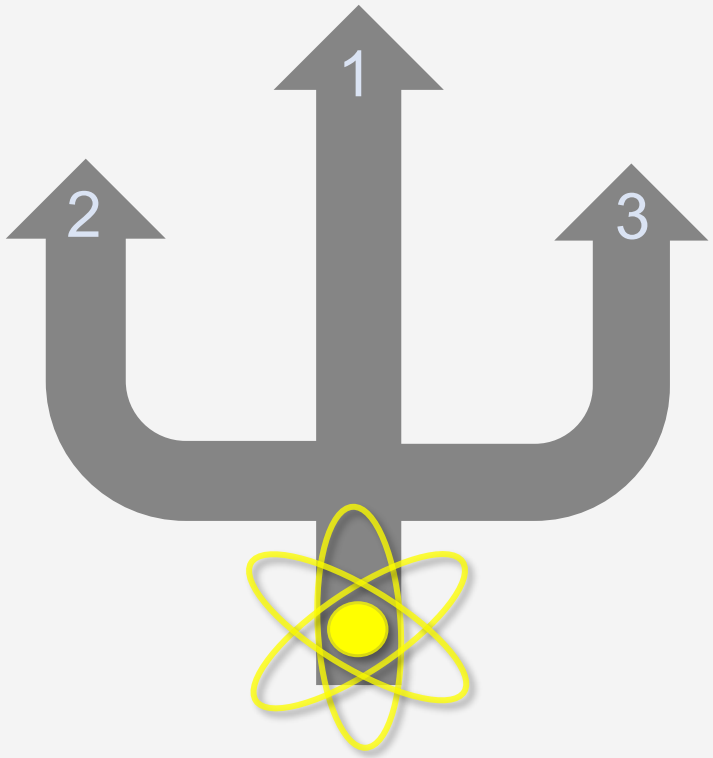
- LAT-1 is upregulated in many cancer tissues
- LAT-1 provides amino acids to rapidly growing tumor – essential for biological function
- TLX101 is a large amino acid analog and a validated substrate for LAT-1
- Delivers a triple-mechanism of action in combination with XRT

Targeted Radiation

Molecularly-targeted radiation, double-stranded DNA damage, bystander effect

Radiosensitiser

Improves susceptibility to external beam radiation (as a combination therapy)



Cytostatic Agent

Inherent selective toxicity

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Clinical Experience

Imaging (^{124}I-IPA)

- Studies in > 100 patients under investigator-led studies in EU has validated basic pharmacology/biology, patient selection
- Use as a research tool only (not a commercial development program)

Therapy (^{131}I-IPA)

- Piloted in relapse patients in Germany to study safety/ dosimetry/targeting as a clinical proof-of-concept in 11 patients. Several patients showed a significant response including 2 complete responses (CRs)
- Brain is the dose-limiting organ, potentially suitable for pediatric use
- Orphan designation in the US / EU
- Received approval in October '18 to commence a multi-centre Phase I/II trial (EU/AU) – IPAX-1

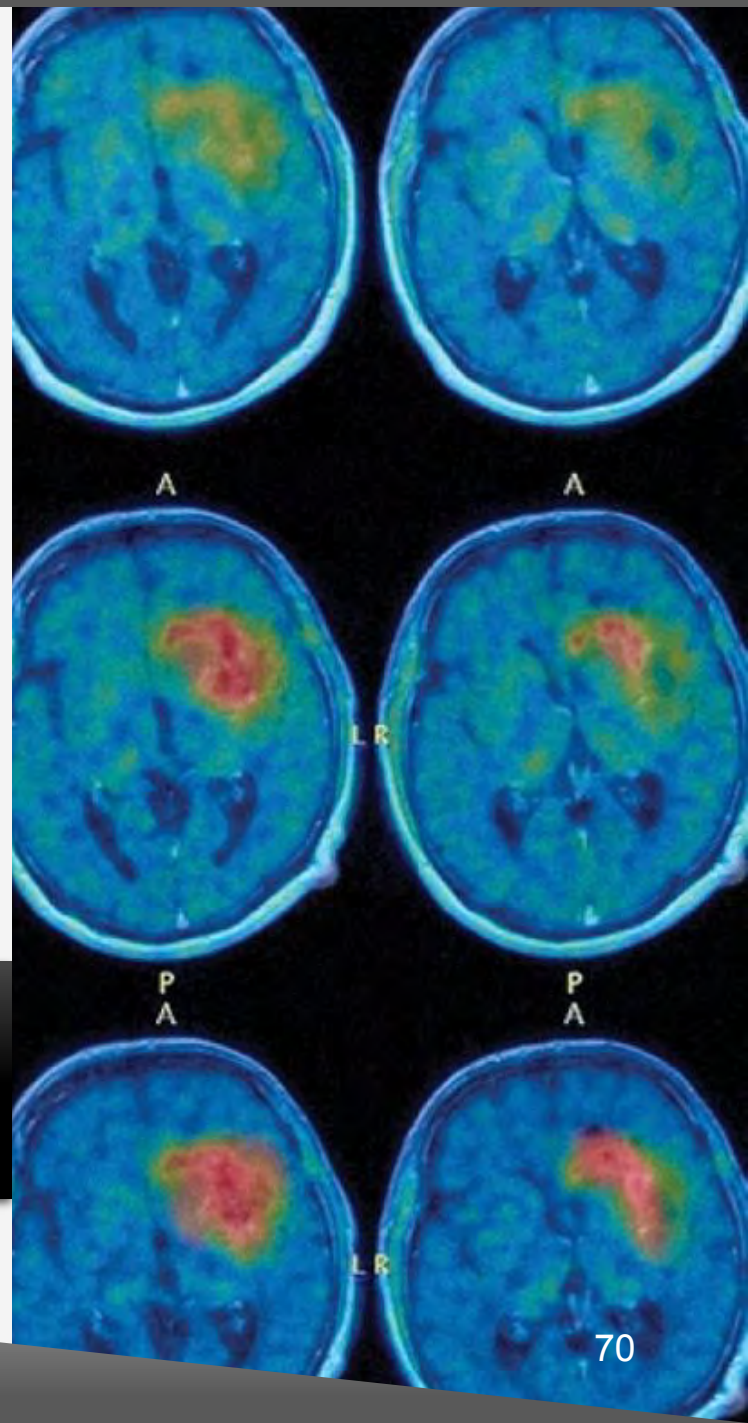
Case Study

- Male, 45 Years Old
- Multiple radiotherapies
- Surgery not available
- Progressive disease

Treatment: with 2GBq ^{131}I-TLX101 single dose I.V.

Safety: no acute, sub-acute or delayed toxicity

Efficacy: Continuous tumor regression over 10 months. Patient remained professionally active for 24 months. Survived >40 months (with further therapy).



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TLX101 (Therapy) : 2019 Goals

- IPAX-1 (IPA + XRT) Phase I/II is an EU/AUS multi-centre study (7 sites) to evaluate the combination of TLX101 and SoC in relapse glioblastoma patients
- 44 patients in total
- This trial is now active and recruiting (EU)
- Recruitment goals for 2019:

1. Preliminary data / case studies by mid-year
2. Dose escalation / optimal dose selection complete by Q3 (~50% enrolment)
3. Trial will likely complete enrolment in 1H 2020

IPAX-1

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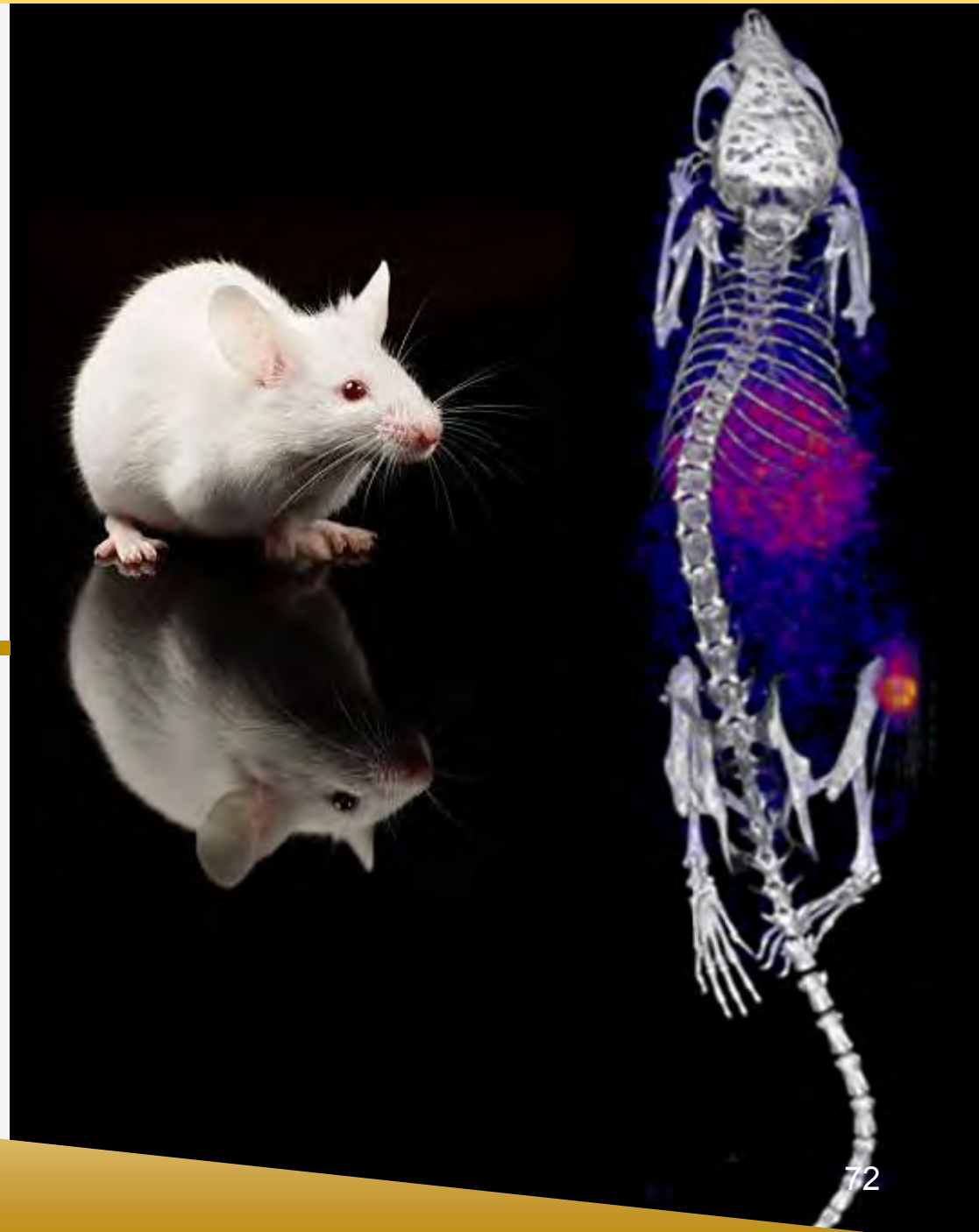
Research Activity

- Alpha Therapy
- Robotic Surgery Guidance
- Imaging Immune Function



TELIX PHARMACEUTICALS

Overview

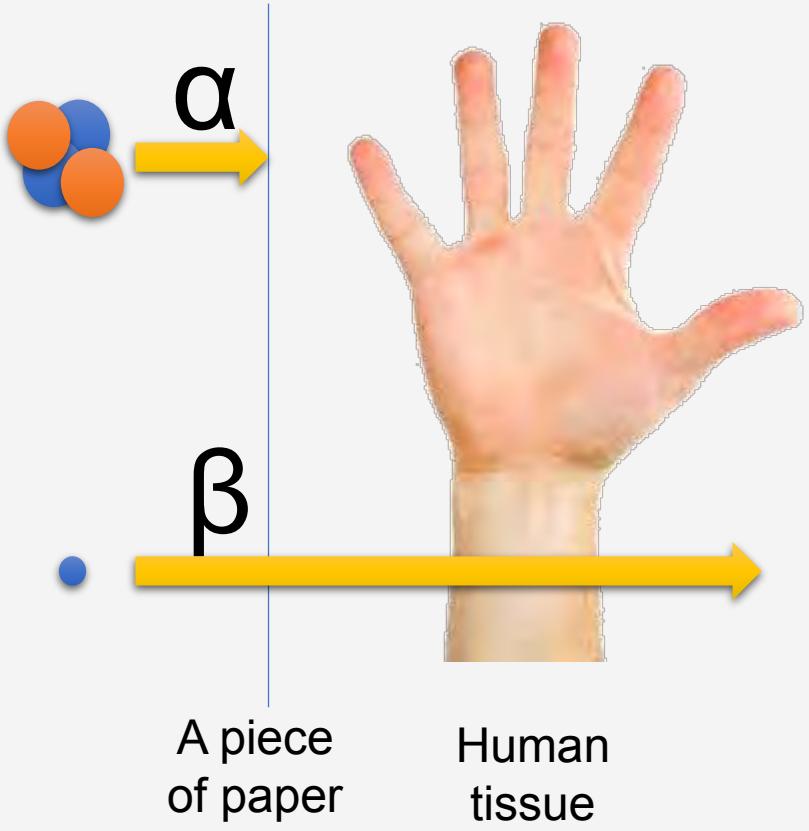
- Telix is mostly a development-stage company with very little in-house research activity that does not relate to product development
- New application areas and indication expansion activity mostly conducted in partnership with academia through a limited number of collaborations and grants

- Telix has three major research focus areas in 2019:
  1. The use of alpha-emitting radionuclides. An opportunity to evaluate a number of Telix's existing targeting agents in new disease settings
  2. "Dual Modality" tracers to extend Telix's existing pipeline into the field of image-guided (robotic) surgery
  3. Imaging of immune response. TLX250 (in particular) will have an important nexus with immunotherapy and therefore imaging the trafficking of immune cells is potentially very powerful

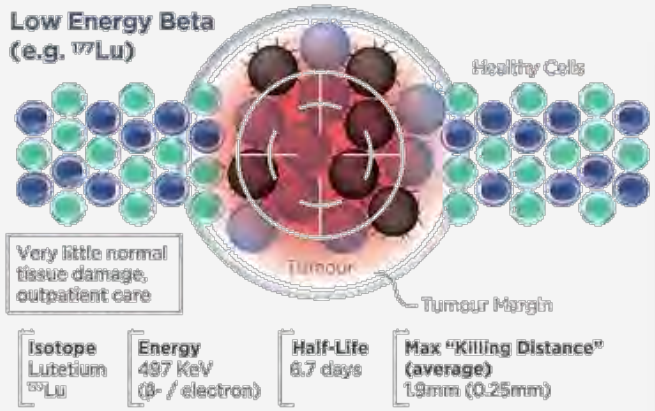
TELIX PHARMACEUTICALS

Research Theme #1 : Alpha Therapeutics

- Alpha emitters are “next generation” radionuclides
- Very high energy but extremely localized radiation profile
- Whereas “beta” emitters (such as ^{177}Lu, ^{131}I) are likely to be better for bulky metastatic disease, “alpha” emitters are likely to have superior utility in micro-metastatic disease or with cancers that have highly disseminated disease in radiation-sensitive organs (e.g. multiple-myeloma)
- Commercial supply chain is not yet well established but there is extensive “big pharma” interest in alpha emitters
- “Alphaceuticals” are much more like conventional drugs because they don’t require extensive shielding and can be more straightforwardly administered in the out-patient setting
- Telix has two collaborative R&D projects: ^{225}Ac-TLX592 (actinium-labelled engineered TLX591) and ^{211}At-TLX102 (astatinated TLX101)



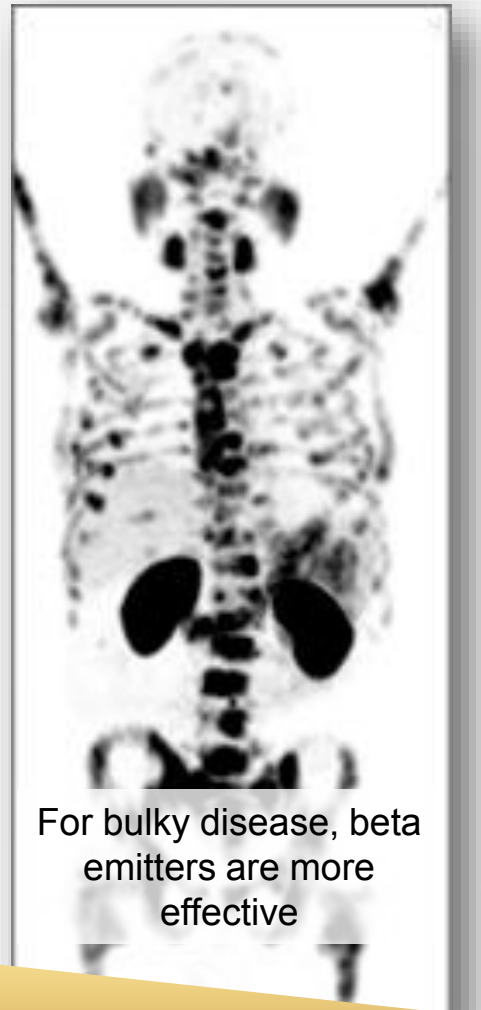
Disease Extent Drives Choice of Isotope



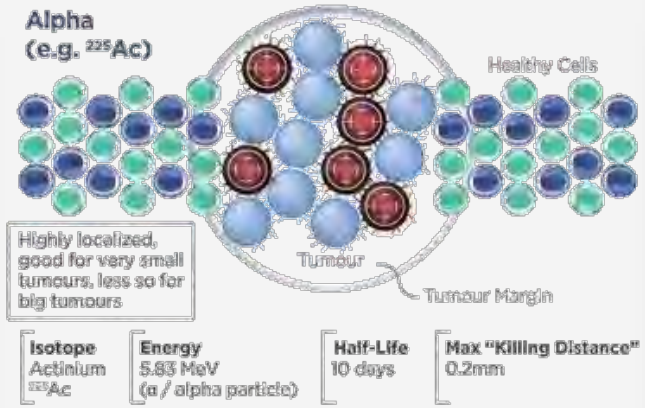
Today:

^{177}Lu / ^{131}I – "Beta"

- Current standard in nuclear medicine, extensive experience
- Well-defined supply chain
- Good for treating advanced and extensive metastatic disease ("bulky" disease)



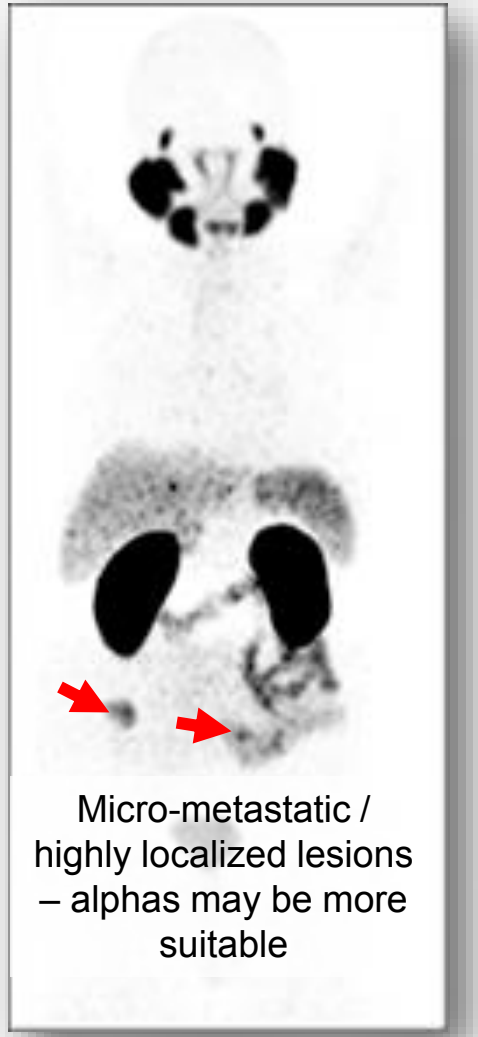
For bulky disease, beta emitters are more effective



Future:

^{225}Ac / ^{211}At – "Alpha"

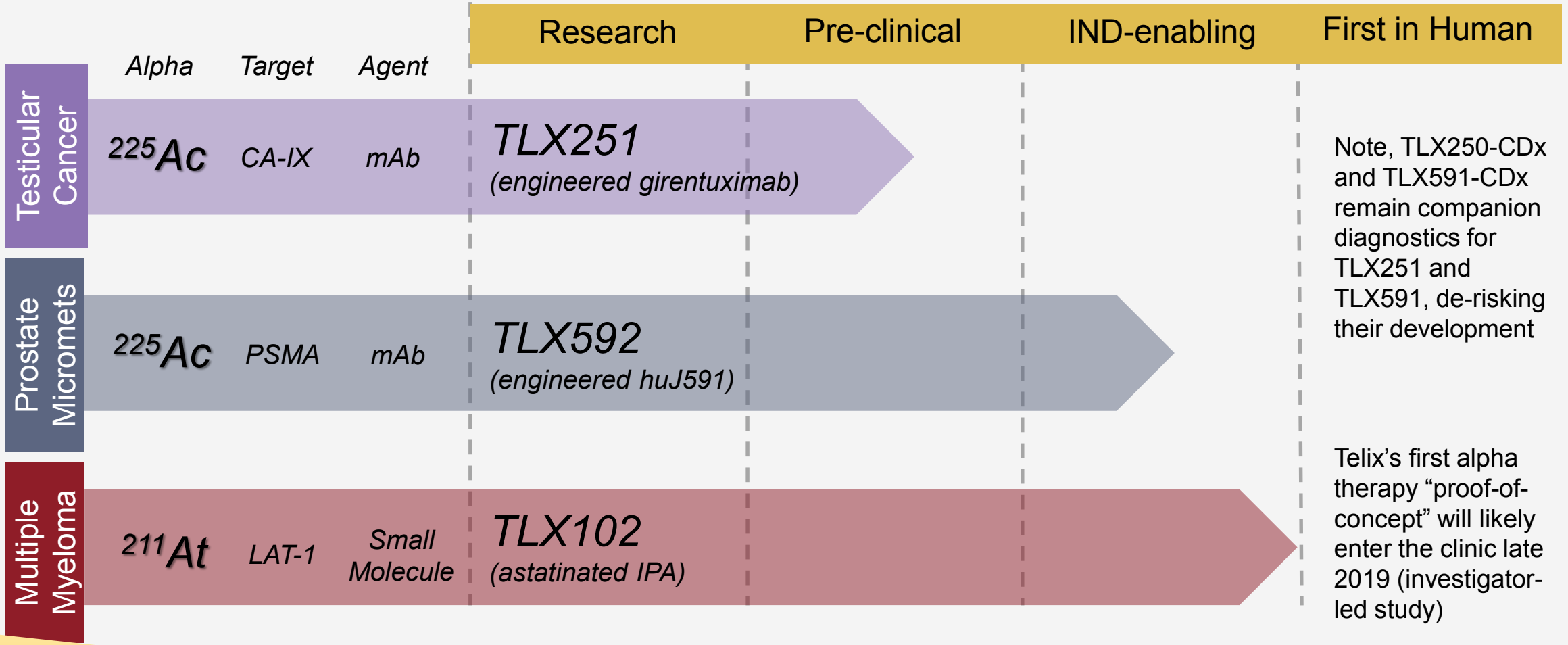
- The next frontier of nuclear medicine, more drug-like
- Supply chain still evolving but "big pharma" is starting to invest
- Very high energy, suitable for patients with small, highly disseminated metastases



Micro-metastatic / highly localized lesions – alphas may be more suitable

TELIX PHARMACEUTICALS

Telix's Alpha Therapeutics Research Pipeline



Note, TLX250-CDx and TLX591-CDx remain companion diagnostics for TLX251 and TLX591, de-risking their development

Telix's first alpha therapy "proof-of-concept" will likely enter the clinic late 2019 (investigator-led study)

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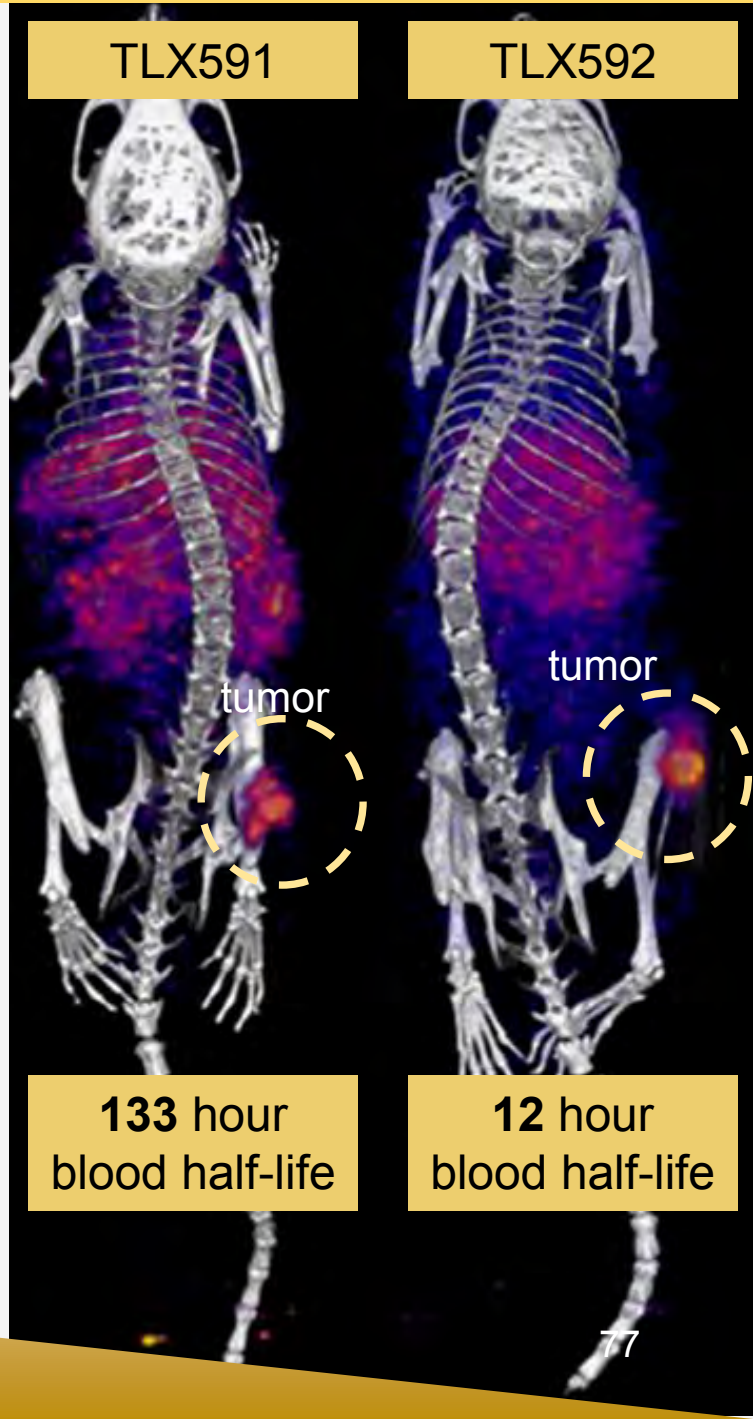
Example : TLX592 “Second Gen” PSMA

1. Radioactive mAbs typically have long circulation times and can cause hematologic (blood/marrow) toxicity if not fractionated / dosed properly
   - We have engineered TLX591 (huJ591) to clear 10x faster but still deliver the same effective dose to the tumor (TLX591)

2. Because antibodies are bigger molecules:
   - Can’t “reach” endogenous PSMA, only tumor PSMA
   - Still the case for TLX592

3. TLX592 still “parks” excess radiation in the liver and not the kidneys
   - Means we can potentially give higher therapeutic doses
   - Means we are better prepared for things like alpha emitters
   - Second-generation product with ^{225}Ac for treating micromets



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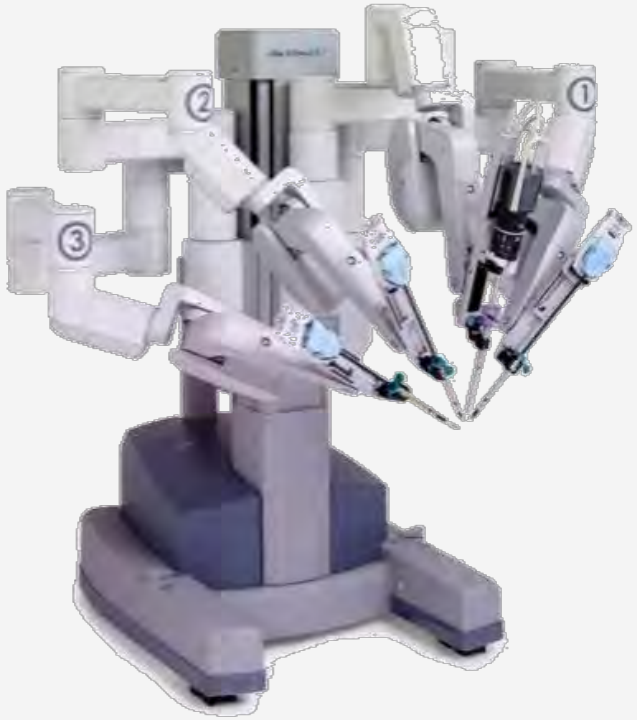
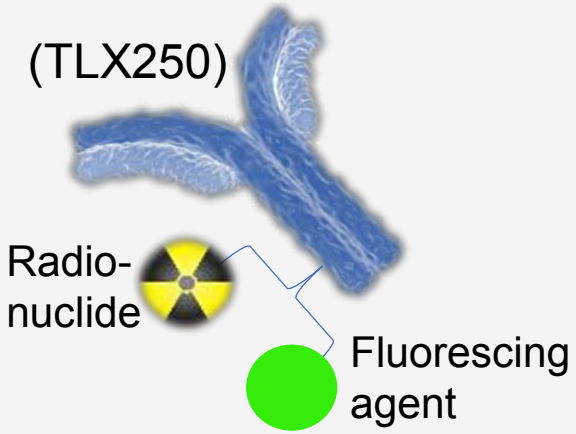
Research Theme #2 : Imaging for Surgical Robotics

- TLX591-CDx and TLX250-CDx can help plan better surgeries:
  - ✓ Imaging with TLX591-CDx can identify lymph node metastases in high-risk prostate cancer patients and guide extended resection. Robotic surgery is an established technique in prostate surgery
  - ✓ Imaging with TLX250-CDx can help surgeons plan nephron (kidney)-sparing surgery (i.e. “partial” nephrectomy), one of the fastest growing robotic surgery procedures in the US
- Modern surgical robotic systems have imaging technology that can visualize fluorescent tracers during surgery
- Telix is developing extensions to the TLX250-CDx and TLX591-CDx products that have both a radioactive (PET) and an optical (fluorescent) signal on the same imaging agent
- One “shot” potentially delivers both the PET scan and intra-operative guidance for up to 72 hours post-injection

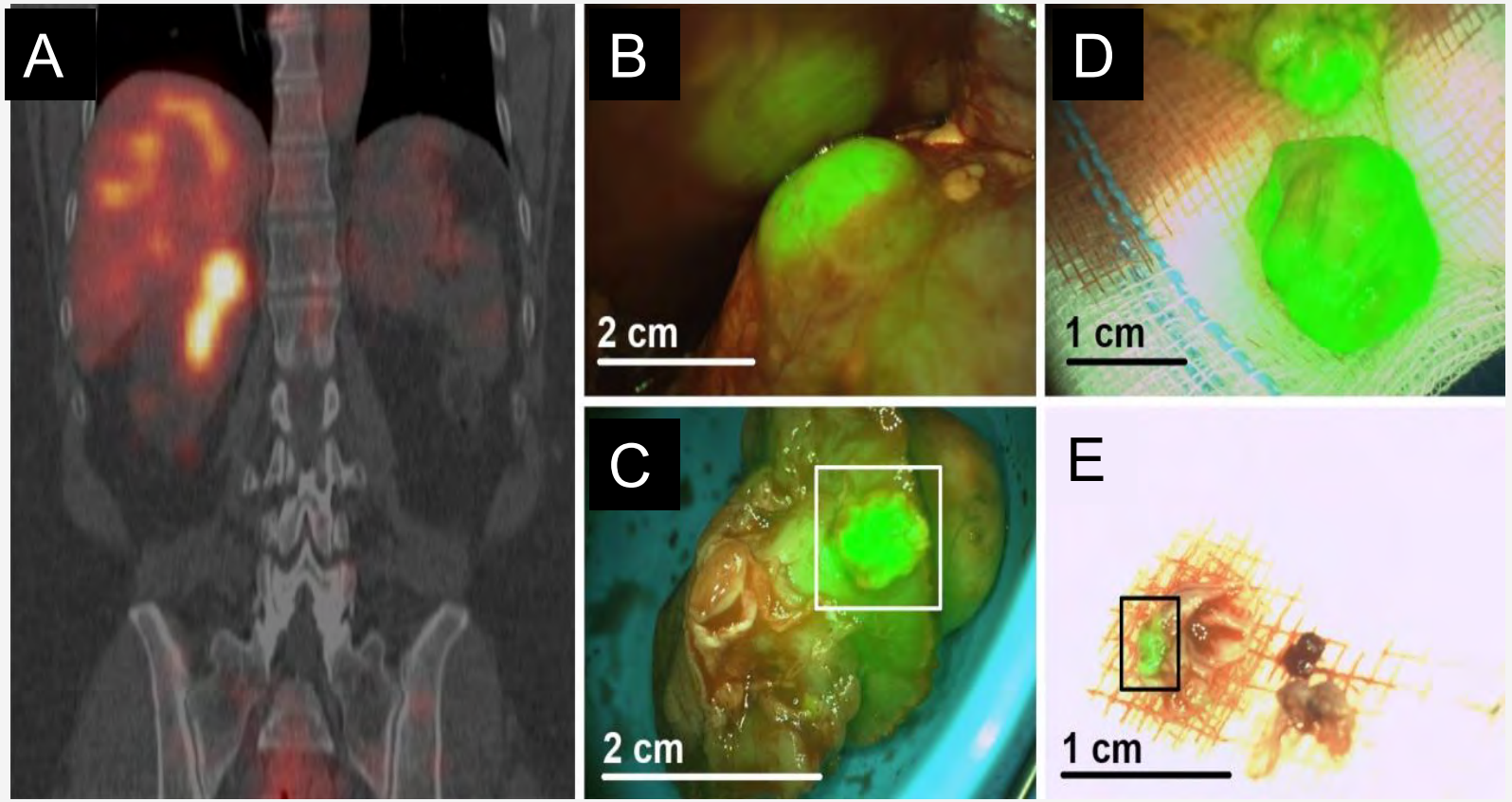


The “DaVinci” Robot (Intuitive Surgical). Systems like this incorporate intra-operative imaging of fluorescent dyes in order to better delineate tissues (nerves, vessels, tumor cells, etc.) but relatively few targeted imaging products exist at this time

Example : Dual-labelled girentuximab : (Whole Body Imaging + Fluorescence)



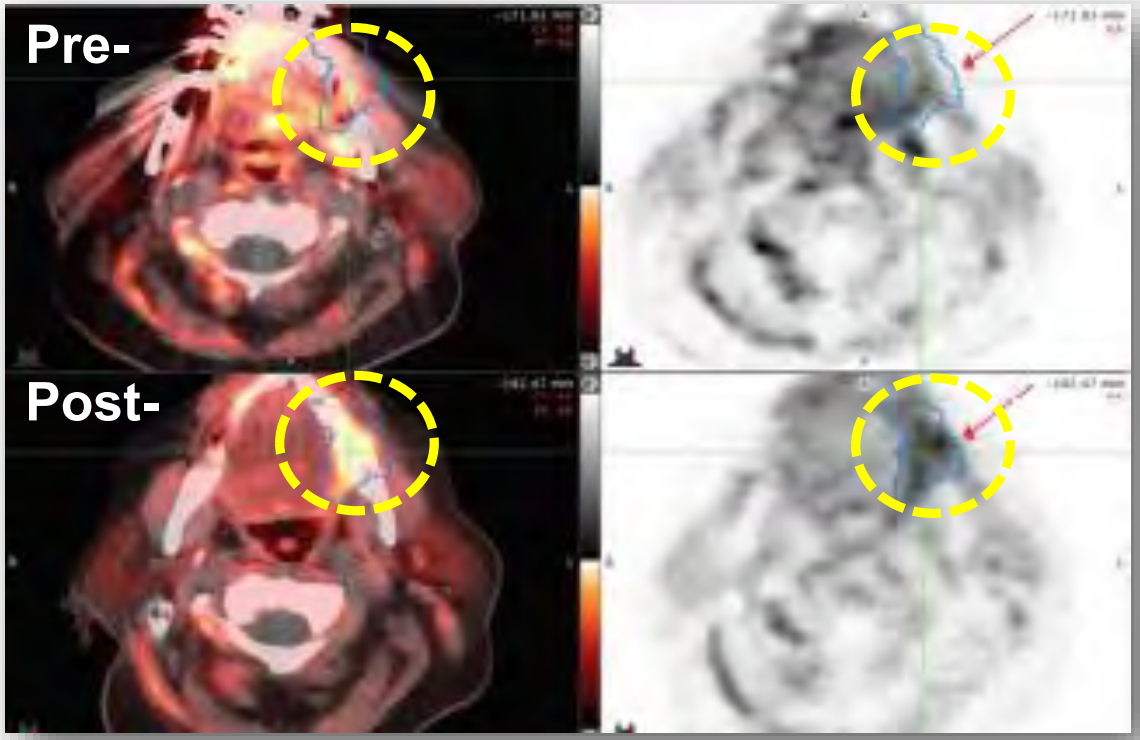
A) Whole body nuclear medicine scan B) primary lesion visualized intra-operatively C) secondary lesion also imaged D), E) resection specimens



Courtesy RUMC

Research Theme #3 : Imaging Immune Response

- Immune response is likely a major part of the efficacy of molecularly-targeted radiation (MTR)
- This is particularly the case for TLX250, which will be studied in combination with “checkpoint inhibitor” immuno-oncology drugs
- To optimize treatment cycling between MTR and checkpoint inhibitors, new methods are needed to determine whether immune cells are trafficking to the tumor
- The VisAcT®[1] tracer (CellSight Technologies, Inc.) has promise in this application by enabling PET to be used to image the localization of activated (killer) immune cells
- Telix and CellSight have a formal clinical and manufacturing collaboration



VisAcT PET tracer (^{18}F-AraG) for imaging activated immune cells that are trafficking to the tumor in response to PD-L1 “checkpoint” therapy in head and neck cancer. *Courtesy Stanford/CellSight*

[1] VisAcT is a registered trademark of CellSight Technologies Inc. under license to Telix International Pty Ltd

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