



**Telix Pharmaceuticals Limited**  
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Australia

## **ASX ANNOUNCEMENT**

### **Telix Investor Day Presentation Materials**

*Melbourne (Australia) and Indianapolis, IN (U.S.) – 11 June 2025.* Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, “Telix”, “the Company”) is holding an Investor Day in New York City on Wednesday, June 11, 2025, 8:30am ET (10:30pm AEST) - 12.00pm ET. A copy of the slides to be presented at the event are included with this lodgement.

The briefing is a hybrid event, with in-person attendance open to institutional investors and analysts.

Virtual participants can join via live webcast. Pre-registration is available at the following link.  
<https://www.streamy.cloud/telixinvestorday.html>.

A recording will be available on Telix’s website following the event.

#### **About Telix Pharmaceuticals Limited**

Telix is a biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals and associated medical technologies. Telix is headquartered in Melbourne, Australia, with international operations in the United States, Brazil, Canada, Europe (Belgium and Switzerland), and Japan. Telix is developing a portfolio of clinical and commercial stage products that aims to address significant unmet medical needs in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (NASDAQ: TLX).

Visit [www.telixpharma.com](http://www.telixpharma.com) for further information about Telix, including details of the latest share price, ASX and SEC filings, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on [LinkedIn](#), [X](#) and [Facebook](#).

#### **Telix Investor Relations**

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*This announcement has been authorized for release by the Telix Pharmaceuticals Limited Disclosure Committee on behalf of the Board.*

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## Legal Notices

*You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the Australian Securities Exchange (ASX), U.S. Securities and Exchange Commission (SEC), including our Annual Report on Form 20-F filed with the SEC, or on our website.*

*The information contained in this announcement is not intended to be an offer for subscription, invitation or recommendation with respect to securities of Telix Pharmaceuticals Limited (Telix) in any jurisdiction, including the United States. The information and opinions contained in this announcement are subject to change without notification. To the maximum extent permitted by law, Telix disclaims any obligation or undertaking to update or revise any information or opinions contained in this announcement, including any forward-looking statements (as referred to below), whether as a result of new information, future developments, a change in expectations or assumptions, or otherwise. No representation or warranty, express or implied, is made in relation to the accuracy or completeness of the information contained or opinions expressed in the course of this announcement.*

*This announcement may contain forward-looking statements, including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that relate to anticipated future events, financial performance, plans, strategies or business developments. Forward-looking statements can generally be identified by the use of words such as “may”, “expect”, “intend”, “plan”, “estimate”, “anticipate”, “believe”, “outlook”, “forecast” and “guidance”, or the negative of these words or other similar terms or expressions. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements are based on Telix’s good-faith assumptions as to the financial, market, regulatory and other risks and considerations that exist and affect Telix’s business and operations in the future and there can be no assurance that any of the assumptions will prove to be correct. In the context of Telix’s business, forward-looking statements may include, but are not limited to, statements about: the initiation, timing, progress and results of Telix’s preclinical and clinical trials, and Telix’s research and development programs; Telix’s ability to advance product candidates into, enrol and successfully complete, clinical studies, including multi-national clinical trials; the timing or likelihood of regulatory filings and approvals for Telix’s product candidates, manufacturing activities and product marketing activities; Telix’s sales, marketing and distribution and manufacturing capabilities and strategies; the commercialization of Telix’s product candidates, if or when they have been approved; Telix’s ability to obtain an adequate supply of raw materials at reasonable costs for its products and product candidates; estimates of Telix’s expenses, future revenues and capital requirements; Telix’s financial performance; developments relating to Telix’s competitors and industry; the anticipated impact of U.S. and foreign tariffs and other macroeconomic conditions on Telix’s business; and the pricing and reimbursement of Telix’s product candidates, if and after they have been approved. Telix’s actual results, performance or achievements may be materially different from those which may be expressed or implied by such statements, and the differences may be adverse. Accordingly, you should not place undue reliance on these forward-looking statements.*

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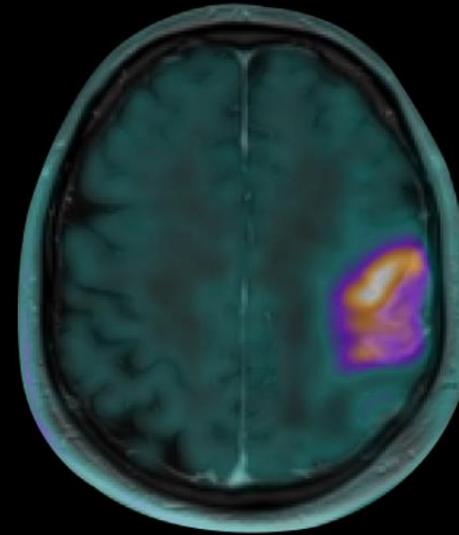
# Growth opportunities

## Telix's competitive advantage

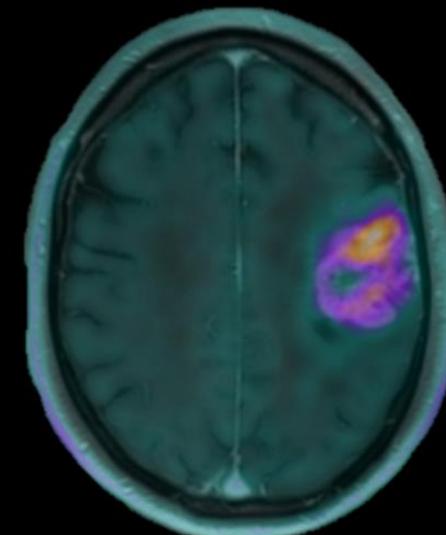
Investor Day  
11 June, 2025

ASX: TLX | NASDAQ: TLX

Glioblastoma patient (salvage) with clinically stable disease  
18 months from initiation of TLX101 therapy



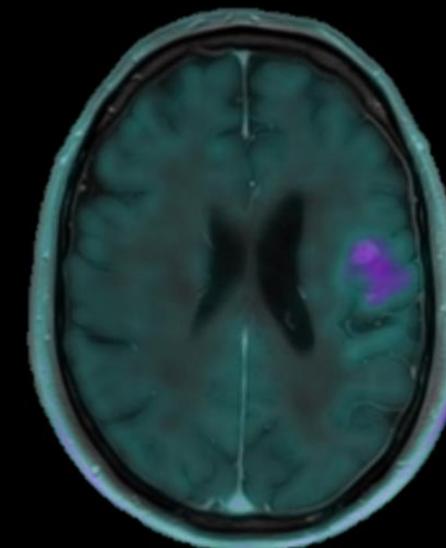
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10 months



16 months



18 months

Patient representative scans - individual results may vary.  
Credit A. Braat, Utrecht.

# Disclaimer

This presentation should be read together with our risk factors, as disclosed in our most recently filed reports with the Australian Securities Exchange (ASX) and the U.S. Securities and Exchange Commission (SEC), including our Annual Report on Form 20-F filed with the SEC, or on our website.

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This presentation also contains estimates and other statistical data made by independent parties and by Telix relating to market size and other data about its industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data and estimates. In addition, projections, assumptions and estimates of Telix’s future performance and the future performance of the markets in which it operates are necessarily subject to a high degree of uncertainty and risk.

Telix’s first generation PSMA-PET imaging product, gallium-68 (<sup>68</sup>Ga) gozetotide injection (also known as <sup>68</sup>Ga PSMA-11 and marketed under the brand name Illuccix®), has been approved by the U.S. Food and Drug Administration (FDA), by the Australian Therapeutic Goods Administration (TGA), by Health Canada, by the Brazilian Health Regulatory Agency (ANVISA), by the UK Medicines and Healthcare Products Regulatory Agency (MHRA), by the French National Agency for the Safety of Medicine and Health Products (ANSM), by the German Federal Institute for Drugs and Medical Devices (BfArM) and in multiple countries within the European Economic Area (EEA) following a positive decentralized procedure (DCP) opinion by (BfArM. Gozellix® (kit for the preparation of gallium-68 (<sup>68</sup>Ga) gozetotide injection) has been approved by the U.S. FDA.

Telix’s osteomyelitis (bone infection) imaging agent, technetium-99m (<sup>99m</sup>Tc) besilesomab (marketed under the brand name Scintimun®) is approved in 32 European countries and Mexico. Telix’s miniaturized surgical gamma probe, SENSEI®, for minimally invasive and robotic-assisted surgery, is registered with the FDA for use in the U.S. and has attained a Conformité Européenne (CE) Mark for use in the EEA.

No other Telix drug or device has received marketing authorization in any jurisdiction. Any other Telix drug or device that is discussed in this presentation is investigational or under development and not approved by any regulatory authority. The safety or efficacy of any unapproved drug or device has not been determined by any regulatory authority.

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# Introduction

**Kyahn Williamson**

**SVP Investor Relations and  
Corporate Communications**



# Today's presenters – Telix



**Kyahn Williamson**  
SVP IR and Corporate  
Communications



**Christian Behrenbruch**  
Managing Director and  
Group CEO



**David N. Cade, MD**  
Group Chief Medical Officer



**Richard Valeix**  
CEO, Therapeutics



**Kevin Richardson**  
CEO, Precision Medicine



**Paul Schaffer**  
Chief Technology Officer



**Pamela Habib, MD**  
Chief Medical Officer,  
Therapeutics



**David Liu, MD**  
Chief Medical Officer,  
Precision Medicine

# Physician presenters



**Joseph Osborne, MD**  
Professor of Radiology  
Weill Cornell Medicine



**Oliver Sartor, MD**  
Director of Transformational  
Prostate Cancer Research  
LCMC Hospitals, New Orleans, LA



**John de Groot, MD**  
Professor of Neurology,  
Neuro-Oncology  
University of California  
San Francisco

Presenters are independent experts not employed by Telix but have been paid fair market value for their time.  
Views expressed are speakers' own. Any presenter's response during Q&A has not been reviewed in advance by Telix.

# Agenda

- Introductions
- CEO Welcome and Vision
- Key trends in radiopharma development
- Precision Medicine & indication expansion in the PSMA market
- Zircaix: Adding depth to our commercial focus & KOL discussion
- Therapeutics
- Urologic oncology & KOL discussion
- Q&A & break
- Urologic oncology cont'd
- Brain cancer & KOL discussion
- Pan Cancer: Spotlight on two key targets (CAIX and FAP)
- Closing remarks / lunch

# Vision

**Dr. Christian Behrenbruch**  
**Managing Director and Group CEO**



# Telix: Defining the future of radiopharma

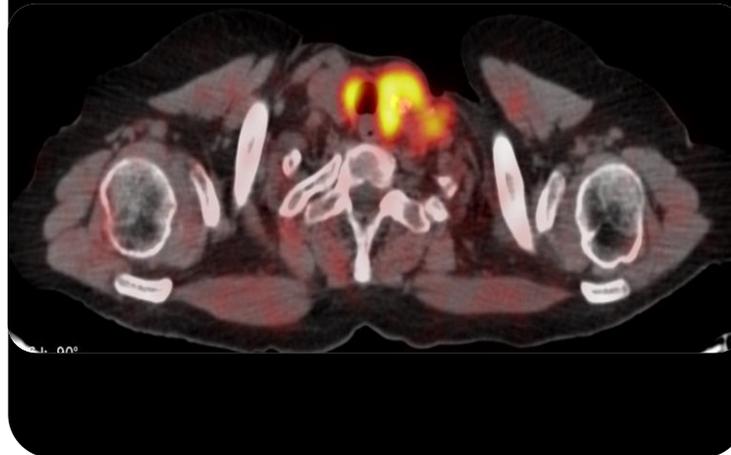
We are leading the theranostic medicine modality

A global radiopharmaceutical company with:

**Established global commercial footprint**  
Only company with two PSMA-PET<sup>1</sup> agents in U.S.



**Deep theranostic pipeline –**  
multiple near-term catalysts  
plus next-generation assets



**Manufacturing, isotope and distribution partnerships**  
**delivering to patients**

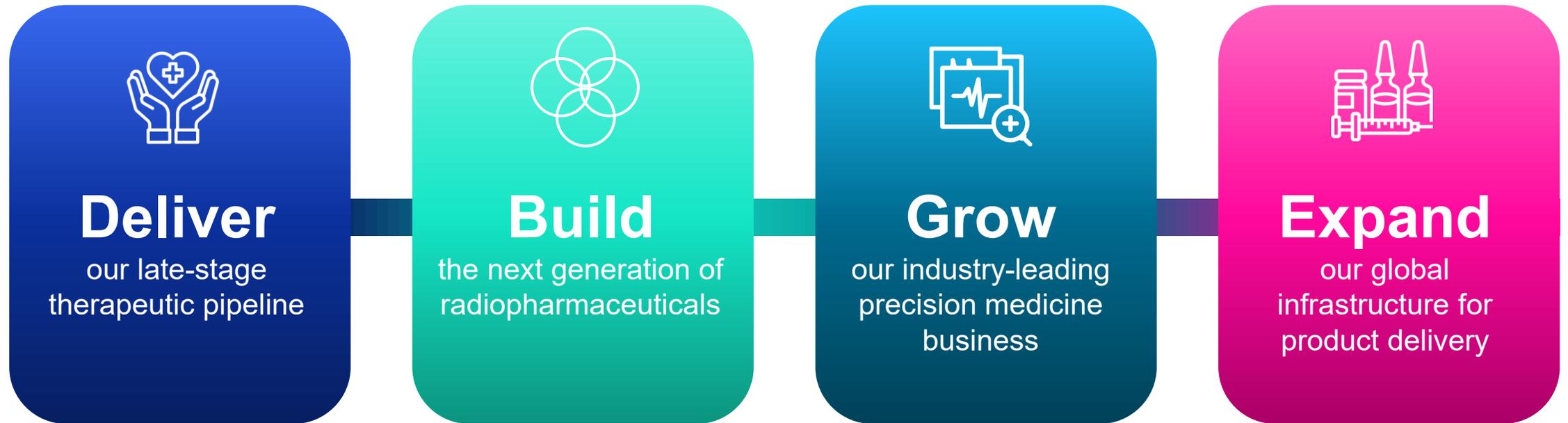


Patient representative scan – individual results may vary.

1. Imaging of prostate-specific membrane antigen with positron emission tomography.

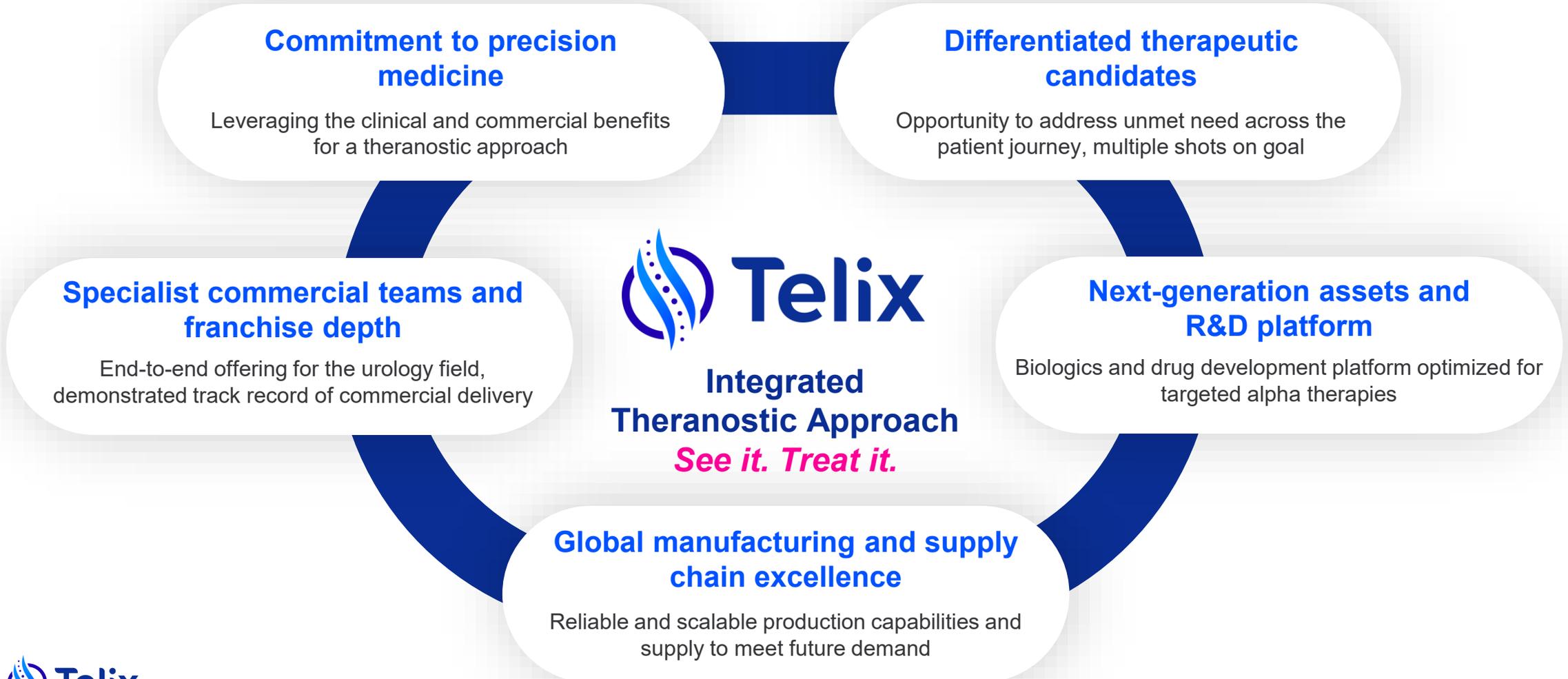
# Our growth strategy

Our mission is to be the global leader in theranostic radiopharmaceuticals



# Building competitive advantage

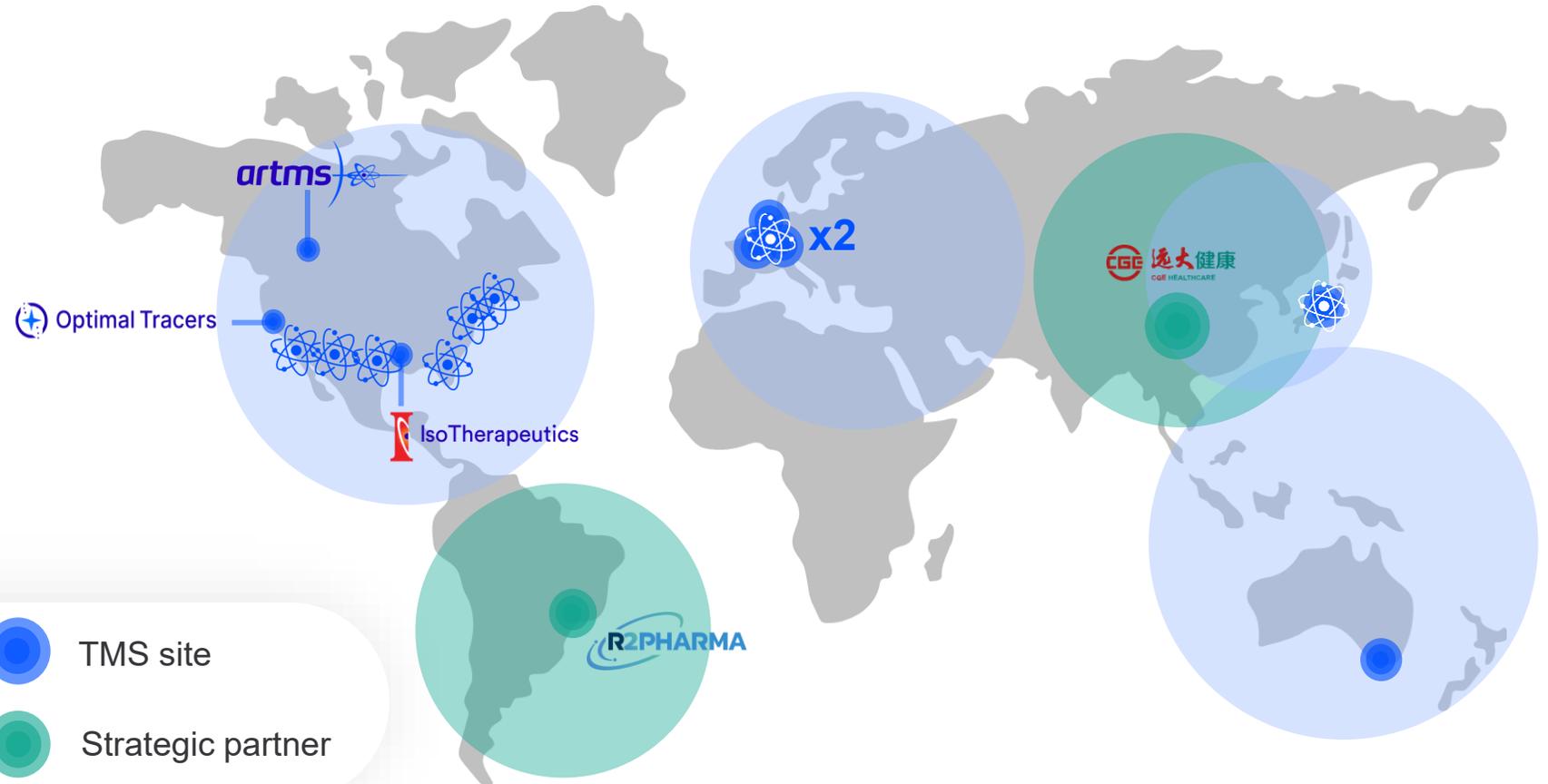
## Telix's key differentiators



# Global product delivery infrastructure is key to success

Our in-house capability and capacity continues to grow

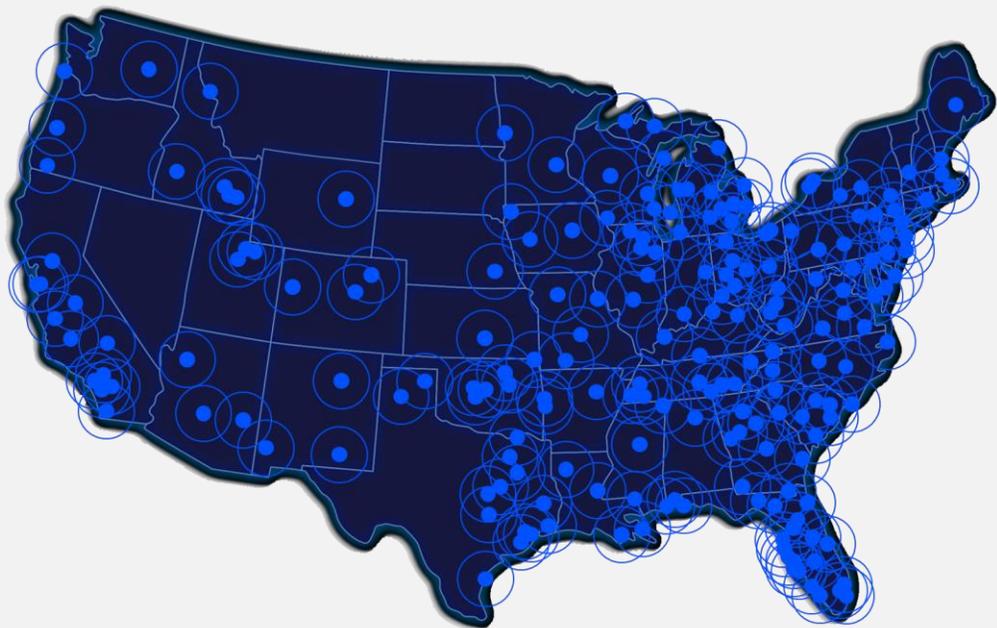
- Telix continues to invest in production infrastructure, including cyclotron installation + ARTMS QIS® technology
- Localized manufacturing for major markets
- Equipped to deliver patient doses to major global markets



# U.S. coverage

Together with partners able to deliver radiopharmaceuticals, at scale, across the U.S.

## Strategic partner pharmacy network

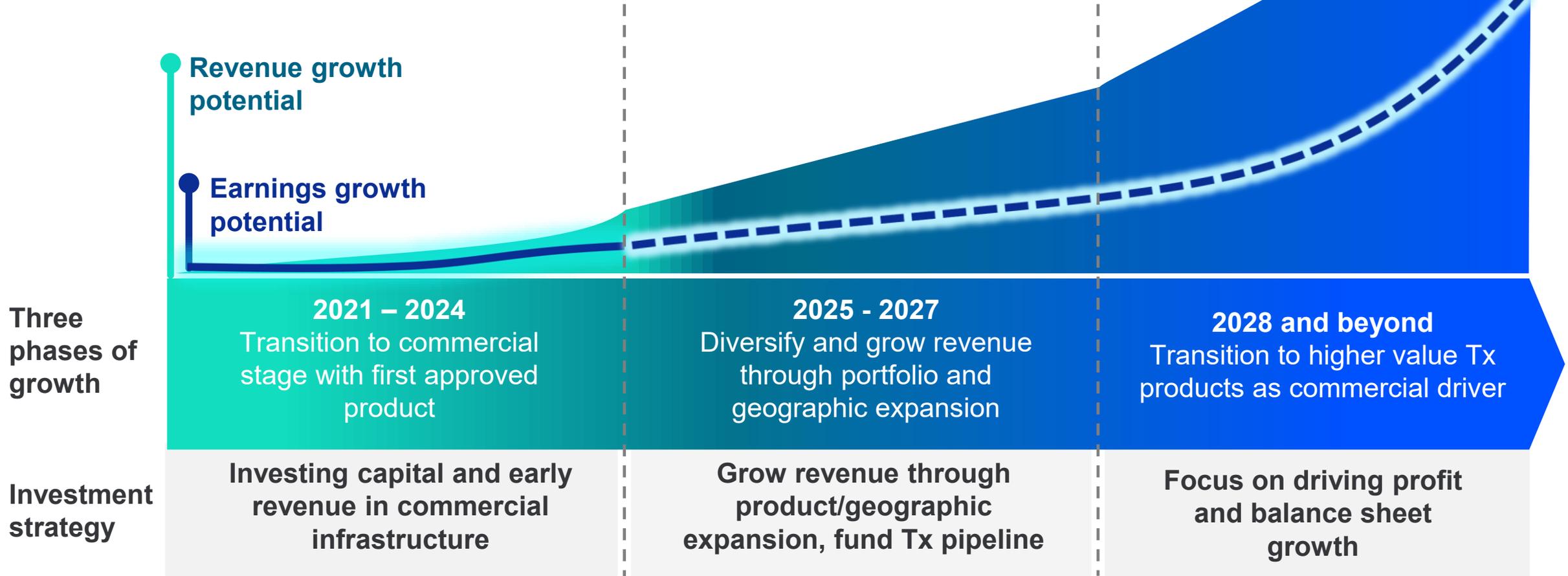


## Telix-owned network



# Investing for sustainable growth

Our financial strategy aligns to our growth opportunities



Not intended as a forecast or guidance, subject to change due to market conditions and regulatory approvals.

# Growth opportunities

Today's session highlights “select” growth opportunities across the portfolio

**E** → Enabling  
core business

PSMA imaging  
market expansion

Zircaix®<sup>1</sup>

Deepening our relationship  
with the urologist

**G** → Driving  
Growth

**Urologic oncology**  
Innovation across multiple  
therapeutic settings

**New therapeutic frontiers**

Glioblastoma and  
pan-cancer opportunities



Not intended as a forecast or guidance, subject to change due to market conditions and regulatory approvals.

1. Brand name subject to final regulatory approval.

# Key trends in radiopharma development

**Dr. Paul Schaffer**  
**Chief Technology Officer**



# The value of radiopharma-specific R&D

Global expertise and leading-edge technology to harness the key trends in radiopharma

## Chemistry & Physics (CTO)

- Targetry & novel radioisotopes
- Radiochemistry & chelators
- Medical physics
- Artificial Intelligence (AI)
- Surgical devices

## Biology & Biologics (Chief Scientist)

- New target selection
- Drug combinations
- Targeting technology
- Bioconjugation & protein chemistry
- In vivo radiobiology

## Benefits of in-house R&D

- Drug development, optimized for radiopharma
- In-house pre-clinical to clinical translation
- Future focused: next-generation assets and enabling technologies
- Supply chain technical excellence
- IP generation

**Telix is building competitive advantage through our highly specialized R&D organization**

# Trend #1: New isotopes entering the clinic

Opportunity to harness the varying properties of isotopes

## Emitters<sup>1</sup>

$\beta^+/\gamma$

<sup>11</sup>C

<sup>18</sup>F

<sup>64</sup>Cu

<sup>68</sup>Ga

<sup>86</sup>Y

<sup>89</sup>Zr

<sup>99m</sup>Tc

<sup>111</sup>In

<sup>123/124</sup>I

<sup>155</sup>Tb

$\beta$

<sup>67</sup>Cu

<sup>89</sup>Sr

<sup>90</sup>Y

<sup>131</sup>I

<sup>153</sup>Sm

<sup>161</sup>Tb

<sup>177</sup>Lu

<sup>188</sup>Re

<sup>212</sup>Pb

$\alpha$

<sup>211</sup>At

<sup>212/213</sup>Bi

<sup>212</sup>Pb

<sup>223</sup>Ra

<sup>225</sup>Ac

<sup>227</sup>Th

<sup>149</sup>Tb

Auger

<sup>58m</sup>Co

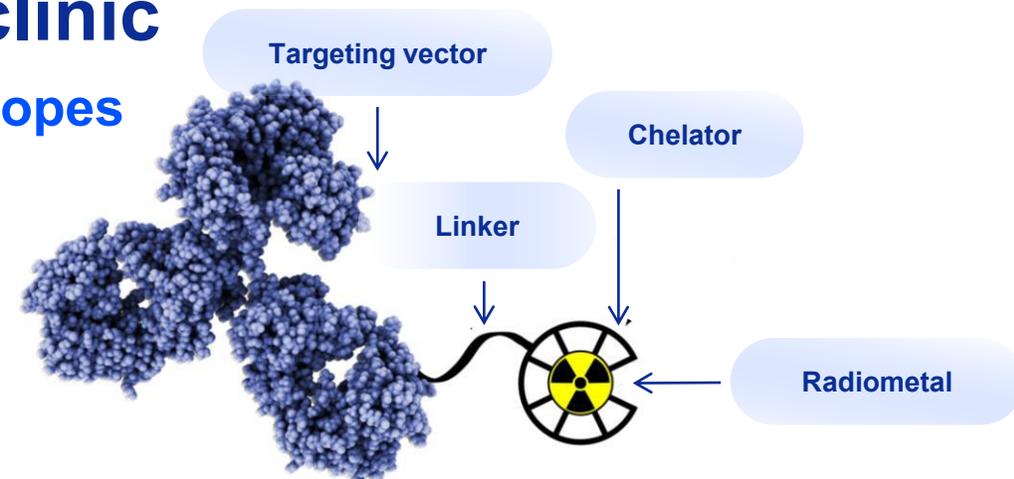
<sup>71</sup>Ge

<sup>103</sup>Pd

<sup>103m</sup>Rh

<sup>119</sup>Sb

<sup>191</sup>Os



## Choice of radioisotope

- Emission profile
- Half-life
- Depth of penetration
- Tumor size / distribution
- Tumor microenvironment

## Choice of targeting agent

- Route of excretion
- Pharmacokinetics
- Binding and cancer specificity
- Internalization and residualization

**Telix selects targeting vectors and isotopes designed to optimize the therapeutic index**

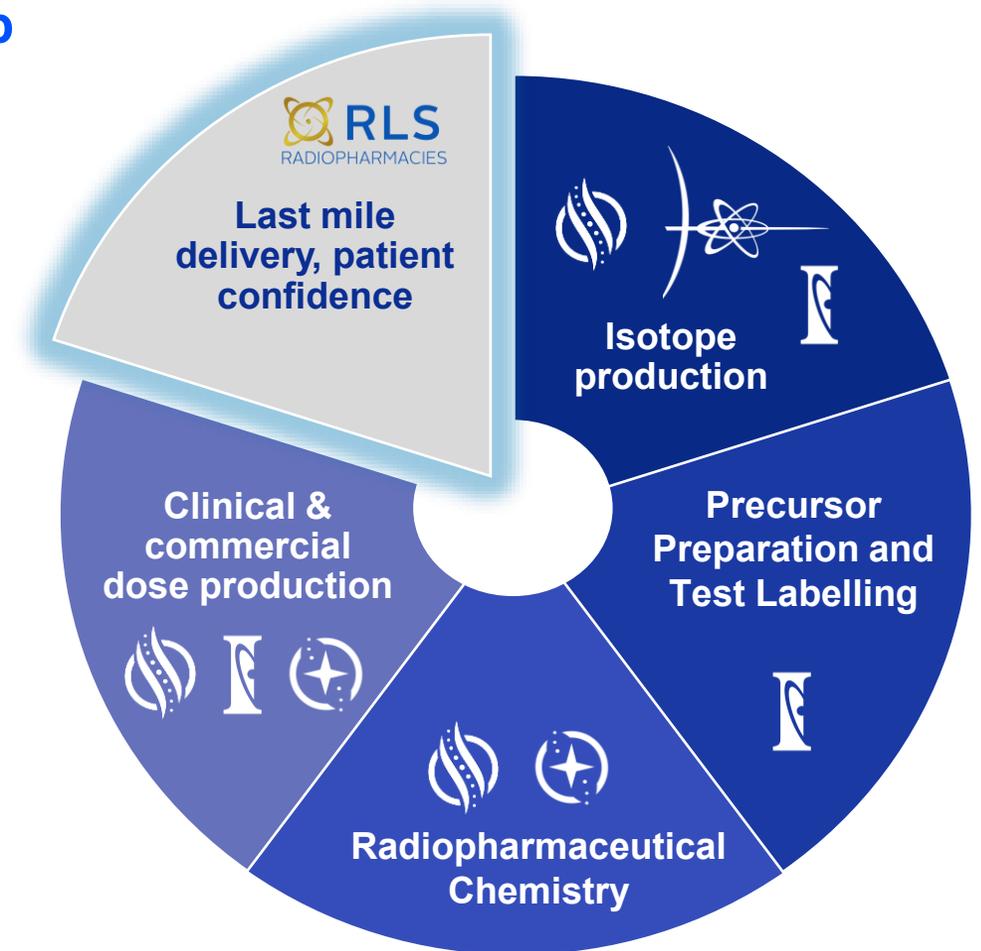
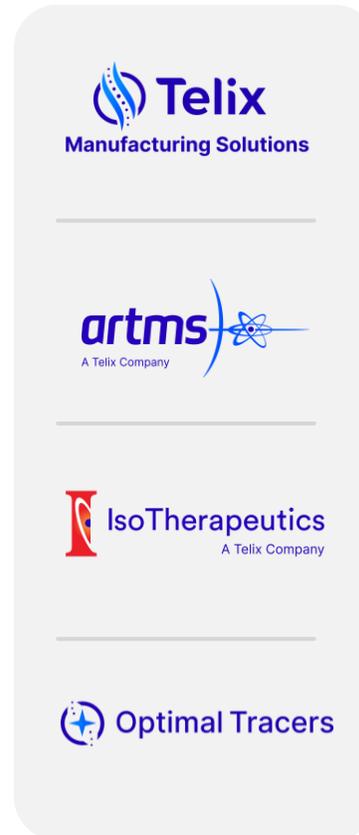
# Trend #2: Evolution of manufacturing processes

Securing supply chain also includes smarter scale-up

## Supply chain excellence

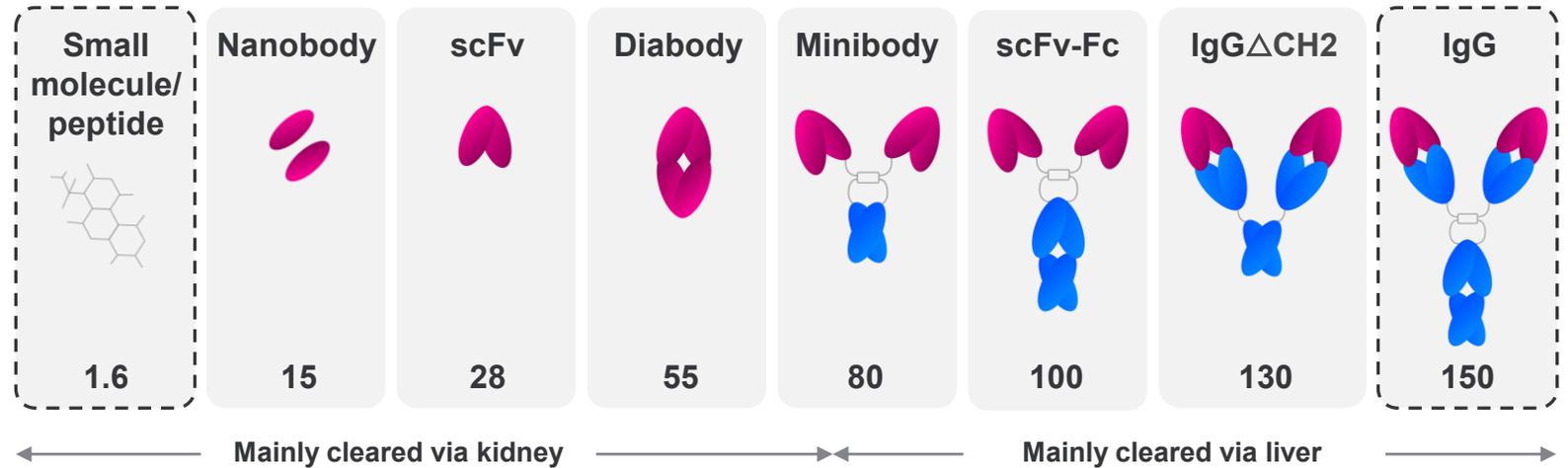
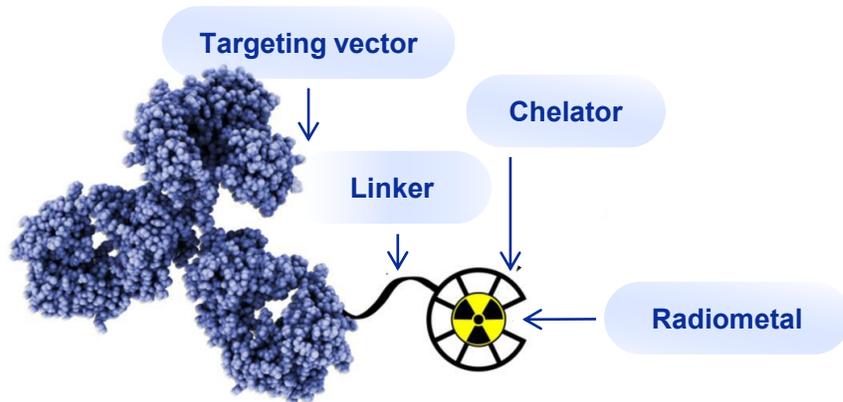
- Secure supply of medically important isotopes
- Investment in novel production technologies to support scale-up
- Building out in-house capacity to meet needs of U.S. and global market
- Strategic external partnerships

**Telex is investing ahead of the curve to meet demand and deliver next-generation therapeutics**

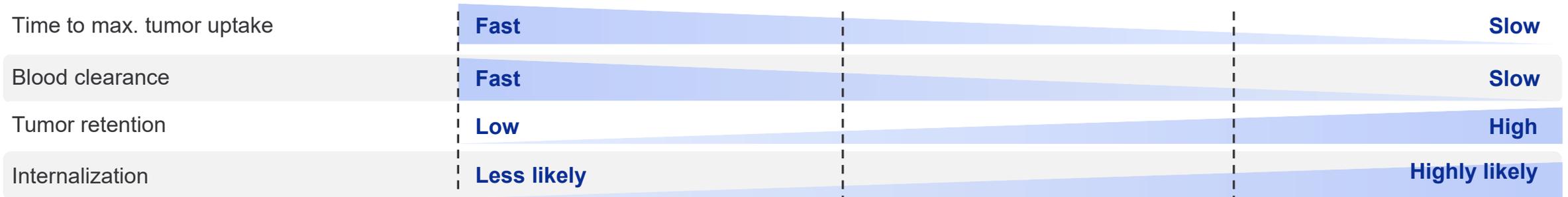


# Trend #3: Targeting vectors no longer straight-out-of-the-box

Antibody engineering creates new possibilities to modulate tumor binding and PK<sup>1</sup>



## Format trade-offs



**Telex's biologics platform<sup>3</sup> can optimize virtually any antibody for use as a radiopharmaceutical**

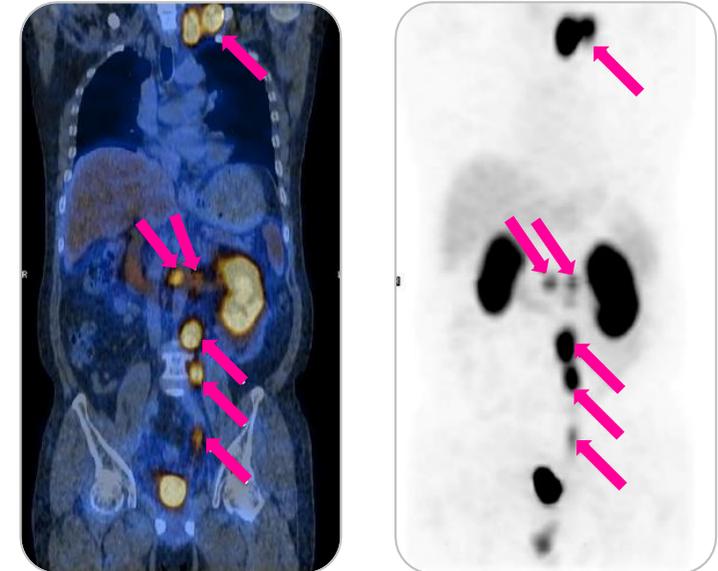


1. Wu et al. *Methods*. 2014; PK: Pharmacokinetics
2. Monoclonal antibody.
3. Telex ASX disclosure 31 January 2025. Telex acquired a proprietary novel biologics technology platform from ImaginAb, Inc.

# Trend #4: Dosimetry will supercharge personalized medicine<sup>1</sup>

## Software and AI will further unlock its potential

- Dosimetry is the scientific measurement, calculation, and assessment of the absorbed radiation dose
- Used to ensure safety and effectiveness of exposure to:
  - Assess the distribution of radiation over time and across tissues
  - Determine amount of radiation absorbed by tissues
  - Anticipate the potential effects on biological systems, including risk of radiation-induced damage.
- **Goal:** Shift from image-guided dosimetry to computer-assisted dosimetry to optimize dose delivery and minimize off-target exposure
- **Future horizon:** Shift to AI-guided therapy



**Dosimetry:** Is there enough dose in the tumor/lesions to be **effective**?  
Is the dose to healthy tissues minimized for **acceptable safety profile**?



1. *Nat Rev Clin Oncol* **19**, 534–550 (2022). <https://doi.org/10.1038/s41571-022-00652-y>

Patient representative scans – individual results may vary.

# Quantitative intelligence for drug design and adaptive therapy

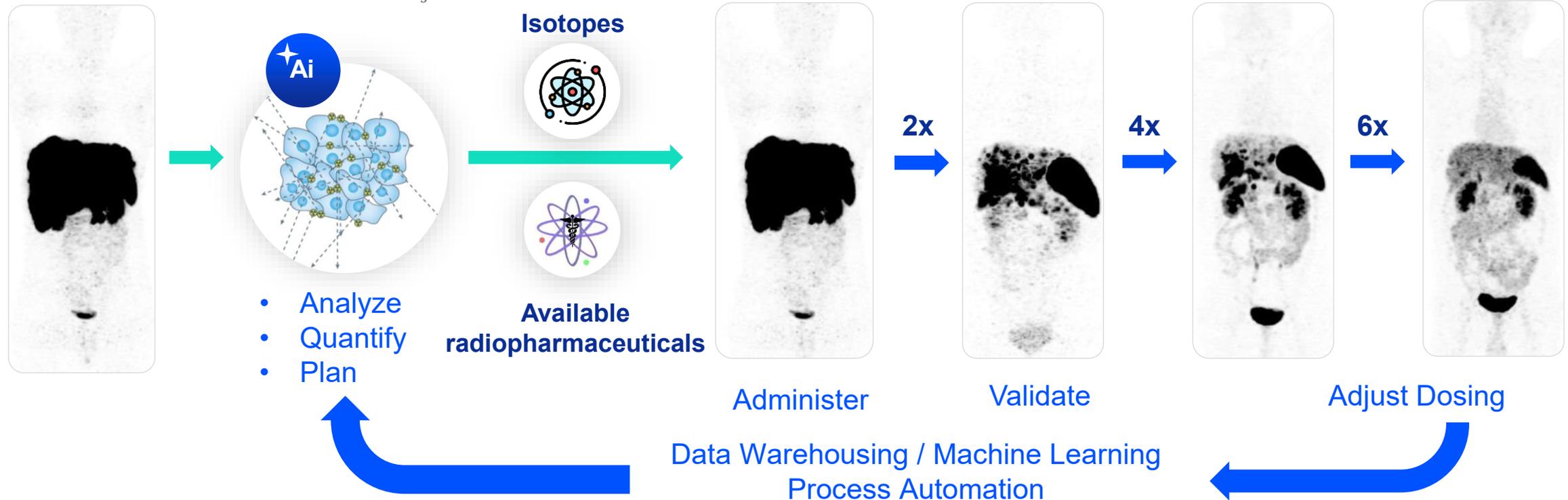
## Optimizing the diagnosis–therapy chain through quantitative feedback and learning<sup>1</sup>

Disease Detected<sup>2</sup>

Proprietary know-how,  
algorithms

Personalized Treatment

$$D(r_T, T_D) = \sum_{r_S} \tilde{A}(r_S, T_D) \cdot S(r_T \leftarrow r_S)$$



1. Yasdani et al. *Diagnostics (Basel)*. 2024  
 2. Sequential dosing with <sup>225</sup>Ac-DOTATATE. Imaging with <sup>68</sup>Ga-DOTANOC PET. Redrawn from Ballal, et al. *J Nucl Med*. 2023, 64: 211-218. Patient representative scans – individual results may vary. Cell dosimetry image redrawn from Sgouros, et al. 2020 *Nat. Rev. Drug Discovery* 19 589–608.

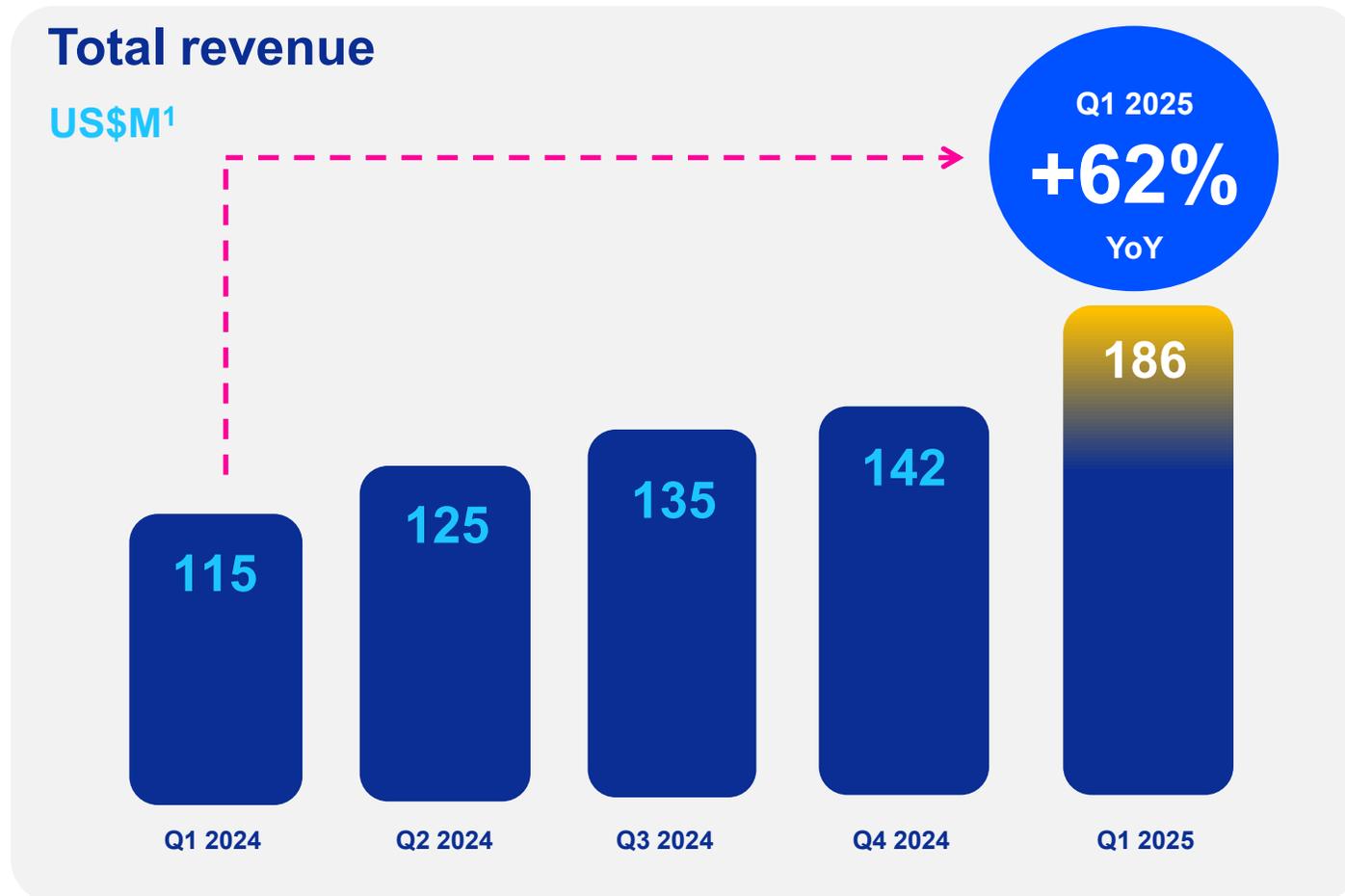
# Precision Medicine

**Kevin Richardson**  
**CEO, Precision Medicine**



# Commercial performance

Driven by Illuccix sales and RLS Radiopharmacies revenue



- Illuccix now approved in 17 countries<sup>1</sup>
- Gozellix now available in the U.S.
- Q1 2025: Continued growth: \$151 million from global sales of Illuccix:
  - up 35% over the prior year corresponding quarter (Q1 2024: \$112 million)
  - QOQ increase of 9% (Q4 2024: \$139 million)
- \$33 million from RLS Radiopharmacies (excluding Illuccix sales) since 27 January 2025



1. U.S., Canada, Australia, New Zealand, Brazil, UK, Czech Republic, Ireland, Malta, Luxembourg, Netherlands, France, Denmark, Finland, Sweden, Portugal and Germany.  
Note: Historical results above recast to US\$ are provided on an unaudited basis and are for comparative purposes only. Refer to ASX and SEC announcement in respect of Telix's Q1 2025 revenue, 22 April 2025.

# Precision medicine growth strategy

We are proactively expanding our global market opportunity

## Expand product offerings



- Launch Zircaix and Pixclara in the U.S.
- Use AI to increase patient throughput
- Ongoing innovation and life cycle management strategy in PSMA

## Expand geographies



- Illuccix global rollout
- Global regulatory filings for Zircaix, Pixclara and Gozellix in planning

## Expand indications



- Label expansion studies in planning for prostate, kidney, and brain cancer imaging
- Expands clinical utilization and label indications

**Commercial  
delivery**

Leading specialist  
commercial teams

Tailored commercial  
playbook for each market

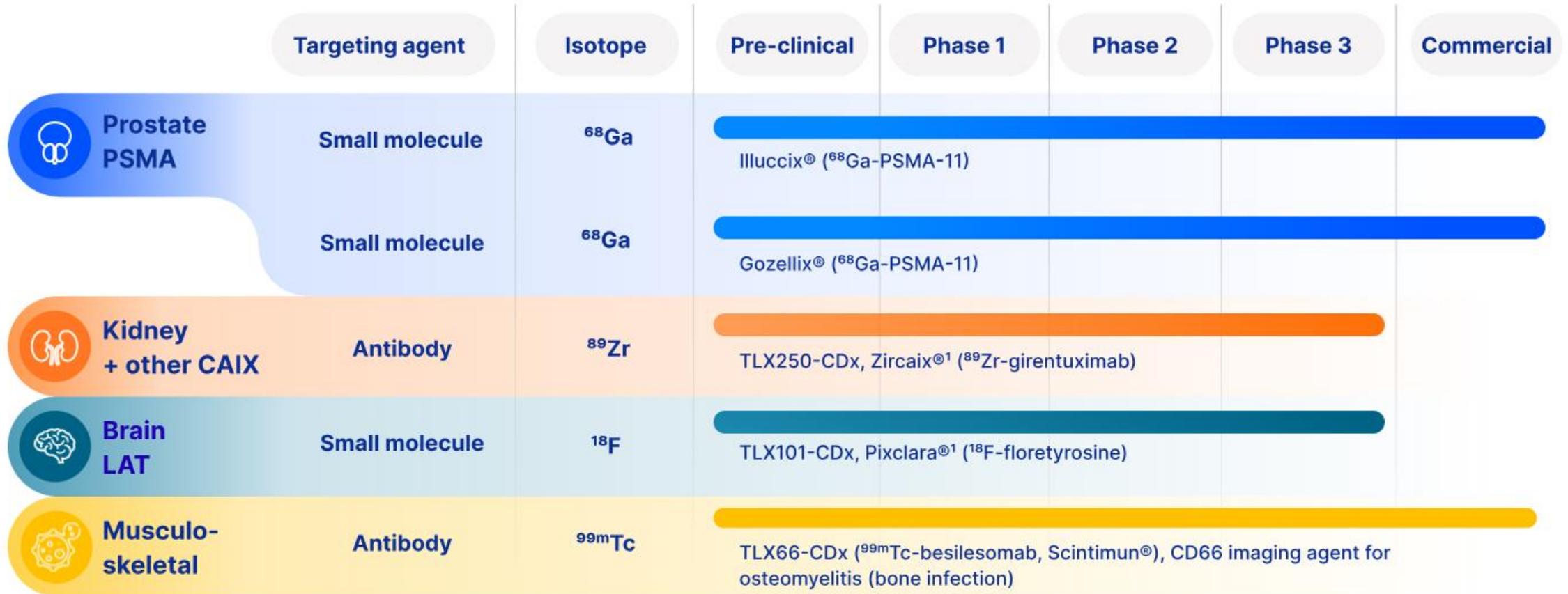
Underpinned by Telix  
reputation for innovation,  
service, and reliability



Zircaix and Pixclara brand names subject to final regulatory approval. All logos are registered trademarks of Telix.

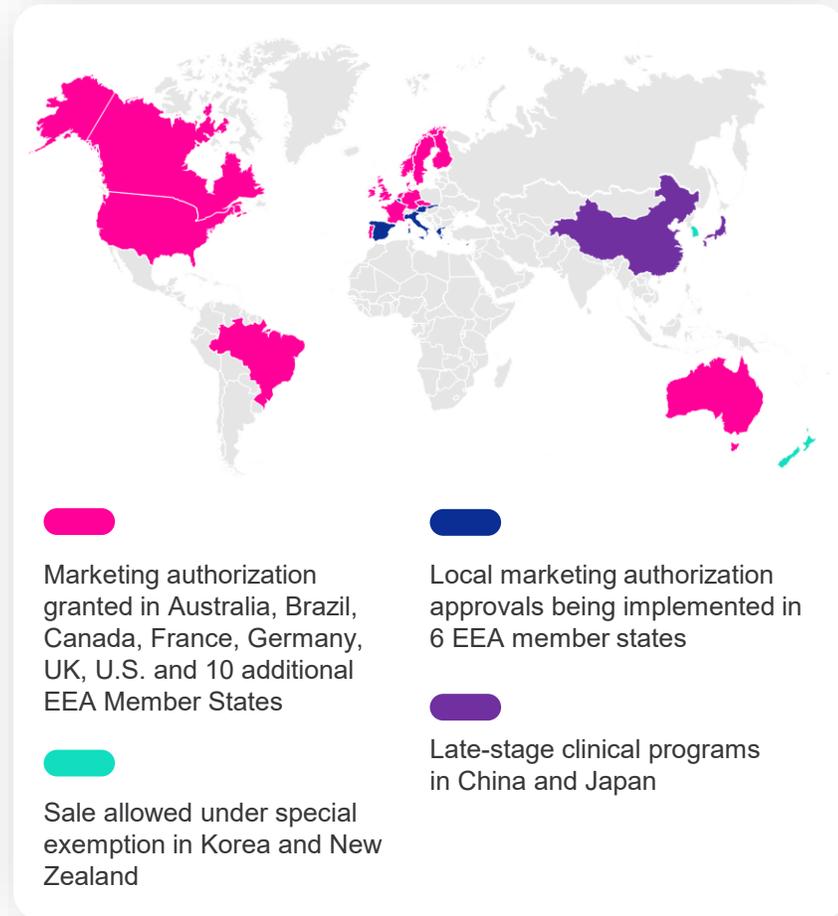
# Precision medicine portfolio

## Expanding commercial portfolio



# Ilucix global rollout

## Commercialization and marketing authorizations progressing in major global markets



### Europe Middle East and Africa:

- Decentralized submission approved by BfArM as Reference Member State for European Economic Area (EEA) Concerned Member States<sup>1</sup>
- Marketing Authorizations granted in France<sup>2</sup>, Germany<sup>3</sup>, the United Kingdom<sup>4</sup> and 10 additional EEA member states<sup>5</sup>

### Asia Pacific:

- Phase 3 registration study in China complete<sup>6</sup>, preparing NDA
- Phase 3 registration study in Japan initiating

### Americas:

- FDA approved label in U.S. expanded to include patient selection for pre-taxane radioligand therapy (RLT)
- Marketing Authorization granted in Brazil<sup>7</sup>, the first full MA for PSMA-PET in Latin America

1. Telix ASX disclosure 17 January 2025.

2. Telix media release 29 April 2025.

3. Telix media release 5 June 2025.

4. Telix ASX disclosure 13 February 2025.

5. Czech Republic, Denmark, Finland, Ireland, Luxembourg, Malta, the Netherlands, Norway, Portugal and Sweden at time of release.

6. Telix media release 13 May 2025.

7. Telix ASX disclosure 18 March 2025.

# Expanding our addressable market through clinical leadership

## Planned label expansion studies across the portfolio

	Study name	Focus	Potential outcomes
	<b>PSMA PET for diagnosis of prostate cancer</b>	Ph 3 study of PSMA PET + MRI compared to SOC for the detection of prostate cancer	<ul style="list-style-type: none"><li>• Personalize biopsy</li><li>• Remove the need to biopsy</li></ul>
	<b>Zirmet study</b>	Assess diagnostic performance of TLX250-CDx in ccRCC <sup>1</sup> patients suspected of recurrence based on conventional imaging	<ul style="list-style-type: none"><li>• Detection of ccRCC recurrence and oligometastatic disease</li></ul>
	<b>TLX101-CDx brain metastasis study</b>	Assessing how accurately <sup>18</sup> FET PET identifies treatment-related changes without incorrectly classifying as tumor progression	<ul style="list-style-type: none"><li>• Address a gap in current diagnosis for brain metastasis</li><li>• Label expansion beyond glioma only</li></ul>

# Our strategy to build a leading PSMA imaging portfolio

Underpinned by a commitment to innovation to better serve patients and customers



1. Subject to favorable clinical trial results and regulatory approval. Refer to slide 33 for addressable market breakdown.

# Telix PSMA multi-product strategy

## Gozellix next-generation in PSMA imaging excellence

- Telix has built a reputation for industry leading reliability, flexibility and service, AND clinical accuracy
- Gozellix further differentiates Telix as the only provider with two FDA-approved PSMA-PET imaging agents
- Expands patient reach and customer choice
- Higher-activity kit allows for enhanced availability, scheduling flexibility and workflow

**illuccix<sup>®</sup>**  
(kit for the preparation of gallium Ga 68 gozetotide Injection)

**Gozellix<sup>™</sup>**  
(kit for the preparation of gallium Ga 68 gozetotide injection)

**SHATTERING LIMITATIONS IN PSMA**

**PSMA Precision Anytime, Anywhere**

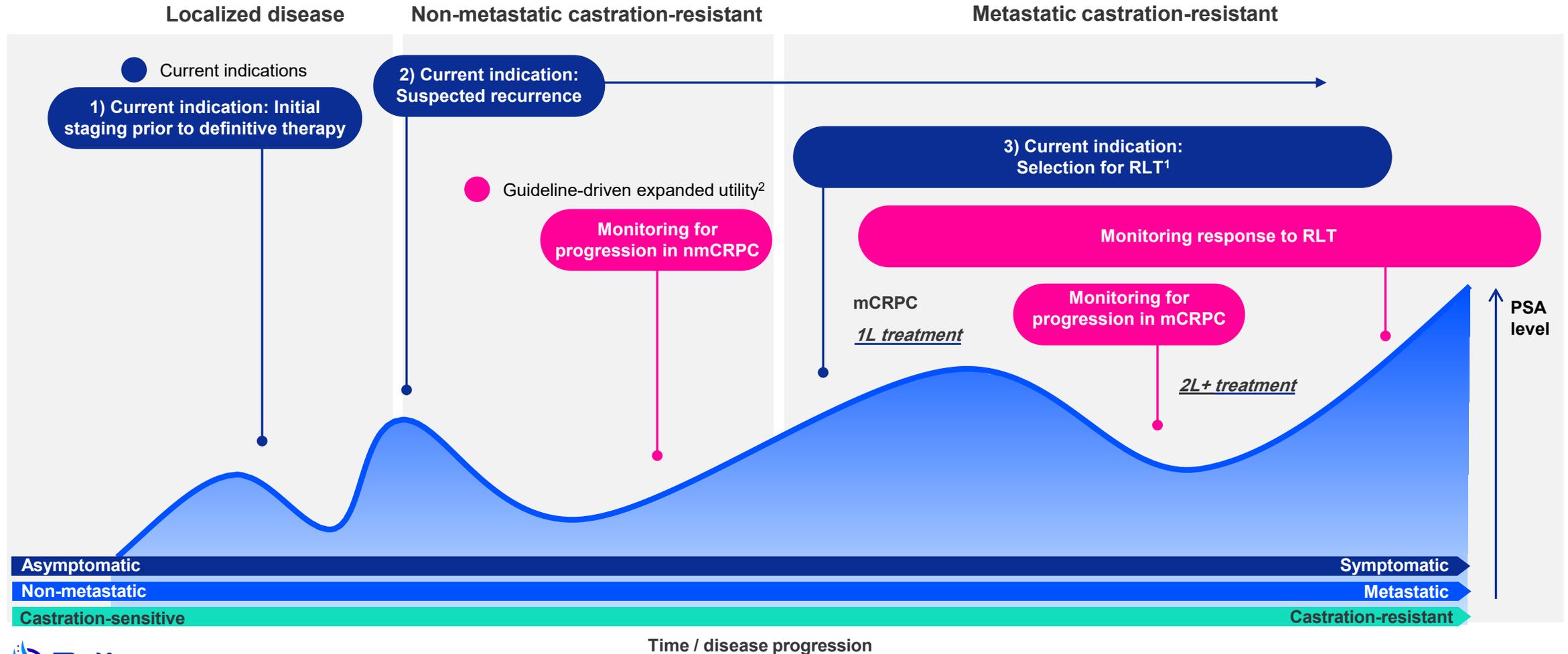
A highly accurate <sup>68</sup>Ga PSMA PET agent<sup>1</sup>  
An advanced tracer that expands the geographic distribution and utility of PSMA<sup>2-4</sup>  
Services and support you can count on



Sample U.S. campaign for U.S. approved product, intended for U.S. healthcare professional audience only. Registrations vary country to country, always refer to local label and approval status. Gozellix is not currently approved in any country outside of the U.S.

# PSMA imaging today, a \$2.5B to \$3.5B addressable market

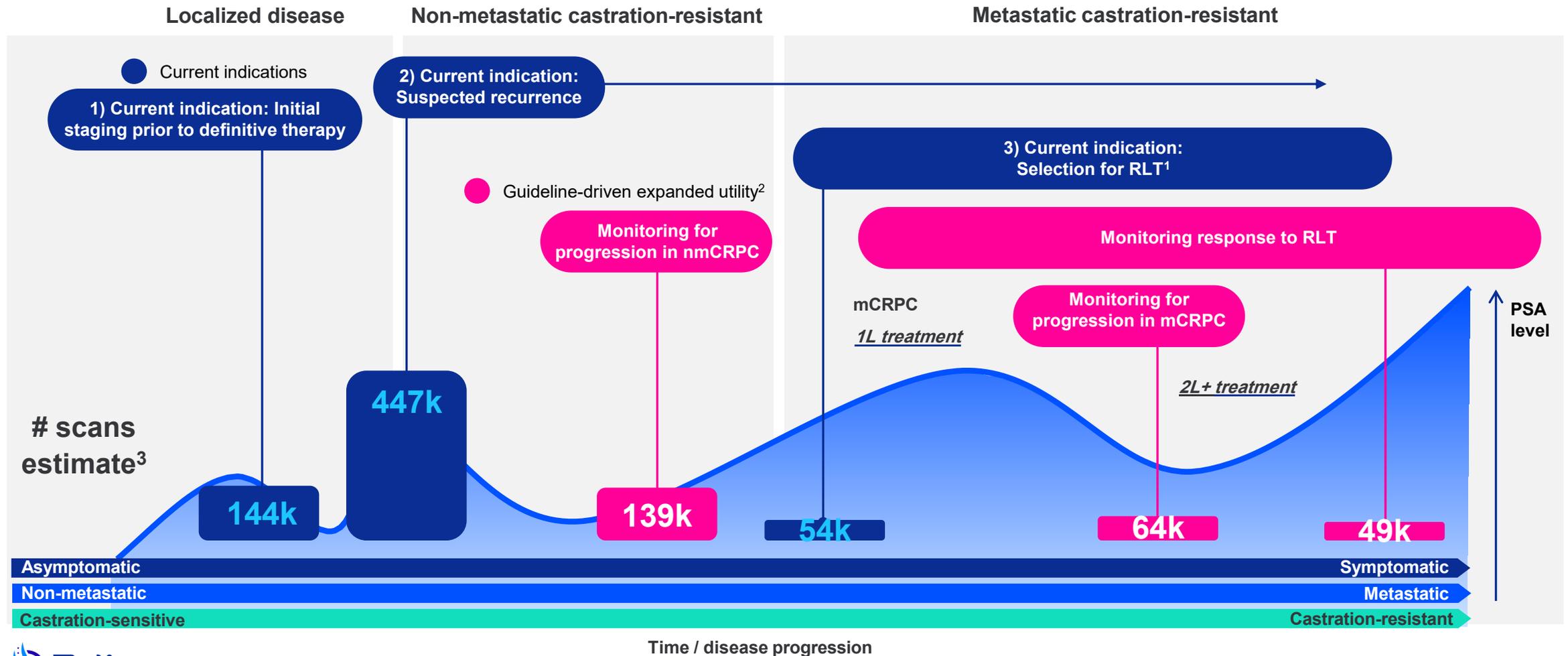
Driven by current label indications and guidelines



1. Radioligand therapy.
2. Based on current guidelines.

# Most PSMA scans are performed when recurrence is suspected

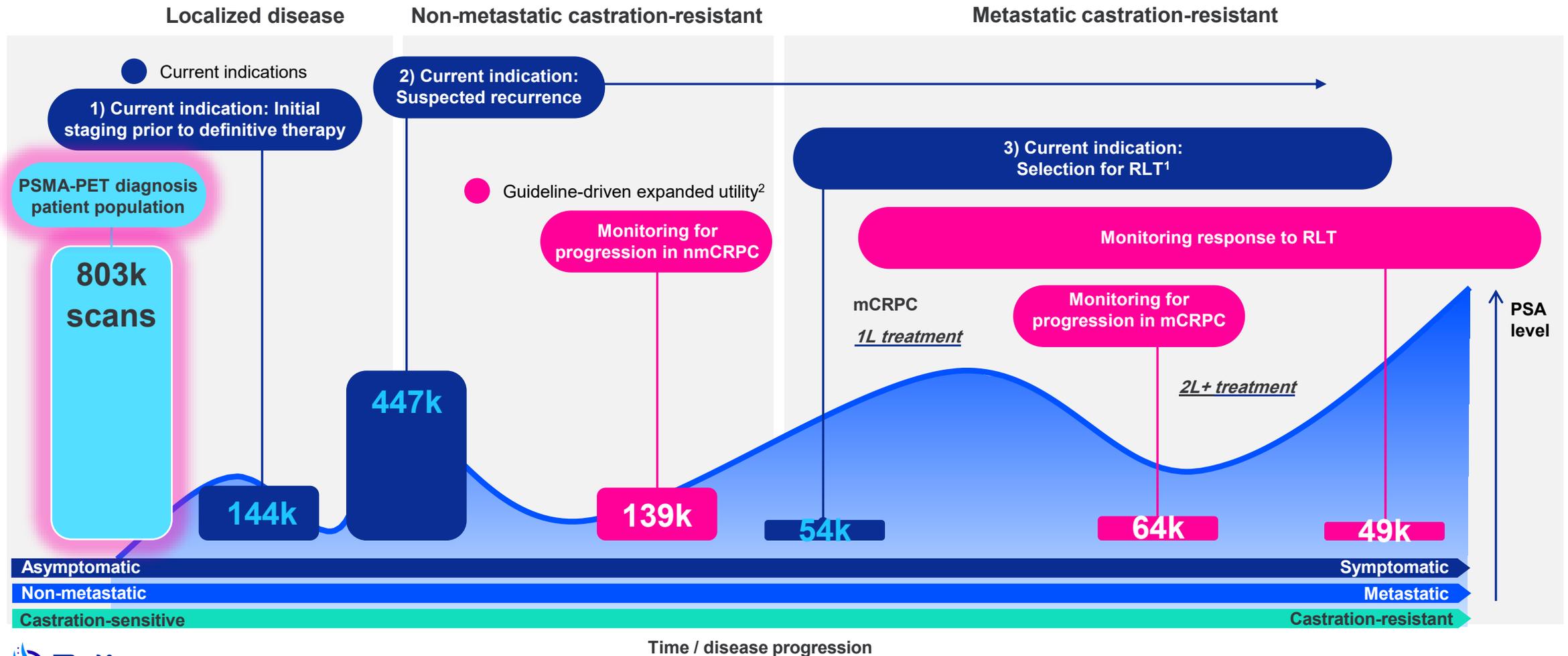
## PSA test, followed by MRI, biopsy is the standard for diagnosis



1. Radioligand therapy.
2. Based on current guidelines.
3. Potential number of scans per year in U.S.

# Expansion into diagnosis enhances the opportunity

## PSMA-PET with the patient at the start of their diagnosis journey



1. Radioligand therapy.
2. Based on current guidelines.

# New and guideline-driven indications for PSMA imaging

Potential to bring the total addressable market up to ~\$6.7 billion in the U.S.

## New indication (subject to FDA approval)

- PSMA-PET for diagnosis (PI-RADS<sup>4</sup> scores 2-4)

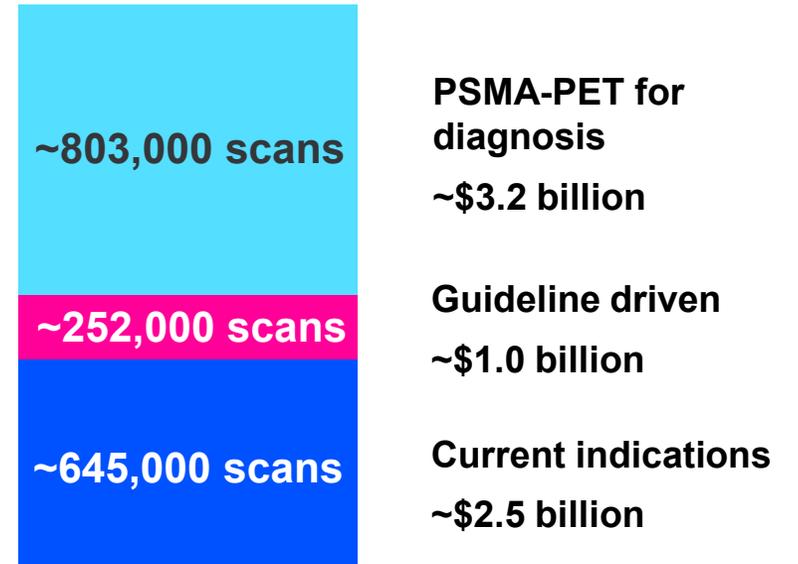
## Guideline driven indications

- Monitoring response to radioligand therapy
- Monitoring for progression in nmCRPC<sup>1</sup> and mCRPC<sup>2</sup> (AUA)<sup>3</sup>

## Current indications

- Initial staging for suspected metastases (NCCN<sup>5</sup>, AUA)
- Suspected recurrence (NCCN, AUA)
- Patient selection for RLT<sup>6</sup> (NCCN, AUA)

Estimated annual scans in the U.S. to reach ~1.7 million scans with a total addressable market of \$6.7 billion<sup>7</sup>



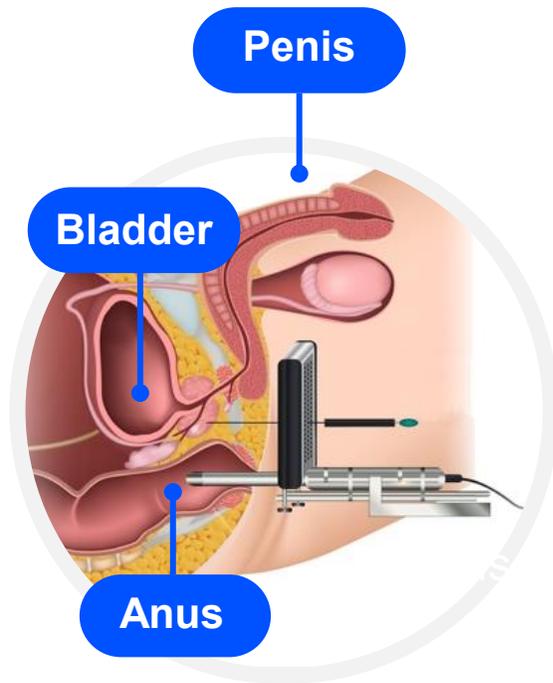
1. Non-metastatic Castration-Resistant Prostate Cancer.  
2. Metastatic Castration-Resistant Prostate Cancer.  
3. American Urological Association.  
4. Prostate Imaging Reporting and Data system

5. National Comprehensive Cancer Network.  
6. Based on licensed indication for 177Lu-PSMA-617, Pluvicto, a registered trademark by Novartis AG, in mCRPC patients who have been treated with androgen receptor (AR) pathway inhibition.  
7. Based on a price of USD 4,000 per scan.

# Over one million men get a biopsy every year

“The most disruptive and transformative advancements in medicine are those that minimize patient trauma, reduce recovery time and lower cost while improving outcomes” – *John Abele, Founder Boston Scientific*

## Transperineal biopsy



## Intravenous injection



Patient representative scan – individual results may vary.

# Unmet need: Improving the diagnostic pathway in prostate cancer

## Opportunity to improve accuracy, minimize invasive biopsy

**Men with elevated PSA values will often be recommended for MRI<sup>1</sup>, followed by biopsy**

- MRI is not specific and often inconclusive, leading to biopsy

**Over 1M biopsies performed in the U.S. each year, majority for initial diagnosis, up to 75% are negative<sup>2</sup>**

- Biopsy is blind to the location of cancer in the prostate
- Only 50% of biopsies successfully retrieve prostate tissue (false negatives)<sup>3</sup>

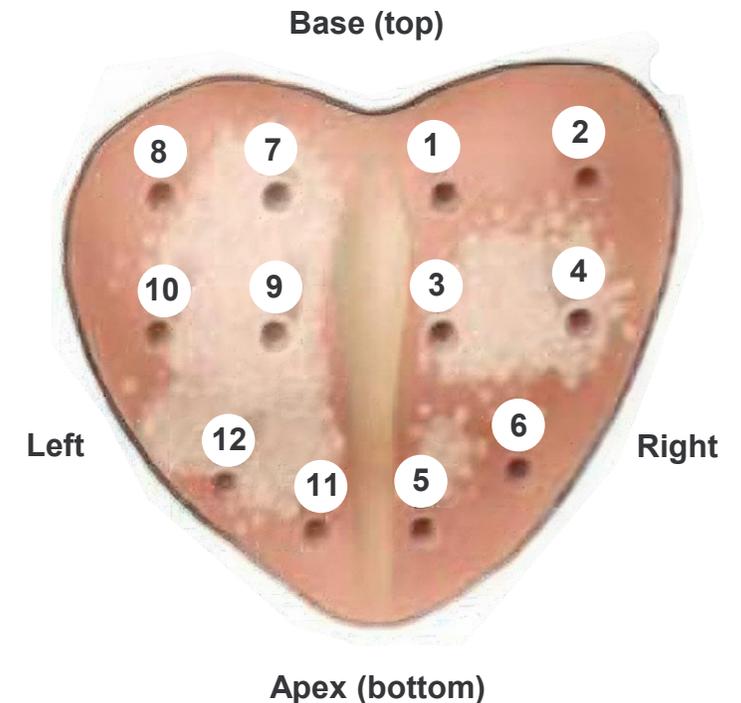
**Biopsies carry real risks<sup>4</sup>**

- Hematuria, rectal bleeding, hematospermia
- Inconsistent practice around anticoagulants adds complexity

**Up to 25% of patients refuse a recommended biopsy<sup>5</sup>**

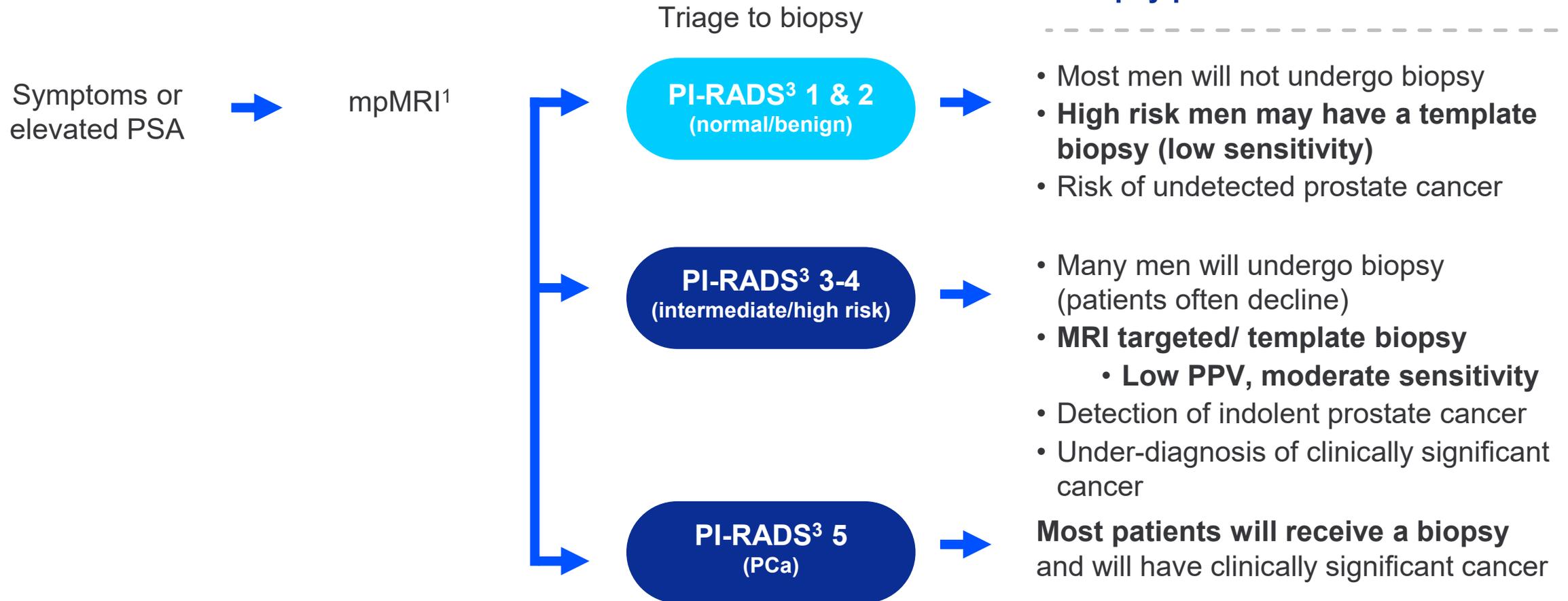
- Reasons for refusal include fear or pain of complications
- Skepticism about the necessity of the procedure

**Areas of biopsy<sup>6</sup>**



# Current diagnosis pathway

Low sensitivity of MRI leads to high rate of biopsy



# A personalized diagnostic pathway with PSMA-PET

Smarter triage BEFORE biopsy. Integrating imaging WITH biopsy.



Symptoms or elevated PSA



PSMA-PET + mpMRI

Risk stratification



Potential high risk  
(PI-RADS<sup>3</sup> 5)

Image-guided biopsy  
Staging and surgical  
planning



PI-RADS<sup>3</sup> 1-4  
PET Positive

Precision biopsy  
'One and Done'



PI-RADS 1-2  
PET Negative

No biopsy  
'None and Done'

## PSMA-PET at diagnosis aims to:

- Improve predictive accuracy
- Reduce 12-40 anatomical biopsies to 1-2 biopsies
- For some, eliminate the need for biopsy altogether
- Decrease risk and anxiety

## Enabling:

- Clearer treatment stratification
- Personalized diagnostic journey
- Expedited therapy

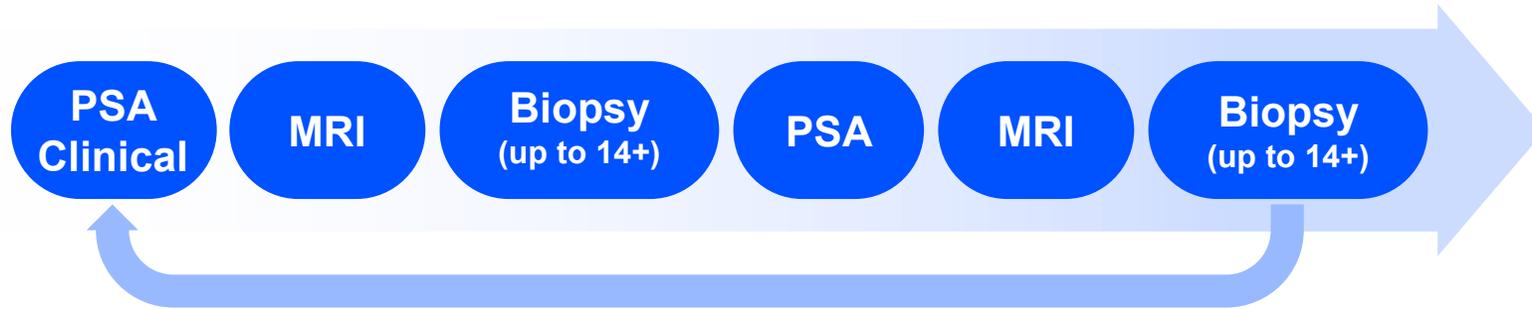


1. Multiparametric MRI.
2. American Cancer Society, Key Statistics for Prostate Cancer, accessed February 2025
3. Prostate Imaging Reporting and Data System, a scoring system used by radiologists to assess the likelihood of prostate cancer based on multiparametric mpMRI findings.

# A patient's journey

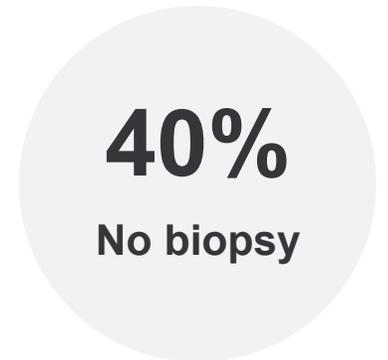
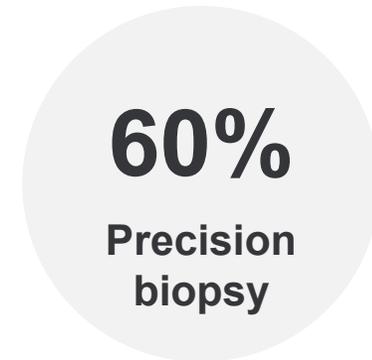
## 1990 – 2025

Multiple biopsies until cancer is detected



## 2026 & beyond

No biopsy or precision biopsy



# Zircaix: Adding depth to our commercial focus on urology



Brand name subject to final regulatory approval.



# TLX250-CDx (Zircaix): Highly accurate in detecting ccRCC

## Phase 3 ZIRCON trial validates CAIX as a novel target<sup>1</sup>

### Product candidate

TLX250-CDx (<sup>89</sup>Zr-DFO-girentuximab)  
FDA Breakthrough Therapy designation<sup>2</sup>

### Targeting molecule / target

Antibody /  
Carbonic anhydrase IX (CAIX)

### Indication

Clear cell renal cell carcinoma

### Clinical experience to date

Demonstrated accuracy and favorable safety profile in Phase 3 ZIRCON study and real-world cases<sup>3</sup>

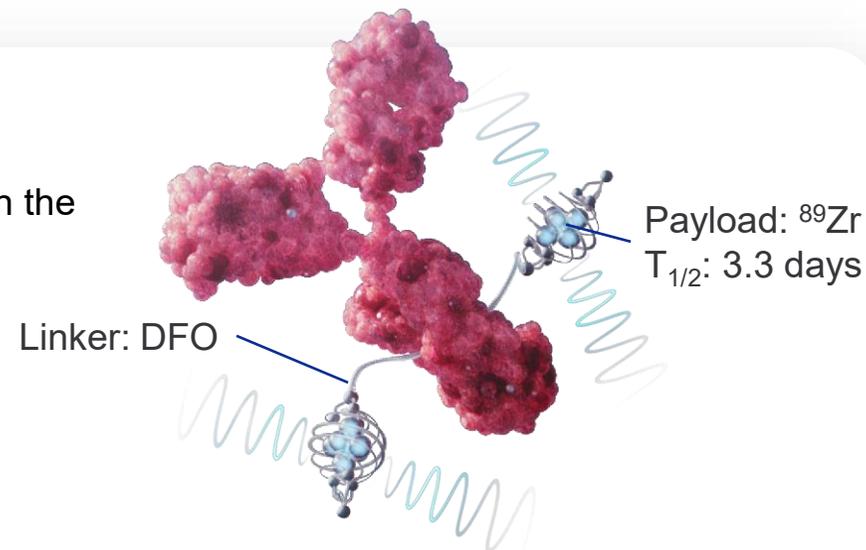
- PET/CT imaging accurately detected ccRCC in patients with cT1 IRM (≤7cm), demonstrating a mean sensitivity of 86%, specificity of 87% and positive predictive value of 93%

### Current status

BLA under FDA review  
Expanded access program active in the U.S.

### Upcoming milestones

PDUFA date 27 August 2025



**Professor Brian Shuch, MD,**  
Director of the Kidney Cancer Program and the Alvin & Carrie Meinhardt Endowed Chair in Kidney Cancer Research at UCLA Institute of Urologic Oncology

*“The challenges and uncertainty in diagnosing ccRCC underscore a critical unmet need for a new, non-invasive technique that accurately detects and differentiates ccRCC from other renal masses in patients, to inform clinical decision making. The ZIRCON trial has shown that TLX250-CDx is a breakthrough technology that can address this need.”*



1. Shuch B, et al. *Lancet Oncol.* 2024;25(10):1277-1287.  
2. Telix ASX disclosure 1 July 2020.  
3. ZIRCON ClinicalTrials.gov ID: NCT03849118.  
Zircaix brand name and marketing authorization subject to regulatory approval.

# A clear value proposition in the diagnosis of ccRCC<sup>1</sup>

## Unmet need

- Conventional imaging (CT, MRI, ultrasound) is limited in characterizing tumor malignancy and identifying (ccRCC)
- Unnecessary surgeries (nephrectomies) and invasive medical procedures (biopsies) are being performed, **up to 1/3 of resected small renal masses are benign<sup>2</sup>**

## + Zircaix PET positive

- Peer reviewed data suggests that Zircaix imaging could quickly characterize ccRCC in the assessment of indeterminate renal tumors, **reducing time to diagnosis**
- Goal is for physicians to have the **confidence** that surgery is performed in the **right patients**, reducing the number of unnecessary surgeries

## - Zircaix PET negative

- Data suggests that biopsies and further imaging are only needed for patients with Zircaix PET-negative imaging – **a smaller patient group** after eliminating ccRCC from diagnosis
- **Suggests lower probability of aggressive disease** in this patient group

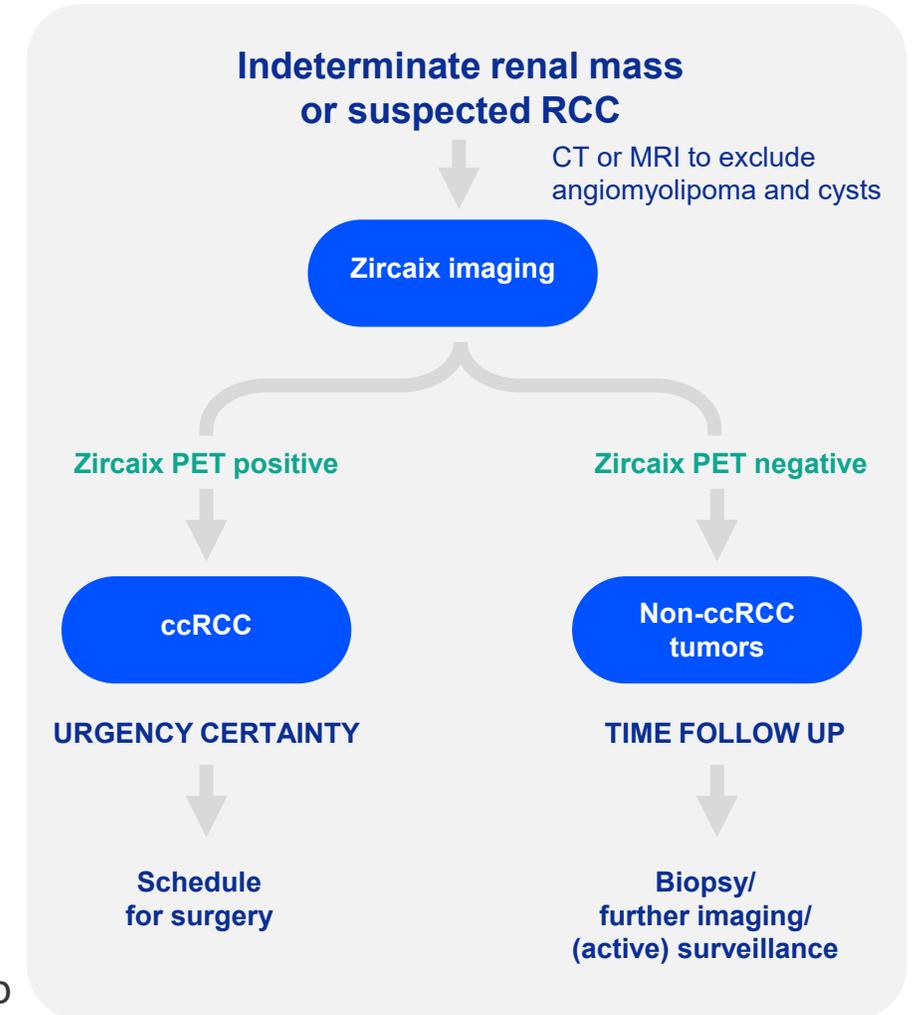


1. Shuch et al. *Lancet Oncol.* 2024.

2. Kim JH, et al. *JAMA Surg.* 2019.

Zircaix brand name subject to final regulatory approval.

ccRCC, clear cell renal cell carcinoma; MRI, magnetic resonance imaging; PET, positron emission tomography.



# Telix's commitment to renal cancer patients

Aiming to transform the management of patients with ccRCC



## Enable

TLX250-CDx (Zircaix) is a first-in-class, radiodiagnostic agent for the diagnosis and characterization of ccRCC



## Grow

Increase adoption and market opportunity through guideline inclusion, label expansion studies



## Transform

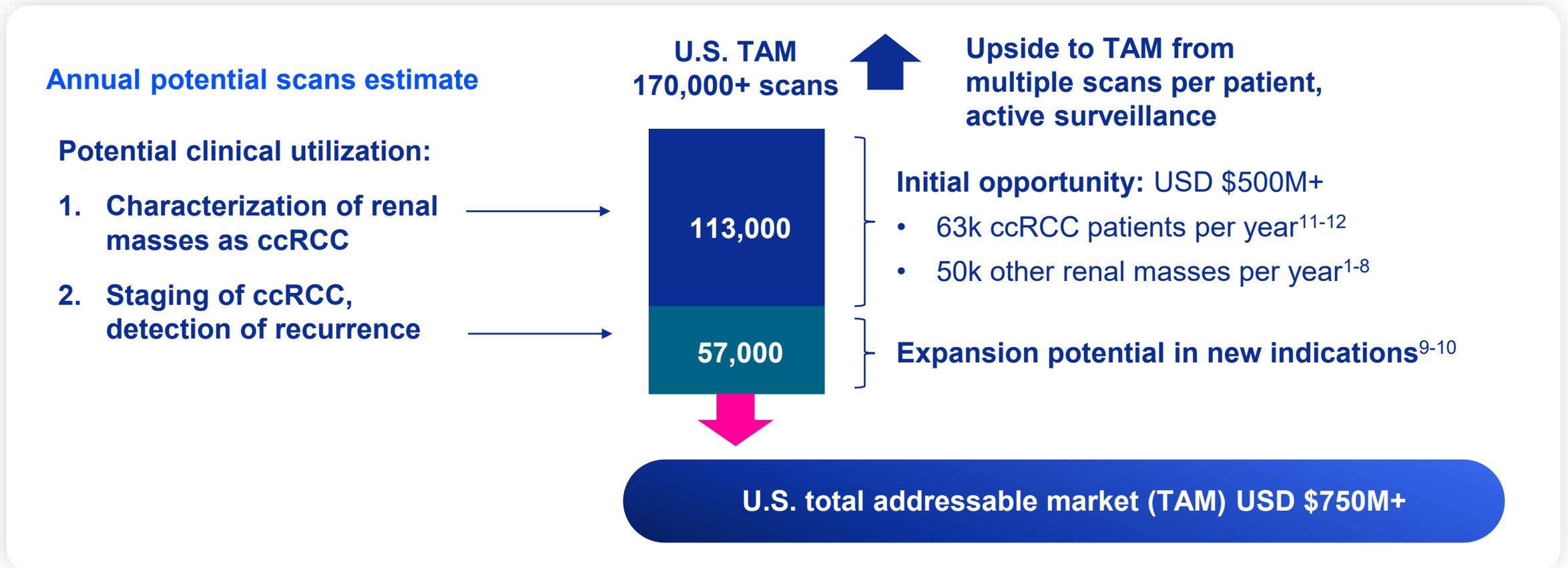
To other carbonic anhydrase IX (CAIX) expressing cancers harnessing data generated from current ongoing studies



Zircaix brand name and marketing authorization subject to regulatory approval.

# Market opportunity for diagnosis of ccRCC

**\$500M+ initial U.S. opportunity, further expansion potential in staging and recurrence**



1. Sigmon et al. 2022, StatPearls Renal cyst article.
2. Garfield et al. 2022, StatPearls Simple Renal Cyst Article; Tay et al. 2018 JCMS.
3. Cancer.Org, Kidney Cancer Key Statistics.
4. Escudier et al. 2019, Annals of Onc; ESMO guidelines RCC.
5. Mittal et al. 2016, Ind J Rad Img.

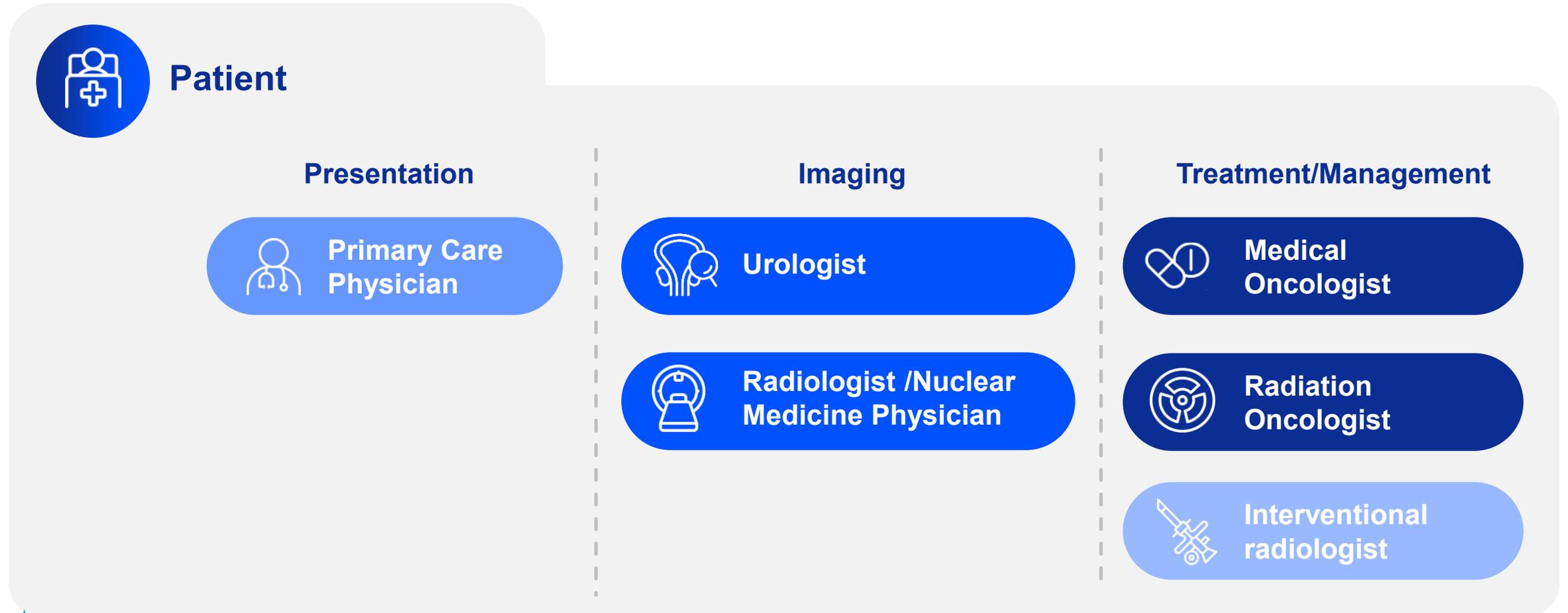
6. Metin et al. 2022, Medicina (Kaunas).
7. Tshering Vogel et al. 2021, Urology; Di Vece et al. 2016, Ultrasound.
8. Vasudev et al. 2020, BMJ.
9. Pharmintelligence RCC – Accessed January 2024.
10. Hollenbeak et al. 2019, BMC Urology.

11. SEER. (2022). Cancer Stat Facts: Kidney and Renal Pelvis Cancer: <https://seer.cancer.gov/statfacts/html/kidrp.html>.
12. STATPEARLS Rahul D. Arora 2020;11(3):79-87.

\* Subject to regulatory approval

# Building on proven success: Elevating value in urology care

Zircaix, Illuccix and Gozellix share common referral stakeholders



# KOL perspective: Renal

**Joseph Osborne, MD**

**Chief of Molecular Imaging  
and Therapeutics and  
Professor of Radiology at  
Weill Cornell Medicine**



# Unmet need in diagnosis of ccRCC

The most common – and one of the most aggressive – forms of renal cancer

## Need for early & accurate diagnosis / treatment

- Up to 85% of RCCs are ccRCC<sup>1,2</sup>
- ccRCC causes ~90% of deaths of all RCC<sup>3,4</sup>
- For patients with small renal masses on active surveillance, ccRCC subtype reported to progress most rapidly<sup>5</sup>

## Limitations of renal biopsy

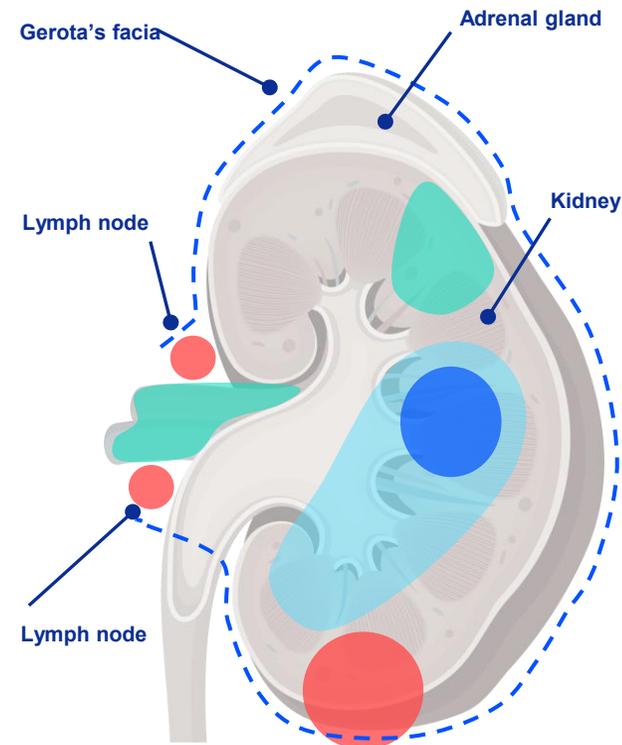
- Non-diagnostic, 10-15%
- Invasive, related risks
- Sampling error, 70% NPV<sup>6</sup>

## Limitations of anatomic imaging (CT, MRI)

- Cannot reliably distinguish benign vs malignant

## Risk of overtreatment & related complications

- Up to 30% resected small renal masses found to be benign<sup>7</sup>
- 30% complication rate of partial nephrectomy in these patients<sup>8</sup>



### Stage I

Tumor <7 cm in greatest dimension and limited to kidney;  
**5-year survival, 95%**

### Stage II

Tumor >7 cm in greatest dimension and limited to kidney;  
**5-year survival, 88%**

### Stage III

Tumor in major veins or adrenal gland, tumor within Gerota's fascia, or 1 regional lymph node involved;  
**5 year survival, 59%**

### Stage IV

Tumor beyond Gerota's fascia, or >1 regional lymph node involved;  
**5 year survival, 20%**

# Small renal masses (<2cm) are often malignant<sup>1</sup>

## Risk statistics by tumor size (in 1cm increments)

### Benign vs. Malignant

1. Thompson, J.H. et al., (2009). *J Urol*  
Benign tumors vs RCC according to size  
in patients treated surgically for renal mass

Size (cm)	Benign (%)	RCC (%)
< 1	6 (37.5)	10 (62.5)
1 to < 2	56 (19.2)	236 (80.8)
2 to < 3	77 (16.5)	391 (83.5)
3 to < 4	58 (13)	390 (87)
4 to < 5	30 (8.7)	315 (91.3)
5 to < 6	23 (10)	206 (90)
6 to < 7	13 (6.6)	183 (93.4)
7 or > 8	48 (7.1)	633 (92.9)

### Low vs. High Grade

Low vs high grade tumors in 1,523 patients  
treated surgically for clear cell RCC

Size (cm)	Low grade (%)	High grade (%)
< 1	6 (100)	0
1 to < 2	138 (84)	26 (16)
2 to < 3	206 (83)	43 (17)
3 to < 4	177 (73)	65 (27)
4 to < 5	131 (67)	64 (42)
5 to < 6	83 (58)	49 (42)
6 to < 7	81 (62)	49 (38)
7 or > 8	163 (41)	232 (59)

# TLX250-CDx: Highly accurate in detecting ccRCC<sup>1</sup>

## Phase 3 ZIRCON trial validates CAIX as a novel target

### <sup>89</sup>Zr-girentuximab

- IgG1 **CAIX-targeting** mAb
- **Payload:** <sup>89</sup>Zr, positron emitter with T<sub>1/2</sub> 3.3 days
- Hepatically cleared
- Demonstrated accuracy and favorable safety profile in **Phase 3 ZIRCON study** and real-world cases<sup>2</sup>

### THE LANCET Oncology

*“As PET–CT imaging with PSMA revolutionized the management of prostate cancer, imaging using TLX250-CDx has the potential to change clinical practice in renal cell carcinoma.”*

### ZIRCON study results summary

Sensitivity & specificity  
(primary endpoints; n=284)

Sensitivity: 86% | Specificity: 87%

#### Sensitivity & specificity of small lesions

##### ≤4 cm (n=145)

- Sensitivity: 85%
- Specificity: 90%

##### ≤2 cm (n=20)

- Sensitivity: 97%
- Specificity: 97%

#### Reader agreement

#### The Fleiss' κ statistic for inter-reader variability:

91% Cohen's κ statistic for intrareader variability: 100% for each reader

#### Safety & tolerability

Favorable profile indicated



CAIX, carbonic anhydrase IX; ccRCC, clear cell renal cell carcinoma; mAb, monoclonal antibody; PET, positron emission tomography; rADC, radio antibody-drug conjugate; T<sub>1/2</sub>, half-life.

1. Shuch B, et al. *Lancet Oncol.* 2024;25(10):1277-1287.

2. ZIRCON ClinicalTrials.gov ID: [NCT03849118](https://clinicaltrials.gov/ct2/show/study/NCT03849118).

# TLX250-CDx: Expanded access program

## Case study: Clinical utility in real-world setting

### Clinical background:

History of prostate cancer with XRT 2017, recurrence in many nodes in 2020 N2M1a - on ADT and darolutamide

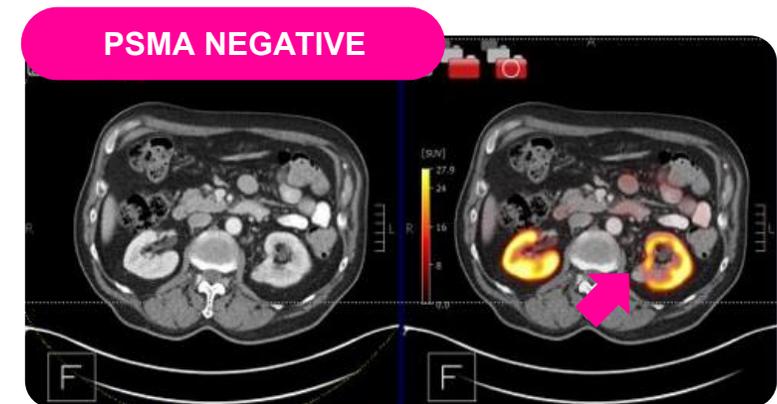
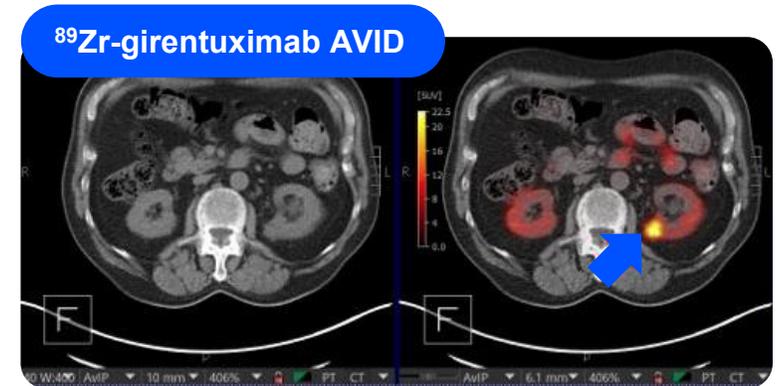
### PSMA PET/CT show lesion in kidney (NOT PSMA AVID)

- Found incidental 3 cm mass in left kidney during PSMA scan for evaluation of metastatic prostate cancer
- Additionally found 1.8 cm bosniak 3 renal lesion in left kidney

Patient desired to watch lesion unless we felt it could be aggressive tumor

Plan was to repeat scan in 6 months but received <sup>89</sup>Zr-girentuximab through EAP

**Positive <sup>89</sup>Zr-girentuximab scan**  
**Outcome:**  
**Management change**  
Patient proceeded with ablation for 3 cm mass; Bosniak 3 lesion was not avid



Illustrative case study only. Individual outcomes may vary.

# Case study: ~1cm renal lesion

## Detection of small ccRCC renal lesions

### Clinical background

- 40-yr-old male with 1.2cm renal lesion
- PET positive ccRCC highly likely
- Similar sized cyst negative for uptake
- Partial nephrectomy
- ccRCC confirmed (T1a stage)

### Right superior kidney

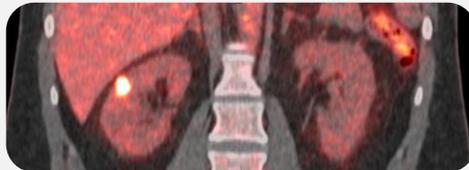
PET positive patient



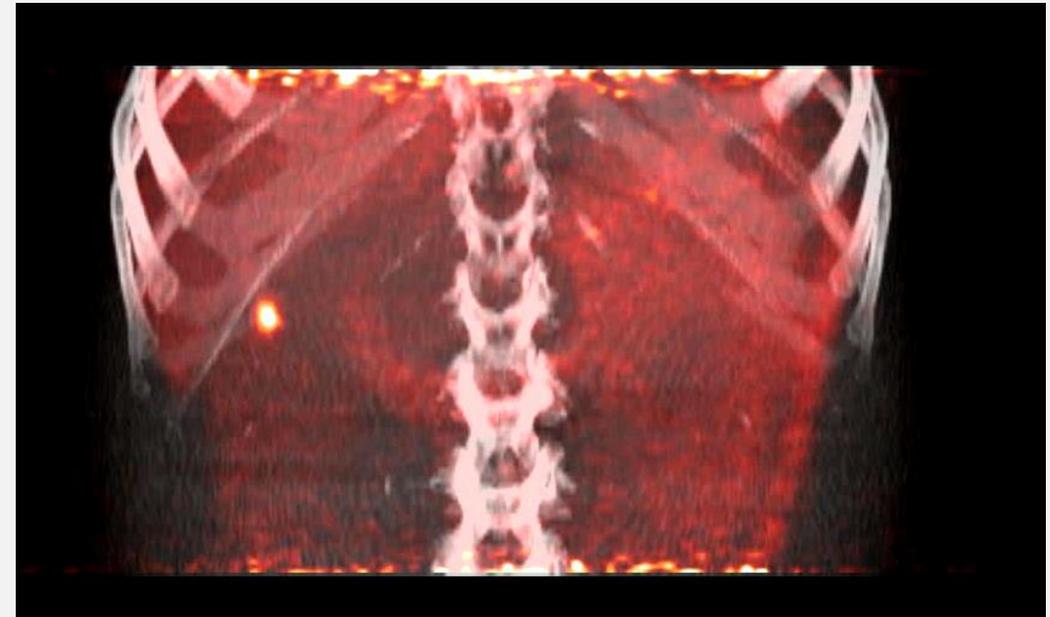
Diagnostic CT



Fused PET/CT



### Fused MIP

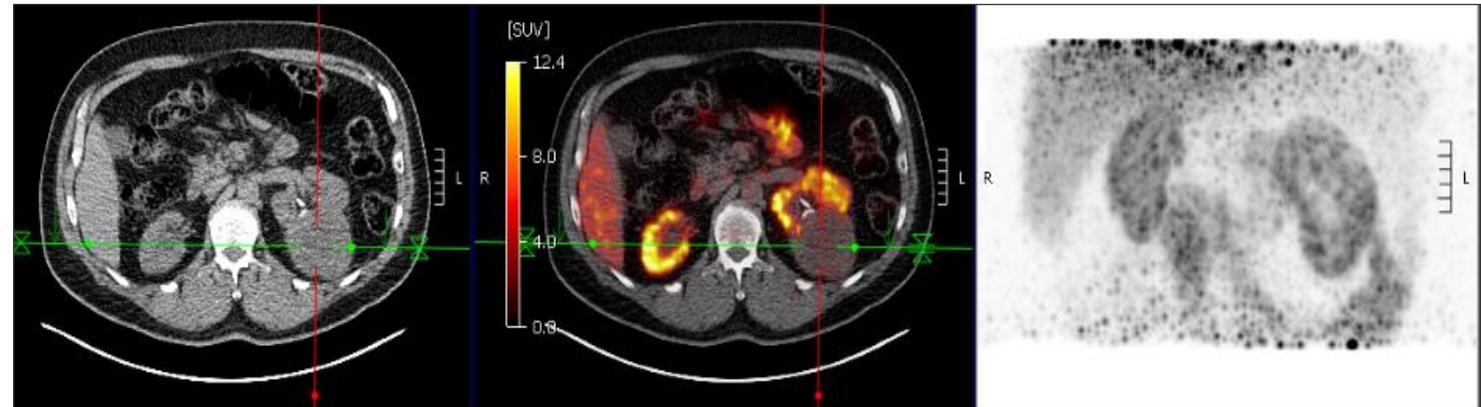


Illustrative case study only. Individual outcomes may vary.

# Case study: Negative TLX250-CDx case

## Detection of absence of ccRCC

- Negative  $^{89}\text{Zr}$ -girentuximab molecular imaging suggests benign or non-ccRCC
- CAIX IHC staining confirms absence of ccRCC



**6 cm Oncocytoma**  
CA-IX PET negative – CA-IX IHC negative

Illustrative case study only. Individual outcomes may vary.

# Scintimun: Scintigraphic imaging of osteomyelitis

Approved and marketed in over 30 countries in Europe and Rest of World

## Product candidate

$^{99m}\text{Tc}$ -besilesomab, also known as TLX66-CDx

## Targeting molecule / target

Antibody / cluster of differentiation 66

## Indication

Approved for imaging osteomyelitis (bone infection)  
Future use as companion patient selection and safety assessment tool for TLX66 ( $^{90}\text{Y}$ -besilesomab)

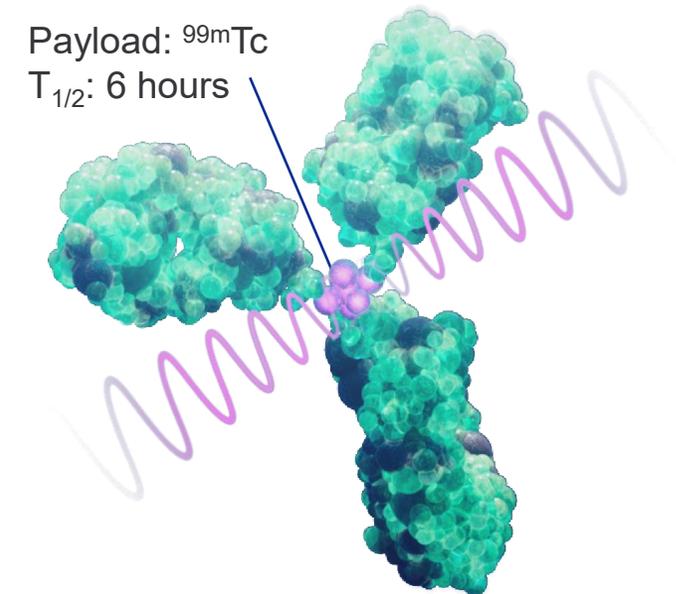
## Clinical experience

Approval based on Phase 3 clinical trial in 22 European centers demonstrating accuracy and tolerability in the diagnosis of peripheral bone infections

## Product status

Marketing authorization granted in Europe / Rest of World (33 countries)

U.S. market feasibility assessment underway for several high-value indications



# Q&A

# Therapeutics

**Richard Valeix**  
**CEO, Therapeutics**



# Therapeutics strategy: Building pipeline depth and breadth

Aiming for three pivotal stage assets, advancing next-gen products to expand opportunity

## Urology: prostate and kidney

Progress multiple late-stage therapeutics

**β** <sup>177</sup>Lu-TLX591  
Potential first radiolabelled antibody (rADC)<sup>1</sup> in mCRPC<sup>2</sup> offering differentiated profile

**β** <sup>177</sup>Lu-TLX250  
Potential first radiotherapeutic (rADC) in metastatic ccRCC

## Brain and rare cancers

**β** <sup>131</sup>I-TLX101  
Potential first systemic radiotherapy in glioblastoma

## Pan-tumor

Advance next-generation platform

**α** <sup>225</sup>Ac-TLX592  
Follow-on Actinium-225 labelled antibody (rADC) as additional radiopharmaceutical option in mCRPC

**β** <sup>153</sup>Sm-TLX090  
Novel bone metastases pain palliation

**α** <sup>211</sup>At-TLX102  
Follow-on opportunity with Astatine-211 alpha emitter

**α** TLX300  
Potential first-in-class radiotherapeutic in soft-tissue sarcoma

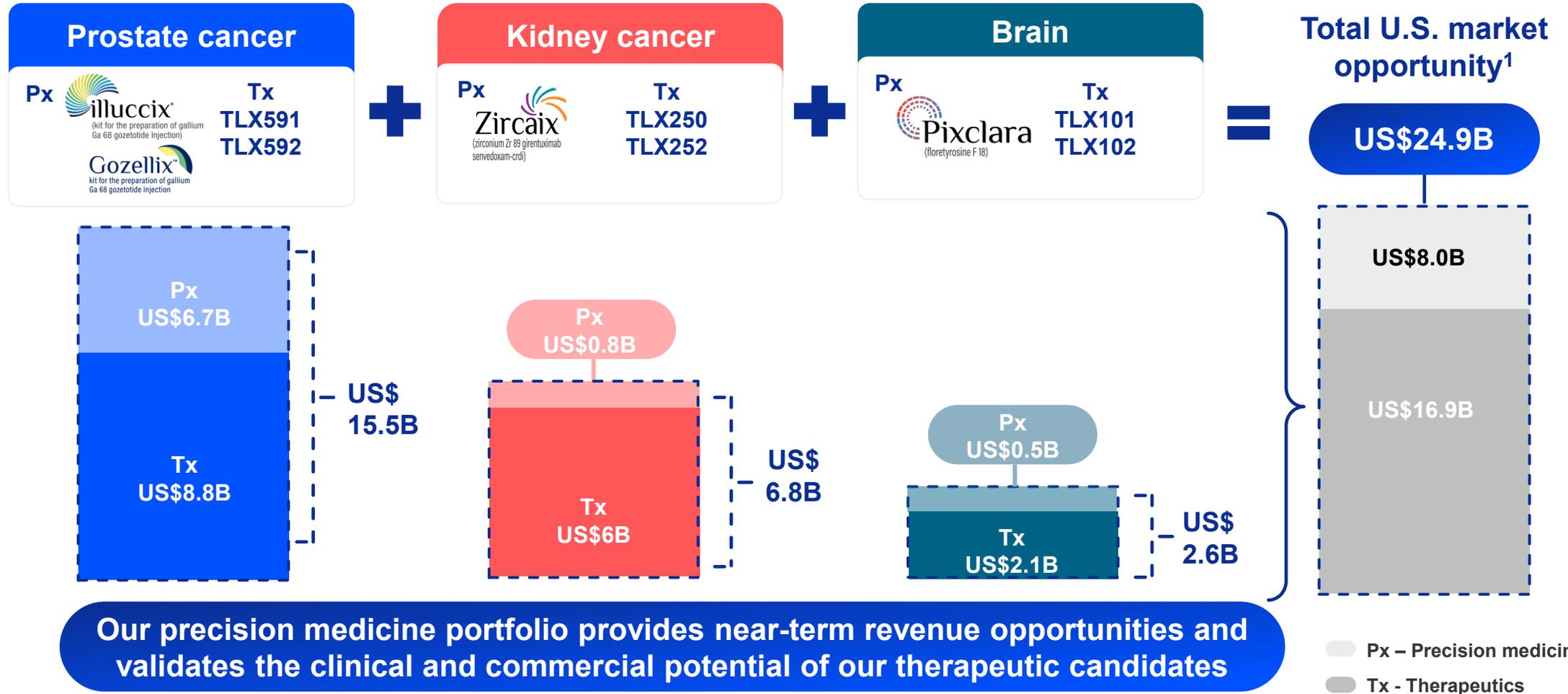
**β** <sup>177</sup>Lu-TLX400  
Next generation FAP<sup>3</sup>-targeting therapy with pan-tumor potential

**α** <sup>225</sup>Ac-TLX252  
Actinium-225 labelled antibody expanding to CAIX-expressing tumors across diseases

1. Radio antibody-drug conjugate.
2. Metastatic castrate resistant prostate cancer.
3. Fibroblast-activated protein.

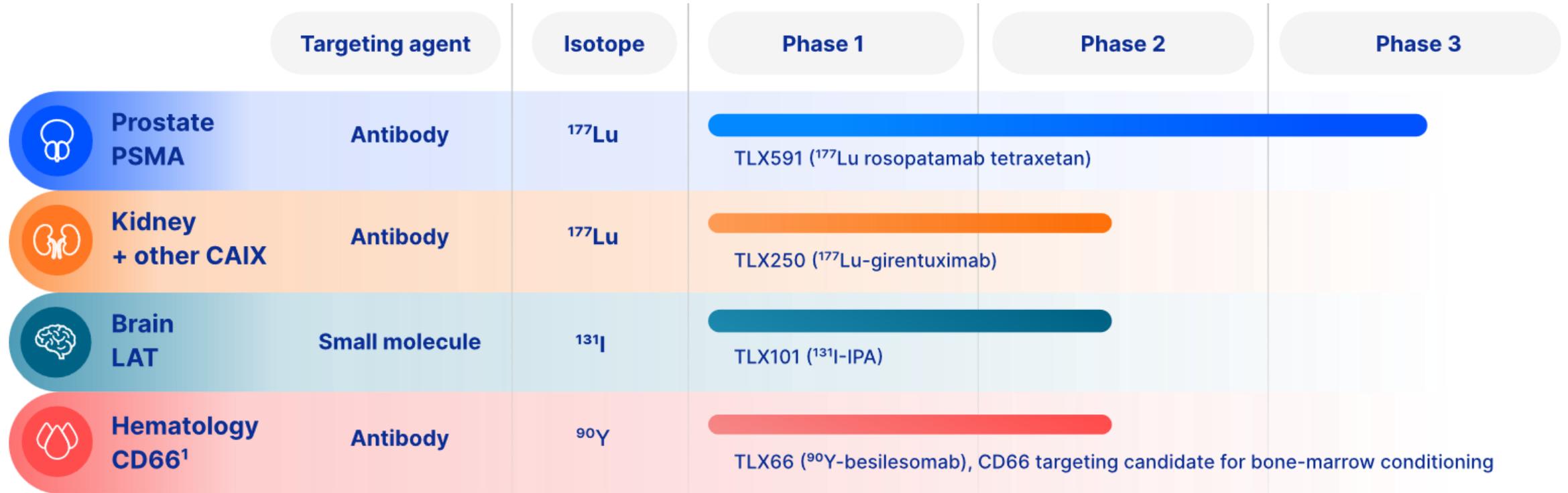
# Expanded opportunity across the pipeline

High unmet medical need, significant potential value creation



Pixclara and Zircaix brand names subject to final regulatory approval.  
 1. Management estimate for 2025 based on latest incidence and pricing models.

# Late-stage pipeline



# Early-stage pipeline

## “Next generation” products

	Targeting agent	Isotope	R&D	Pre-clinical	Clinical (Ph 0/1)
 Prostate PSMA	Antibody	$^{225}\text{Ac}$ (alpha)	TLX592 ( $^{225}\text{Ac}$ -RADmAb <sup>®</sup> )		
 Kidney + other CAIX	Antibody	$^{225}\text{Ac}$ (alpha)	TLX252 ( $^{225}\text{Ac}$ -girentuximab)		
 Bladder FAP	Small molecule	Undisclosed	TLX400 (New in-license)		
 Brain LAT	Small molecule	$^{211}\text{At}$ (alpha)	TLX102 ( $^{211}\text{At}$ -APA)		
 Musculo- skeletal	Antibody	Undisclosed	TLX300 (-olaratumab), PDGFR $\alpha$ <sup>1</sup> targeting candidate for soft tissue sarcoma		
	Small molecule	$^{153}\text{Sm}$	TLX090 ( $^{153}\text{Sm}$ -DOTMP), bone-seeking agent for bone metastases and pain palliation		

# Momentum across the therapeutics pipeline

## Upcoming catalysts



# Urologic oncology:

Innovation across multiple  
therapeutic settings



# TLX591: First-in-class rADC for advanced prostate cancer

## A differentiated approach in the emerging field of PSMA therapy

### Product candidate

TLX591 (<sup>177</sup>Lu-rosopitamab tetraxetan)

### Targeting agent / target

Antibody /

Prostate-specific membrane antigen

### Indication

Metastatic castrate-resistant prostate cancer (mCRPC)

### Clinical experience to date

- 242 pts, 8 Phase 1 and 2 trials<sup>1</sup>
- ProstACT Select study demonstrated safety profile and biodistribution<sup>2</sup>
- Encouraging efficacy signal
  - Median rPFS 8.8 mos<sup>3</sup>

### Clinical trials



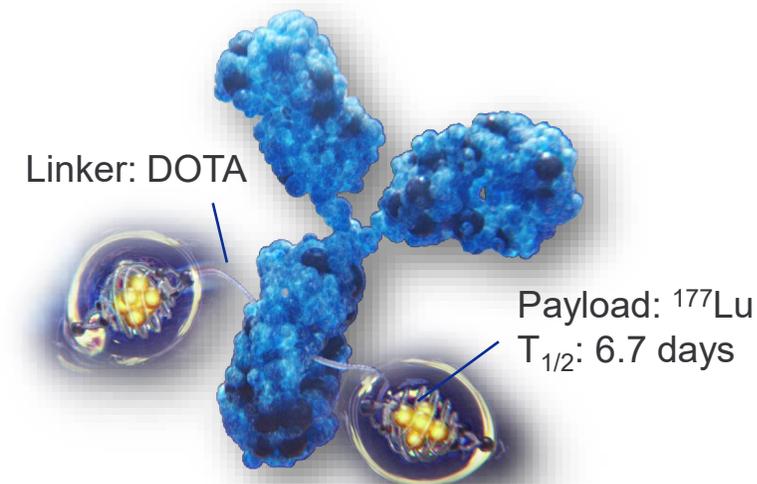
- **Phase 3** ProstACT Global trial dosing patients in ANZ and U.S.
- ClinicalTrials.gov ID: [NCT06520345](https://clinicaltrials.gov/ct2/show/study/NCT06520345)

### Upcoming milestones

- ProstACT Global Part 1 interim readout (safety and dosimetry)



**Scott T. Tagawa, MD**  
Professor of Medicine  
and Urology, Weill  
Cornell Medicine (NY)



*“Latest data provides further evidence of the long retention and internalization of TLX591 in the tumor (and metastases), which may maximize the cell-killing effect of the <sup>177</sup>Lu radioisotope at the site of the tumor.”*

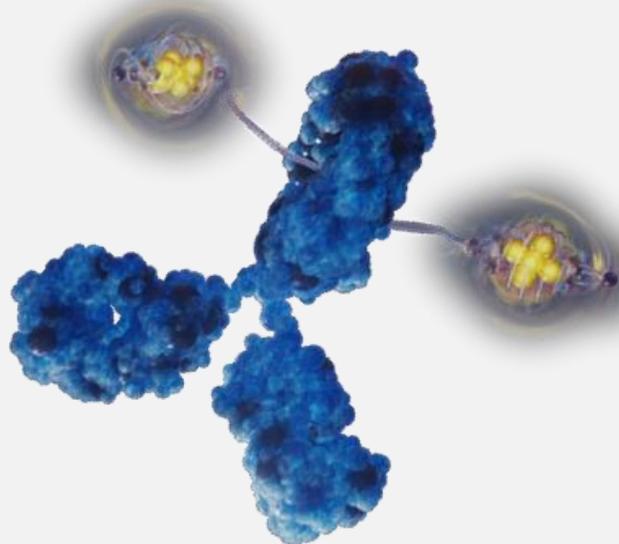


1. Bander et al. *J Clin Oncol.* 2005; Tagawa et al. *Clin Cancer Res.* 2013; Tagawa et al. *Cancer.* 2019; Batra et al. *Urol Oncol.* 2020; Niaz et al. *Oncologist.* 2020.  
2. Telix ASX disclosure 19 October 2023. ClinicalTrials.gov ID: [NCT04786847](https://clinicaltrials.gov/ct2/show/study/NCT04786847)  
3. Telix ASX disclosure 31 May 2024.

# TLX591: Novel PSMA therapy addressing key unmet needs

Potential to overcome limitations of small molecule approach

Lutetium (<sup>177</sup>Lu)  
rosopatamab tetraxetan



## MOA<sup>1</sup>

mAbs are distinguished by their internalization, long retention & functional selectivity

## SURVIVAL

42.3 months median OS demonstrated in early studies<sup>2</sup>

## DOSING

Simple 2-dose regimen. Lower cumulative radiation exposure (152 mCi v 1200 mCi)

## QoL<sup>3</sup>

Limited off target side effects: renal toxicity, dry mouth, dry eye, ganglia irritation. Predictable hematological response<sup>4</sup>

1. Mechanism of action.

2. Tagawa, et al. *Cancer*. 2019 (Open label, single-arm Phase 1/2 clinical trial in 17 patients with advanced mCRPC).

3. Quality of life.

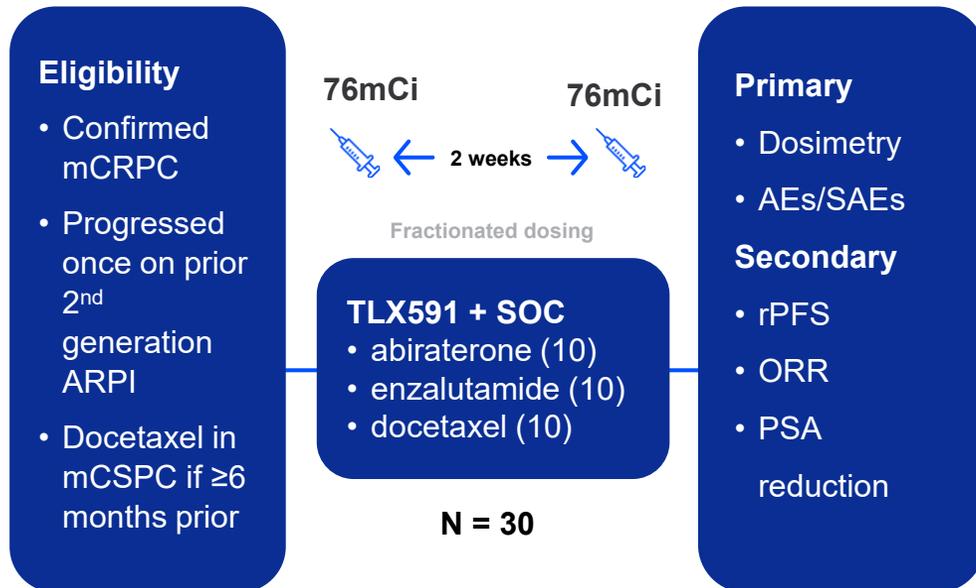
4. ProstACT SELECT data on file.

# ProstACT Global trial<sup>1</sup>

## Design and status update

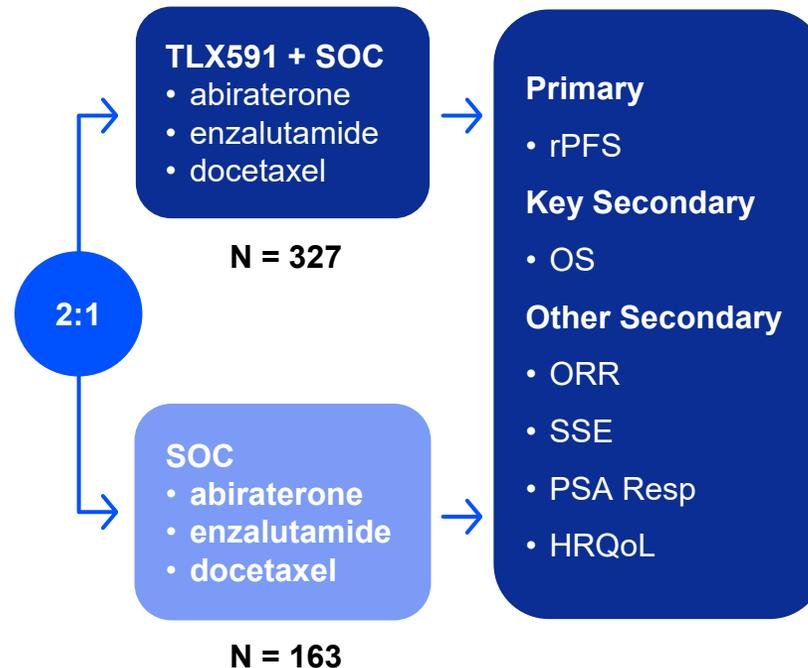


### Part 1: Dosimetry & Safety Lead-In (n = 30)



Characterize biodistribution & safety profiles of TLX591 + SOC combinations

### Part 2: Randomized Treatment Expansion (n = 490)



Interim Analysis

**Upcoming catalyst:**  
Part 1 readout (safety and dosimetry)



1. ClinicalTrials.gov ID: [NCT06520345](https://clinicaltrials.gov/ct2/show/study/NCT06520345).

# **KOL perspective: TLX591**

**Oliver Sartor, MD**

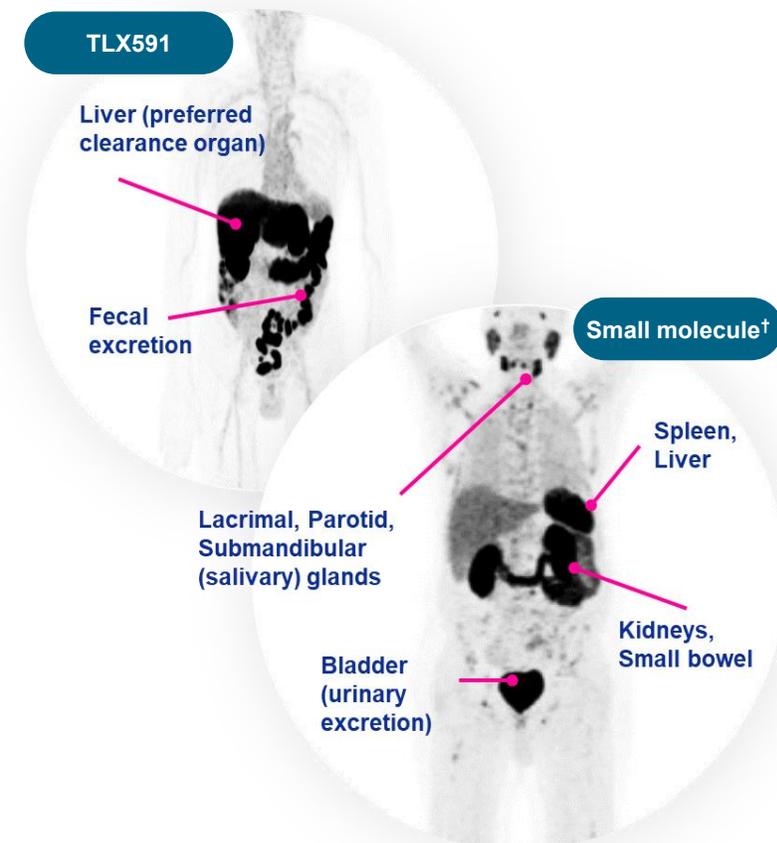
**Director of Transformational  
Prostate Cancer Research  
LCMC Hospitals, New Orleans, LA**



# TLX591 rADC vs small molecule RLT characteristics

Key differences underpin PSMA tumor targeting, internalization, retention

	rADC	RLT
Radiopharmaceutical description	TLX591 <sup>1-4</sup>	Small Molecule <sup>5</sup>
Recommended adult dose	2 x 76 mCi (14 days apart)	6 x 200 mCi <sup>6</sup> (6 weeks apart)
Molecule size	Antibody Large (mw ~150,000)	Peptide Small (mw ~1200)
Terminal Half-Life (t <sub>1/2</sub> )	5.6 days	1.7 days
Off-tumor organ diffusion exposure	Liver, spleen	Salivary glands, GI tract, kidneys, other sites
Excretion route and time	Hepatic 80% cleared within 44+/-15 hours	Renal ~70% excreted in 12 hours



rADC = radio-Antibody Drug Conjugate, RLT = Radio-ligand therapy, PSMA = Prostate specific membrane antigen, mw = molecular weight, GI = gastrointestinal

1. Sartor O, et al. Presented at: American Society of Clinical Oncology Annual Meeting; May 31-June 4, 2024; Chicago, IL. TPS5115. 2. Sun M, et al. *Curr Oncol Rep.* 2021;23(5):59.

3. Data on file. Telix Pharmaceuticals Limited. 4. Tagawa ST, et al. *Cancer.* 2019;125(15):2561-2569. 5. Lu177-PSMA617. Prescribing information. 2022. Novartis Pharmaceuticals Corp. 6. 177Lu-PSMA-617 prescribing information. Administered every 6 weeks for up to 6 treatments, solution for injection contains 200 mCi (7.4 GBq) at time of use.

# Patient pain points and unmet needs

TLX591 has the potential to overcome current challenges

## Patient burden

6 infusions over 30 weeks →

**Clinical burden**

High off-target organ diffusion →

**Dry mouth, renal toxicity**

Emerging PSMA RT standard of care (<sup>177</sup>Lu-PSMA-617) still leaves room to improve efficacy, tolerability, & dosing regimen

## Why TLX591? Three core differentiators

2-dose regimen (14 days apart) reduces clinic visits

Hepatic clearance avoids renal dosimetric problems

Antibody avoids salivary gland uptake

# TLX591 targeting unmet needs for mCRPC patients



<sup>177</sup>Lu-PSMA-617 peptide therapy approved but ...

- Opportunity to improve on efficacy
- Opportunity to reduce off-target organ diffusion to improve tolerability
- Opportunity to improve patient dosing regimen and radiation exposure



**TLX591 target initial patient population:**  
55k incident U.S. mCRPC patients per annum<sup>1</sup>, ARPI and taxanes as current SoCs

Metastatic castrate-resistant  
1L treatment

2L+ treatment

**ProstACT Select** Phase 1 dosimetry & biodistribution

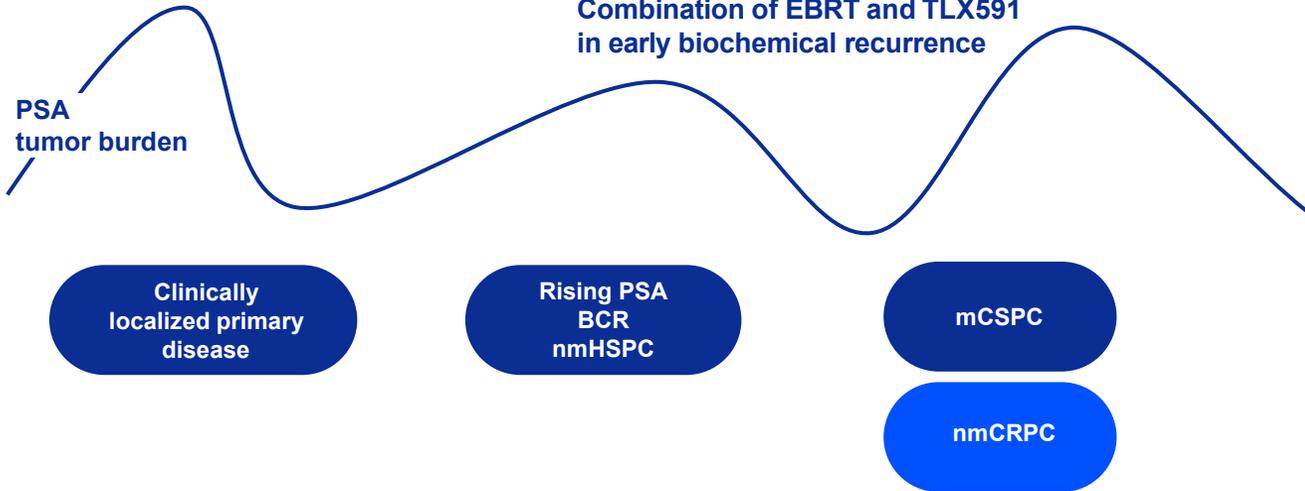
**ProstACT Global** Phase 3 in PSMA+ mCRPC patients previously treated with ARPI therapy  
**TARGET PATIENT POPULATION**

Abiraterone enzalutamide docetaxel	Abiraterone enzalutamide docetaxel	Cabazitaxel docetaxel re-challenge <sup>177</sup> Lu-PSMA-617	Carboplatin
<b>mCRPC 1<sup>st</sup> Line</b>	<b>mCRPC 2<sup>nd</sup> Line</b>	<b>mCRPC 3<sup>rd</sup> Line</b>	<b>mCRPC 4<sup>th</sup> Line</b>

**PSMAfore / SPLASH / Eclipse**      **VISION**

Combination of EBRT and TLX591 in early biochemical recurrence

PSA tumor burden



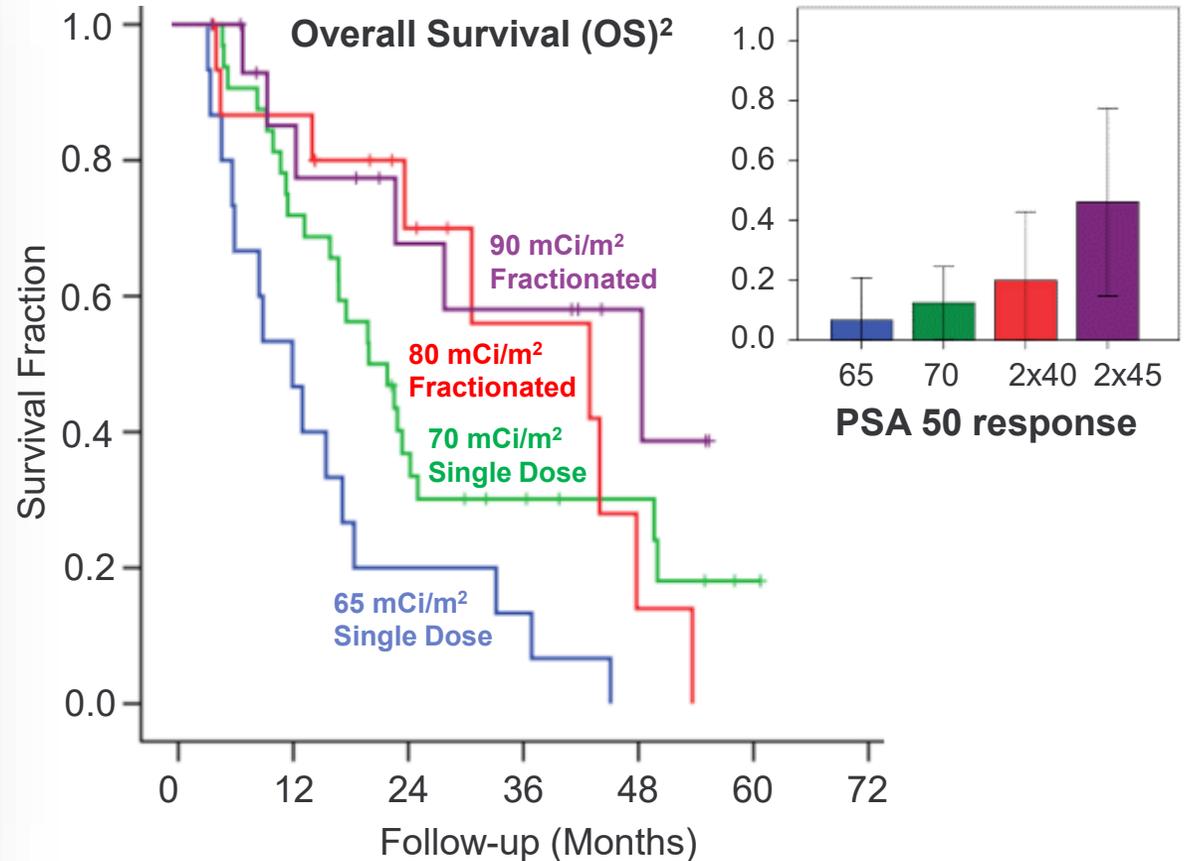
Adapted from Calais J. UCLA 2023 EANM 2023; NCCN Guidelines Version 4.2023 Category 1 Preferred Scher 2015, PLoS1; Nezoslosky 2018, Journal of Clinical Oncology; ASCO Cancer.NET, Prostate Cancer Statistics, accessed November 2023.

# Demonstrated anti-tumor effect and overall survival benefit<sup>1,2</sup>

## Clinical development and current efficacy data

- To date: evaluated in 242 prostate cancer patients in eight Ph1/2 studies
- Evidence of anti-tumor effect and a clear dose-response profile for key measures of efficacy
  - Prostate-specific antigen (PSA) response
  - Overall survival (OS) – **published 42.3 months** median survival in end-stage (heavily pre-treated) patients<sup>1</sup>
- Well-tolerated with predictable and transient hematological toxicity, with subsequent recovery

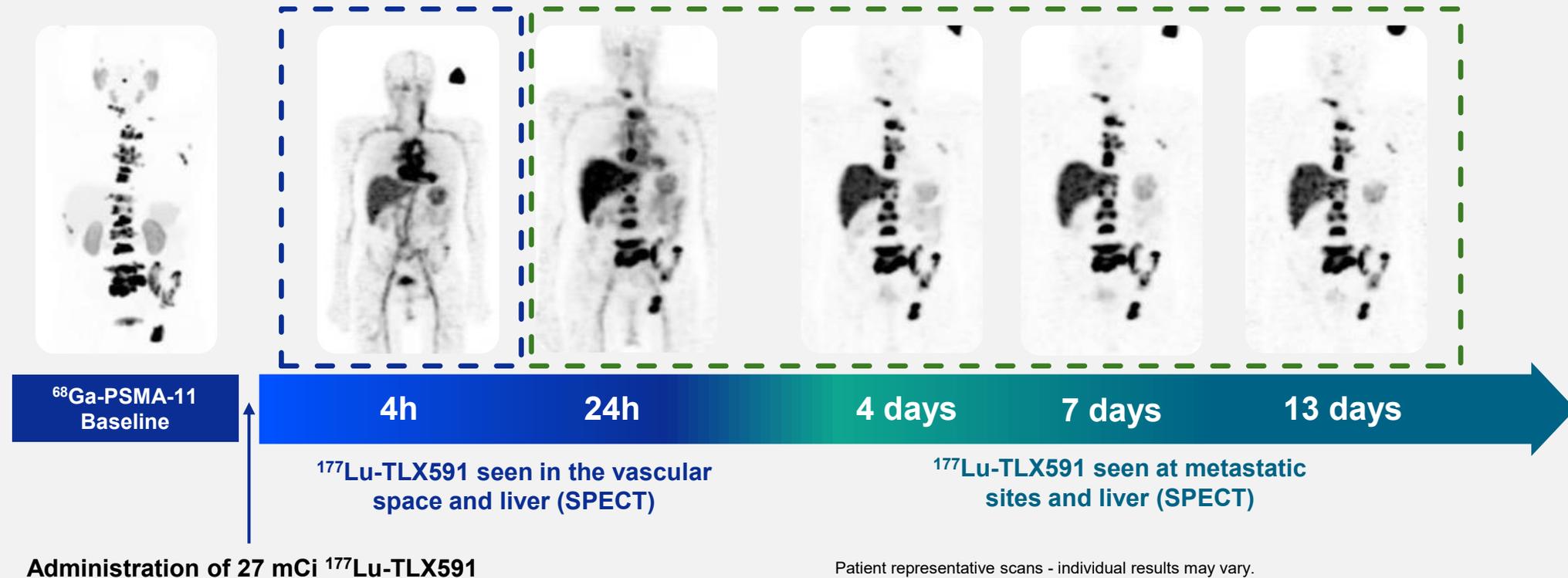
**Fractionated dosing manages hematologic safety while delivering a highly targeted and potent radiation dose to prostate cancer metastases**



# Initial biodistribution

TLX591 in the blood is rapidly cleared by the liver

Distribution of  $^{177}\text{Lu}$ -TLX591 over 13 days<sup>1\*</sup>



**Abbreviated ProstACT SELECT study design:** A phase 1 study (N=28) to evaluate the safety, tolerability, biodistribution, and dosimetry of  $^{177}\text{Lu}$ -TLX591 in patients with PSMA-expressing mCRPC<sup>2</sup>.

\*Scans of high disease burden patient with mCRPC from ProstACT SELECT<sup>1</sup>.

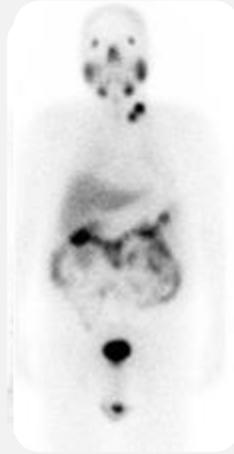
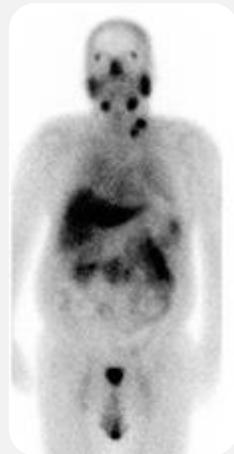
$^{68}\text{Ga}$ =gallium 68;  $^{177}\text{Lu}$ =Lutetium-177; mCRPC=metastatic castration-resistant prostate cancer; PSMA=prostate specific membrane antigen.

1. Data on File. Telix Pharmaceuticals Limited. 2. Lenzo N, et al. *J Nucl Med*. 2024;65(suppl 2). Abstract 241503.

# Biodistribution: $^{177}\text{Lu}$ -PSMA-617

## Distribution of $^{177}\text{Lu}$ -PSMA-617 over 5 days<sup>1</sup> (SPECT)

Early uptake is seen in the salivary glands and bladder, as well as within metastatic lesions in the neck and abdomen



4h

24h

2 days

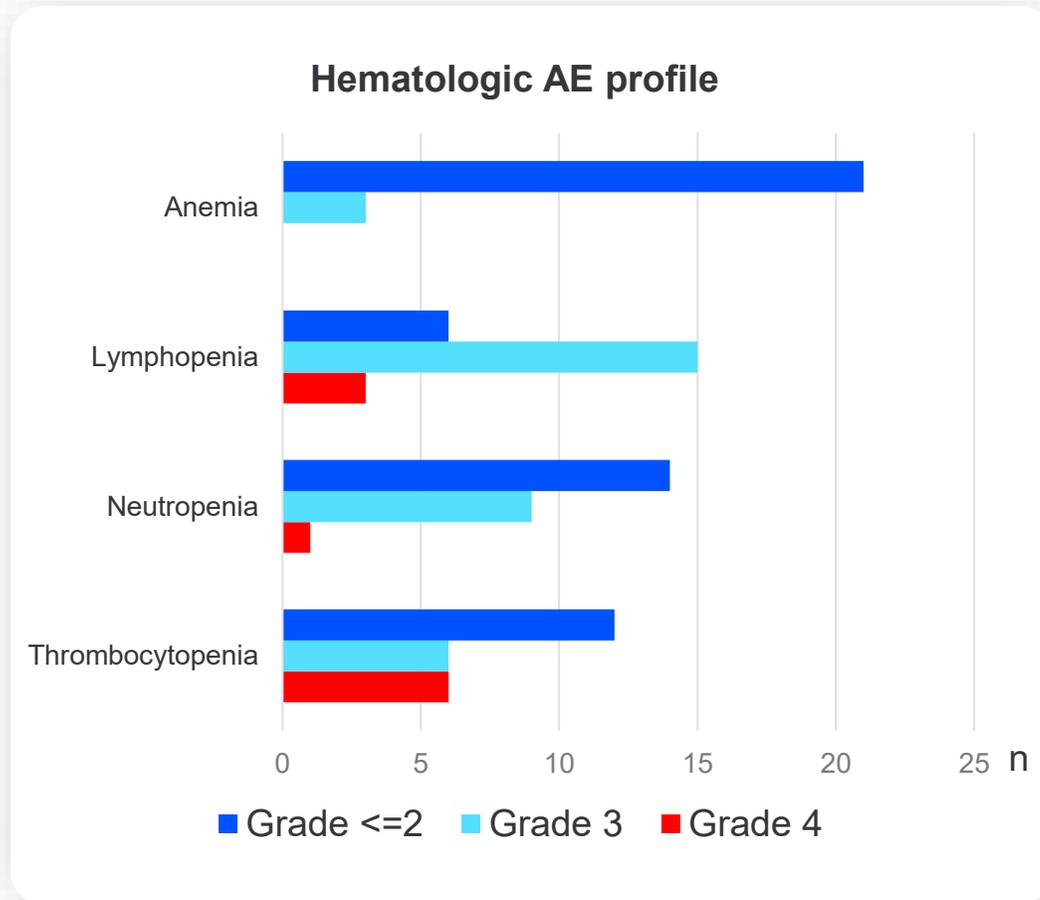
5 days

Administration of  $^{177}\text{Lu}$ -PSMA-617

Patient representative scans - individual results may vary.

# Recap: Safety data reported from ProstACT SELECT study<sup>1</sup>

## Safety and tolerability profile



## Hematologic laboratory profile

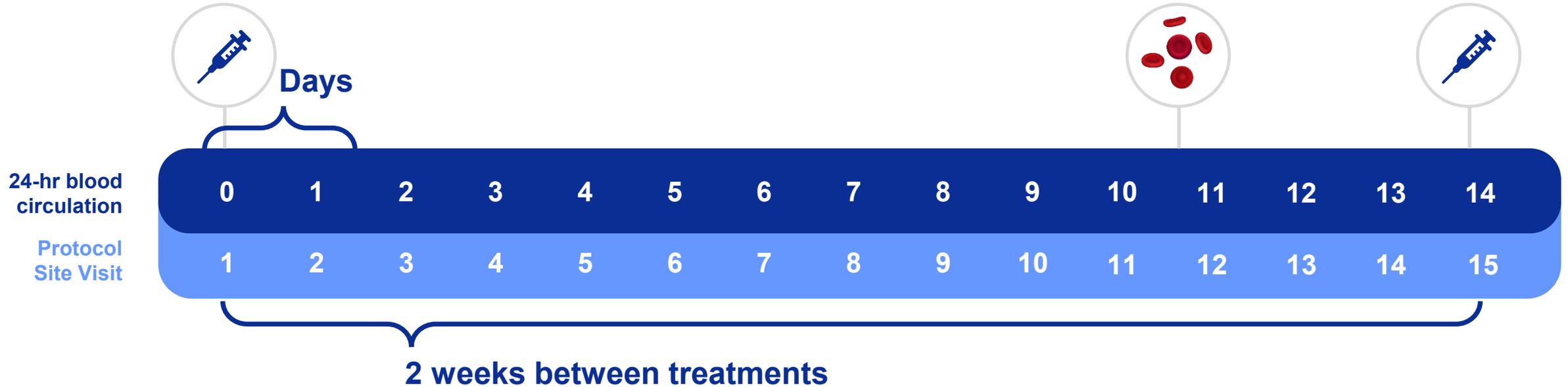
- Grade 3 thrombocytopenia (25%) and neutropenia (38%) events in line with profile expected for this class of therapy
- Grade 4 thrombocytopenia (25%) and neutropenia (4%) were transient
- Four patients (17%) received intervention for hematologic toxicity in the form of platelets, growth factors or both

## Non-hematologic events

- All drug-related non-hematologic events were grade 1 or grade 2
- The most prevalent non-hematological adverse events were fatigue (76%), nausea (20%) and loss of appetite (20%)

# Dosing regimen for TLX591

Designed to manage hematologic toxicity



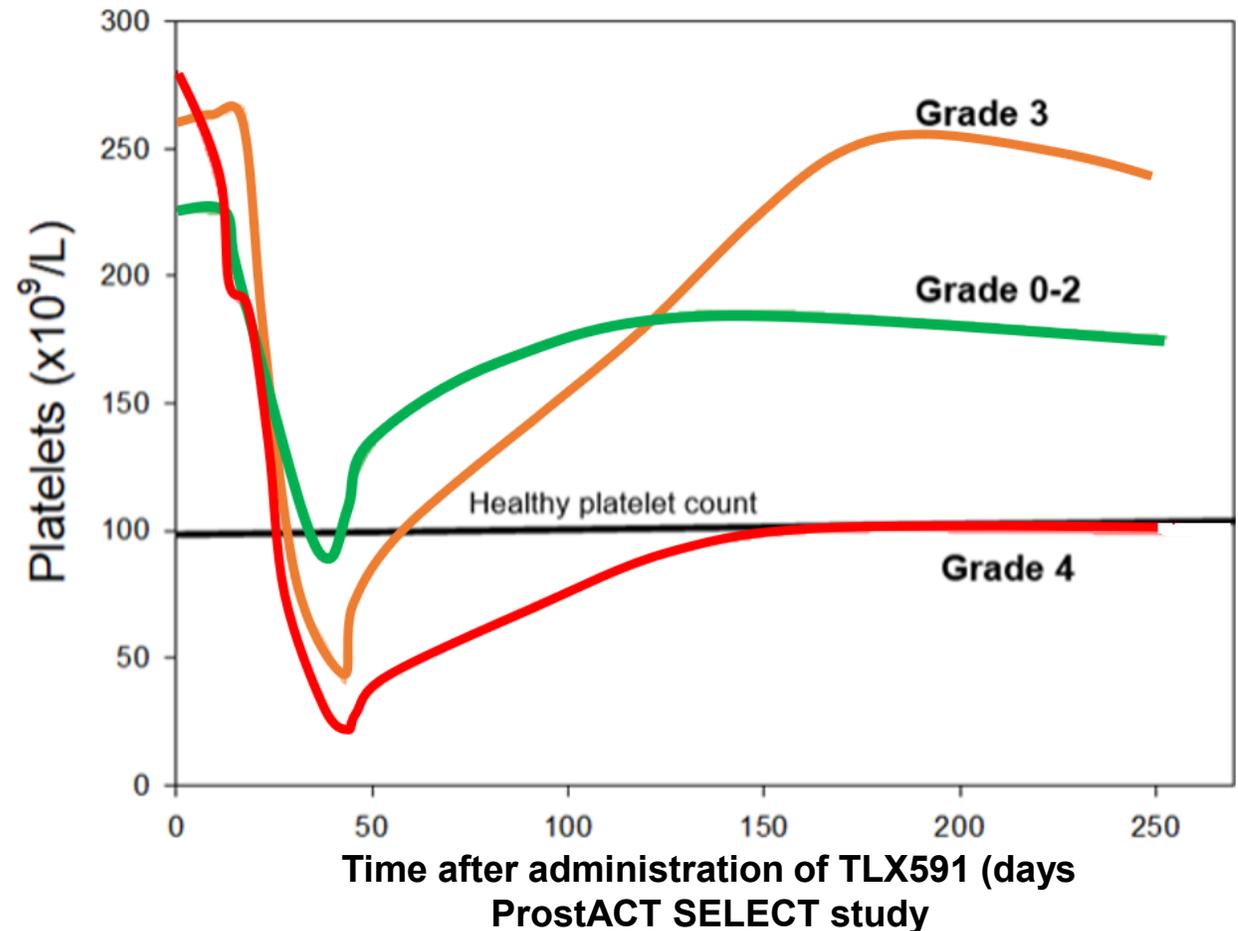
- Day 0 TLX591 solution for injection
  - **SKU1** 2.8 GBq (76 mCi)
- 2 treatments administered 14 days apart
- Hematological assessment (day 11)\* (Grade 2 & Grade 3 AEs for Thrombocytopenia, Anemia, Neutropenia)
- Slow intravenous (IV) injection (5 to 15 minutes)
- Day 14 TLX591 solution for injection
  - **SKU2 50% reduction** 38 mCi (equivalent to an administered activity of 22.4 mCi/m<sup>2</sup> in a 1.7m<sup>2</sup> individual)

# Hematologic profile is predictable and consistent

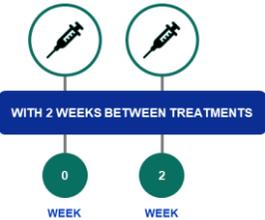
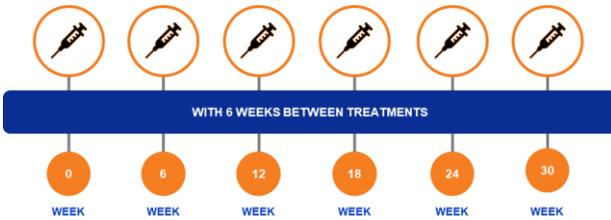
Data suggests manageable hematologic toxicity profile<sup>1</sup>

## Hematological safety profile

- The change in platelet count following the administration of TLX591 was predictable, transient and manageable
- Consistent with prior clinical experience across multiple Phase 1 and 2 studies
- No patient treated with two therapeutic doses of TLX591 was discontinued from study due to adverse events



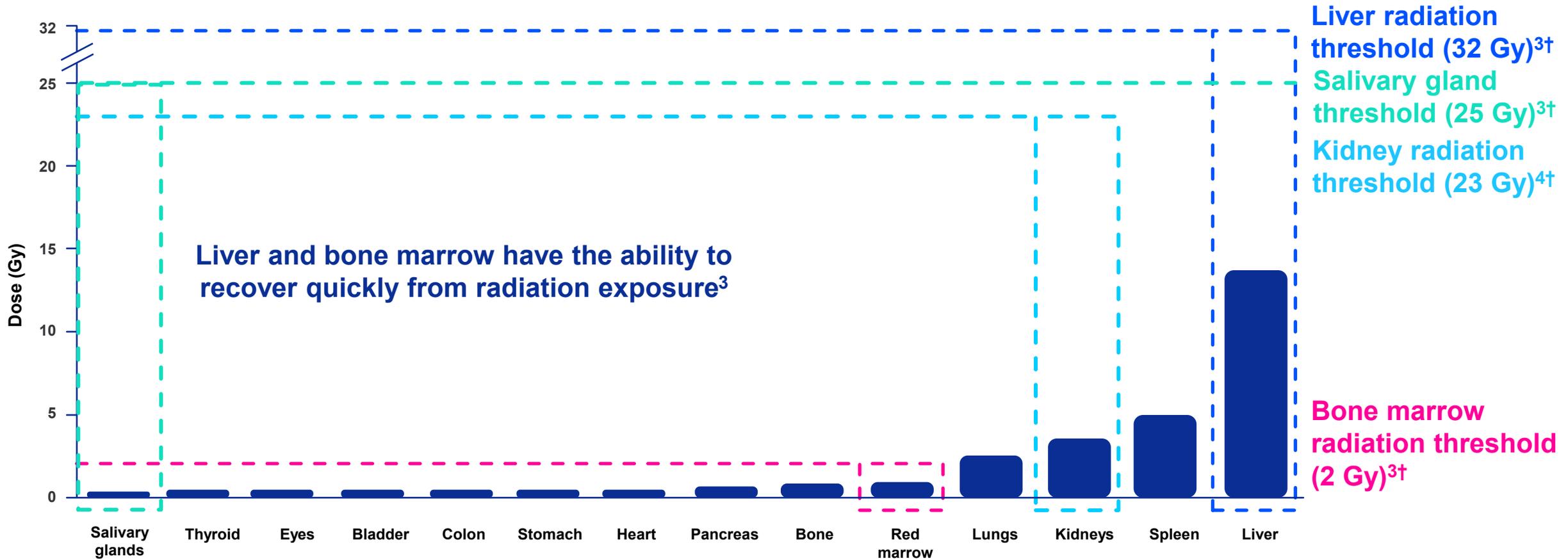
# Cumulative injected activity

	mCRPC Tx Setting	Dose per Treatment	Administration	Total Tx Period	Cumulative Radiation Exposure	Patient Management
<b>TLX591</b>	1L / 2L	76 mCi	<p>Every 2 wks for 2 cycles</p> 	2 weeks	152 mCi	<ul style="list-style-type: none"> <li>• Treatment room or treatment chair</li> <li>• No special toileting required</li> <li>• Minimal safety requirements post treatment<sup>1</sup></li> </ul>
<b><sup>177</sup>Lu-PSMA-617</b>	1L / 2L 3L+	200 mCi	<p>Every 6 wks for up to 6 cycles</p> 	30 weeks	1200 mCi	<ul style="list-style-type: none"> <li>• Increase oral fluids, frequent urinary voiding to reduce bladder irradiation</li> <li>• Treatment room with dedicated adjacent bathroom</li> <li>• Minimize close contact for 2-7 days<sup>2</sup></li> </ul>



1. Phase 3 ProstACT Global IMP Handling Guide.  
 2. A Comprehensive Guide to Administering Pluvicto

# Liver, kidney and red marrow received radiation doses below recommended thresholds in ProstACT SELECT study<sup>1,2</sup>



**Abbreviated ProstACT SELECT study design:** A phase 1 study (N=28) to evaluate the safety, tolerability, biodistribution, and dosimetry of <sup>177</sup>Lu-TLX591 in patients with PSMA-expressing mCRPC.

\*In cohort 2 of ProstACT SELECT (n=23), patients received 76 mCi of <sup>177</sup>Lu-TLX591 x 2 doses 14 days apart

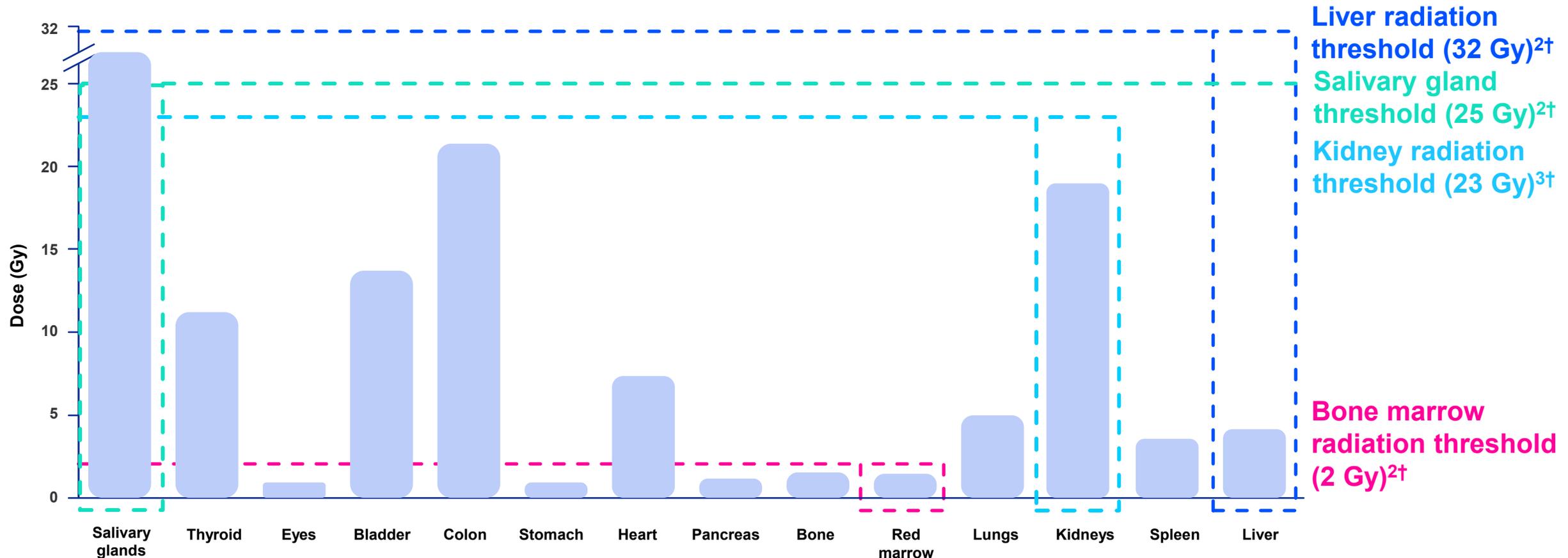
†External beam radiation limits.

1. Data on file. Telix Pharmaceuticals Limited. 2. Lenzo N, et al. *J Nucl Med.* 2024;65(suppl 2). Abstract 241503. 3. Wahl RL, et al. *JNuclMedicine.* 2021; 62 (12, suppl 3): 23S-35

4. <https://www.fda.gov/media/144845/download> 5.



# Liver, kidney and red marrow received radiation doses for $^{177}\text{Lu-PSMA-617}^1$



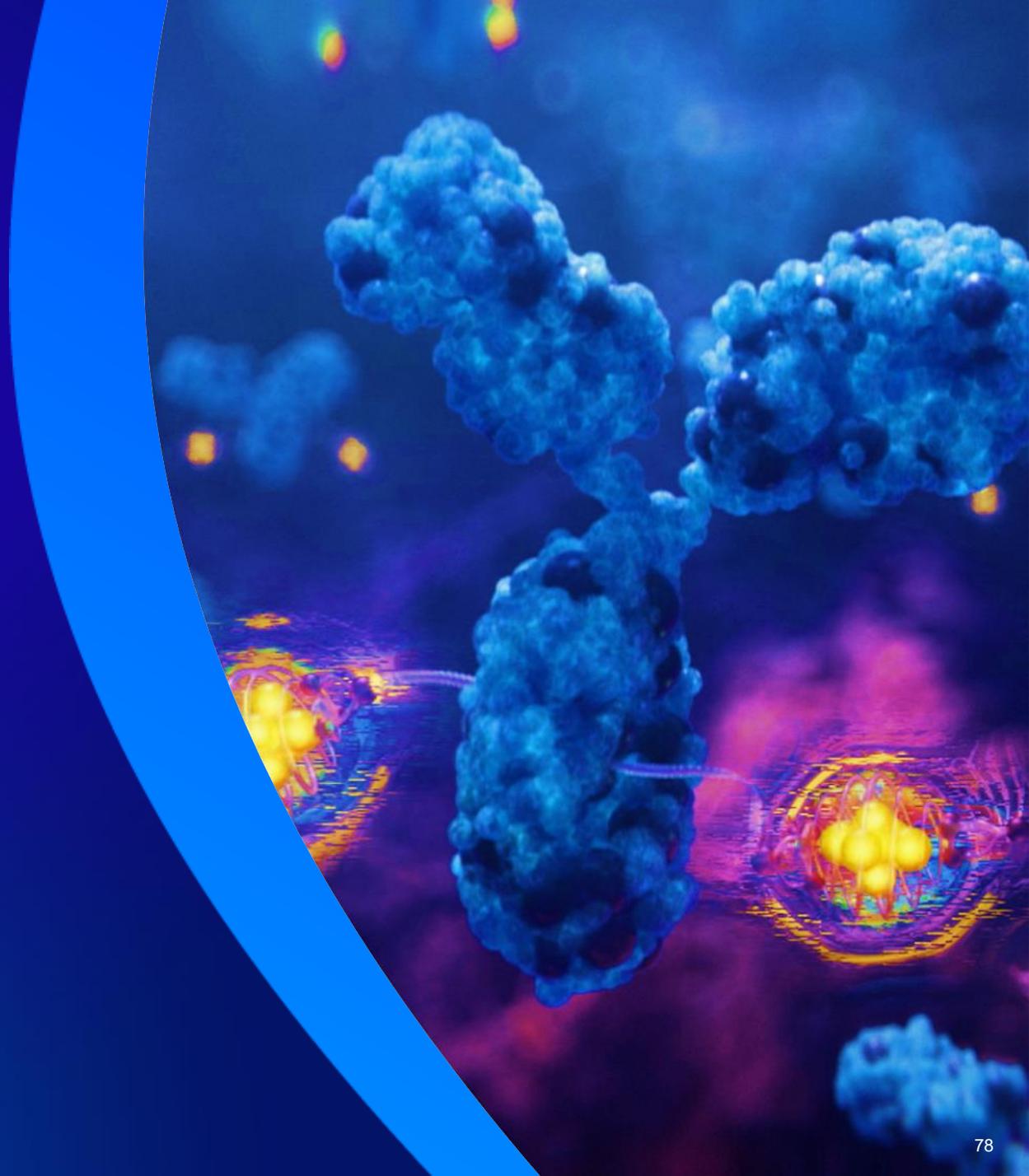
**Abbreviated VISION sub-study design:** A separate substudy (N=30) to evaluate the safety, dosimetry, and biodistribution of  $^{177}\text{Lu-PSMA-617}$  in patients with mCRPC.

1. Herrmann K, et al. *J Nucl Med.* 2024;65(1):71-78. 2. Wahl RL, et al. *J Nucl Med.* 2021;62(12, suppl 3). <https://www.fda.gov/media/144845/download> †External beam radiation limits. Left colon data were used for Lu177-PSMA617. Right colon dosimetry was 14 (8.1-27) Gy.



# Q&A

# TLX592



# TLX592: $^{225}\text{Ac}$ -PSMA therapy leveraging next generation antibody

Safety, PK, and dosimetry demonstrated in the CUPID trial<sup>1</sup>

## Product candidate

TLX592 ( $^{225}\text{Ac}$ -PSMA-RADmAb)

## Targeting molecule / target

Engineered antibody /  
Prostate-specific membrane antigen

## Indication

Metastatic castrate-resistant prostate cancer (mCRPC)

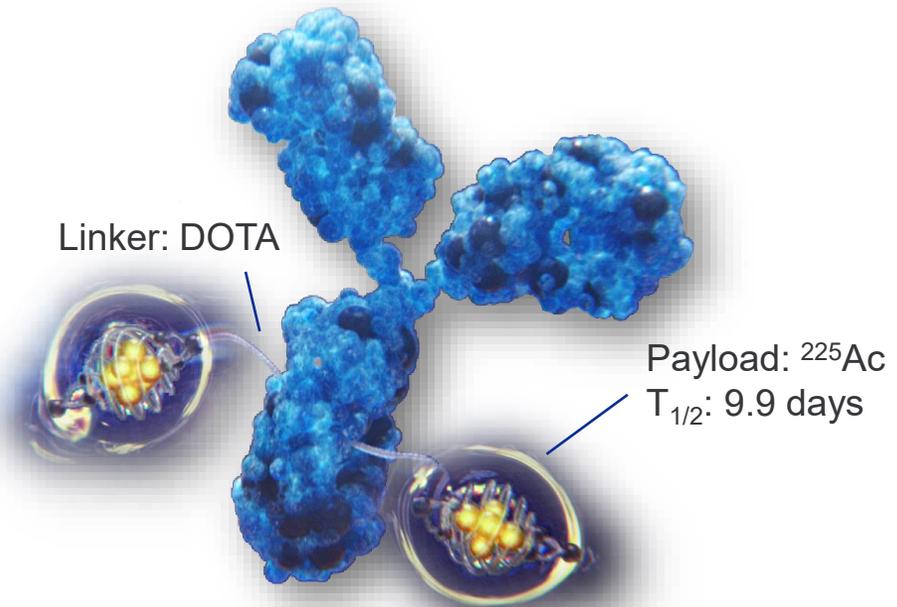
## Clinical experience to date

CUPID Phase 1 Study demonstrated:

- $^{64}\text{Cu}$ -TLX592 clears the blood more rapidly than  $^{177}\text{Lu}$ -rosopitamab with similar biodistribution
- $^{64}\text{Cu}$ -TLX592 had acceptable safe profile and was well tolerated

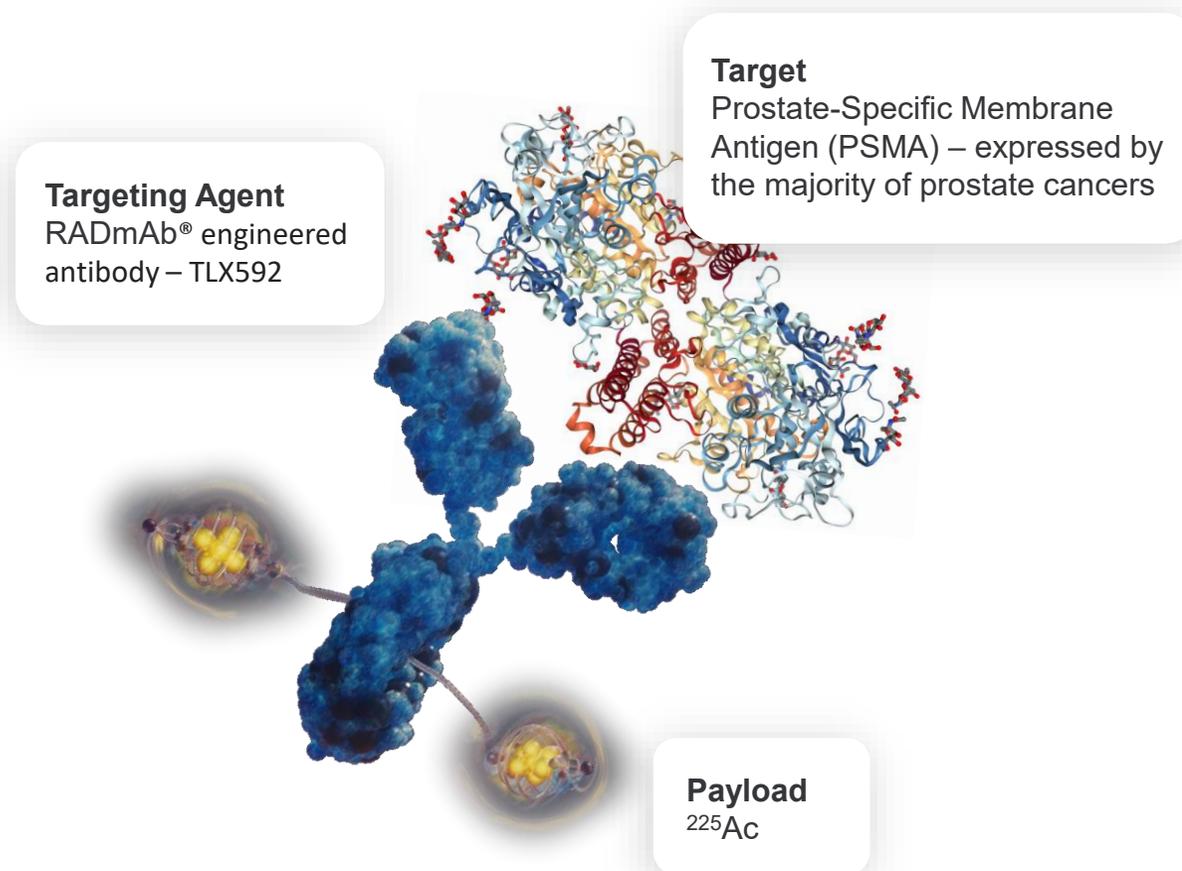
## Clinical trials

- Phase 1/2 first-in-human therapeutic study in planning, anticipated to commenced in H2 2025



# TLX592: Next-generation alpha therapy candidate

Antibody with novel properties to facilitate rapid clearance<sup>1</sup>



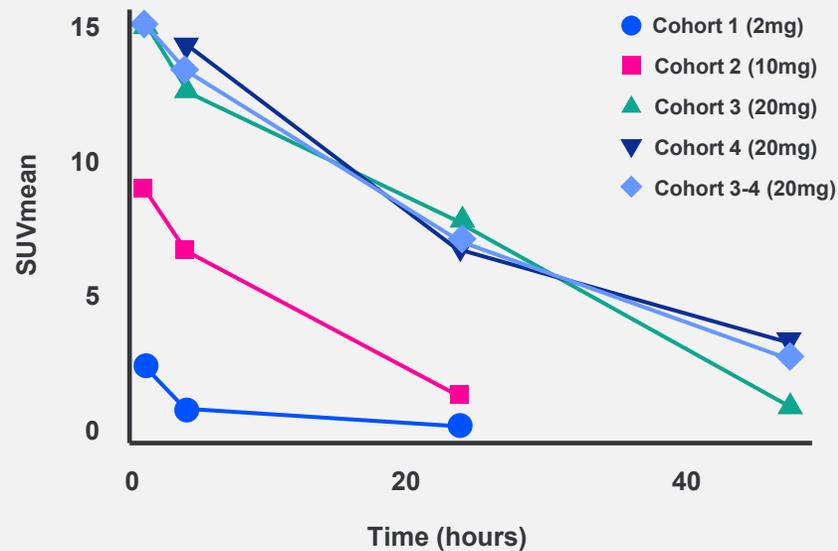
- RADmAb® is a proprietary antibody engineered for use with <sup>225</sup>Ac for targeted alpha therapy
- Designed to have faster elimination from circulation than standard antibodies
- Designed to reduce bone marrow residence time to mitigate hematologic toxicity and retain PSMA-mediated tumor localization and cytotoxic activity
- Designed to be liver-cleared, no exocrine uptake
- **Development status: Phase 1 CUPID proof-of-concept study completed** using <sup>64</sup>Cu (detectable by PET) as a surrogate for <sup>225</sup>Ac; **first-in-human therapeutic study in planning**

# TLX592: Safety profile, pharmacokinetics and dosimetry

## CUPID study data presented at ASCO-GU 2025

### Pharmacokinetics

- $^{64}\text{Cu}$ -PSMA-RADmAb blood clearance rate:  $T_{1/2}=19.86+1.96\text{h}$  at 20 mg
- $^{64}\text{Cu}$ -PSMA-RADmAb biological half-life in blood showed a clear mass dose response

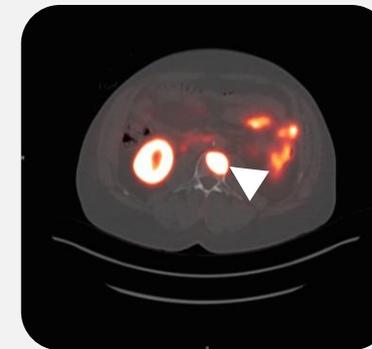


### Absorbed radiation doses

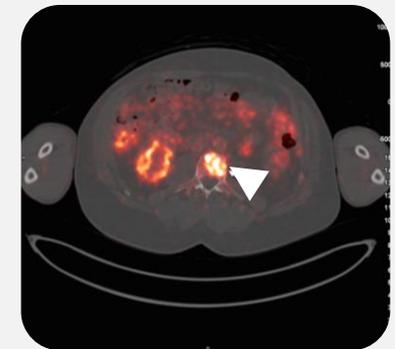
- Whole-body effective dose (mean  $\pm$  SD mSv/MBq):
  - Group 3:  $0.043 \pm 0.007$
  - Group 4:  $0.042 \pm 0.002$
- $^{64}\text{Cu}$ -PSMA-RADmAb uptake in bone lesions in Group 4 correlated with  $^{68}\text{Ga}$ -PSMA-11 uptake ( $r=0.756$ ,  $P=0.003$ ) at 20h timepoint

PET targeting of PC metastasis in L3 lumbar vertebral body (arrow)

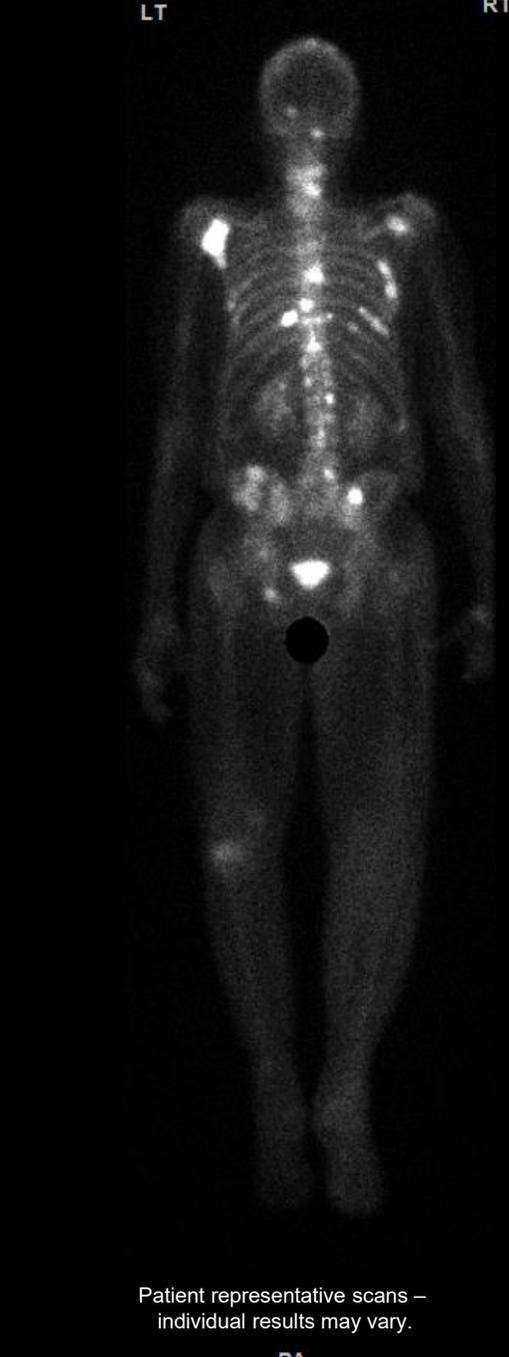
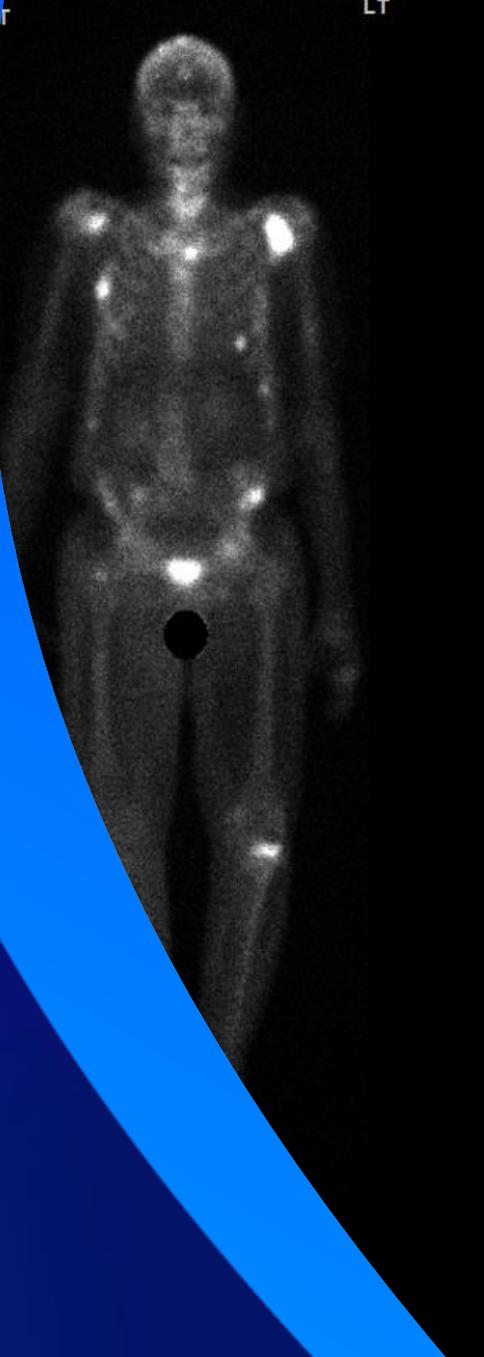
$^{68}\text{Ga}$ -PSMA-11



$^{64}\text{Cu}$ -PSMA-RADmAb (20mg)



Scan after first dose of TLX090



# TLX090



Patient representative scans – individual results may vary.

PA

# TLX090: A proprietary formulation of Samarium-153

## Advancing development as a treatment for metastatic bone pain

### Product candidate

TLX090 ( $^{153}\text{Sm}$ -DOTMP)

FDA Orphan Drug designation

### Targeting molecule / target

Small molecule

Selectively binds to hydroxyapatite in areas of high bone turnover

### Indication

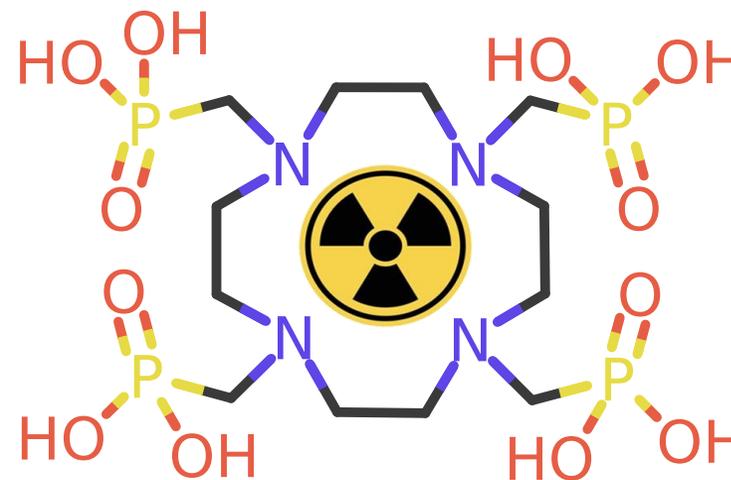
Palliation of bone pain from metastatic prostate cancer or breast cancer

### Clinical experience to date

Phase 1 data demonstrate favorable early safety profile and encouraging efficacy signal

### Current status / planned clinical activity

Phase 1 bridging study targeting commencement in 2025



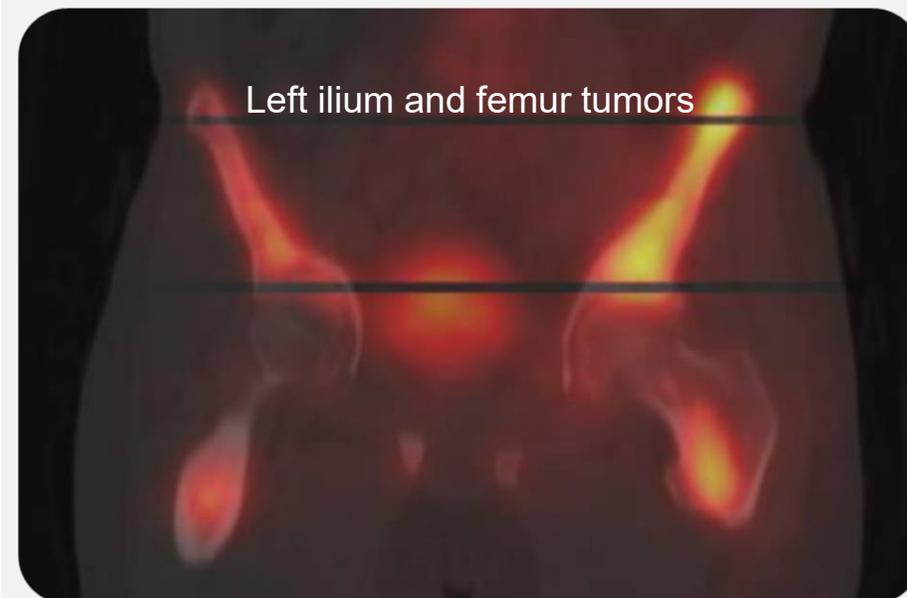
# TLX090: Next-generation, bone-seeking radiopharmaceutical

Advancing development as a treatment for metastatic bone pain

## TLX090 ( $^{153}\text{Sm}$ DOTMP)

- **Bone-seeking small molecule**, proven isotope platform + novel chelator seeks to improve tolerability
- Being developed as a palliative / pain management of bone metastases; future potential therapeutic application(s) in malignancies affecting bone
- Potentially avoids skeletal saturation, leading to lower marrow dose and safe organ clearance; improves potential for safe and repeat dosing to manage pain
- Early studies in pain setting have demonstrated quality of life improvements
- **Phase 1 bridging study targeting commencement in 2025**

### Metastatic Prostate Cancer Patient



Targeted bone tumor uptake clear in SPECT/CT scan; no soft tissue exposure seen

Illustrative example only. Individual outcomes may vary.

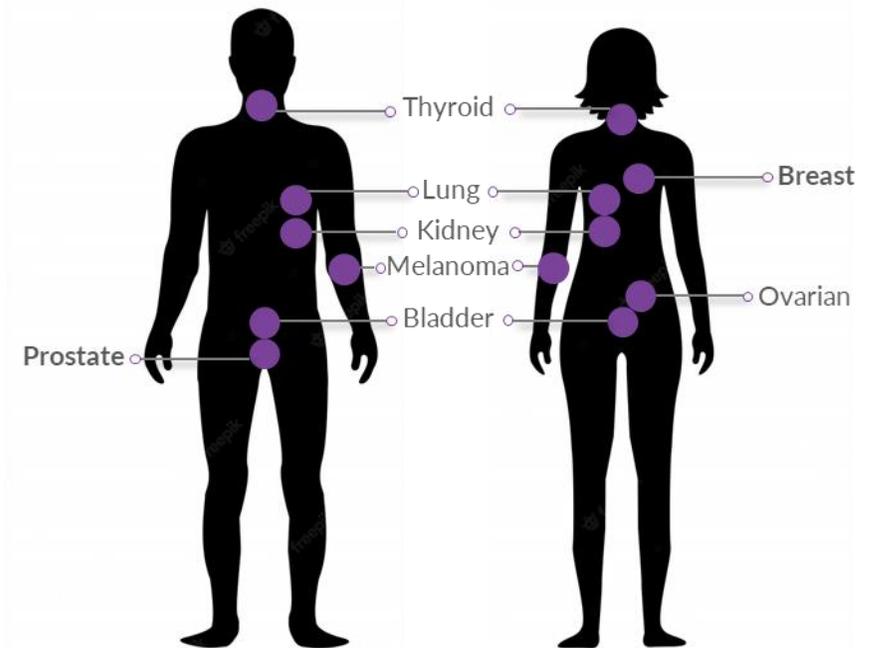
# Clinical utility: Treating metastatic bone pain

## Significant unmet medical need and opportunity to improve quality of life

### Palliative utility (low dose, single dose)

- Patients with multifocal bone metastases often experience severe, persistent pain that significantly impairs quality of life
- Common treatments like opioids, steroids, and bisphosphonates offer only partial relief and carry substantial side effects
- EBRT is localized, logistically demanding, and unsuitable for widespread skeletal disease<sup>1</sup>
- Approx. 80–90% of metastatic prostate cancer patients<sup>2</sup> and 65–75% of metastatic breast cancer patients develop bone lesions<sup>3</sup> often with severe, multifocal pain
- TLX090 may offer a differentiated alternative: Targeted, systemic pain palliation through a single intravenous dose

*Bone metastases occurs when cancer cells spread from their original site to a bone*



# TLX090 Clinical profile

## Phase 1 data demonstrate favorable early safety profile and encouraging efficacy signal

### Pain relief and symptom improvement

- Consistent pain reduction: All patients experienced >20% reduction in pain scores by week 6
- Functional benefit: Anecdotal reports suggest improved mobility
- Opioid reduction: Opportunity to decrease usage of opioids

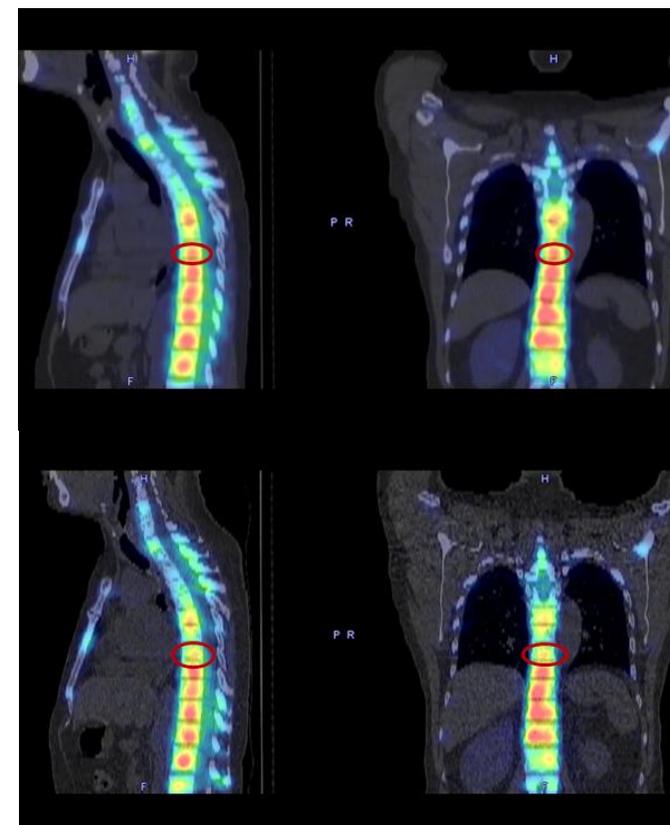
### Favorable safety profile

- Well tolerated: All patients completed treatment without dose-limiting toxicities.
- Minimal hematologic impact: Hematologic toxicities were clinically insignificant
- Stable organ function: No clinically significant changes in liver or kidney function observed

### Isolated adverse events:

- One case of thrombocytopenia in a patient with extensive skeletal metastases (superscan features)
- One Grade 3 QTc<sup>1</sup> prolongation in a patient with pre-existing cardiac comorbidities. No other Grade 3 or 4 adverse events reported

**Patient with mCRPC bone mets treated with TLX090.**  
Tumor shows 19% decrease in absorbed dose within 8 days indicating rapid efficacy.



Illustrative case study only. Individual outcomes may vary.



Data on file. ClinicalTrials.gov ID NCT06008483.

1. Corrected QT interval, a measurement on an electrocardiogram (ECG) that accounts for heart rate variations.

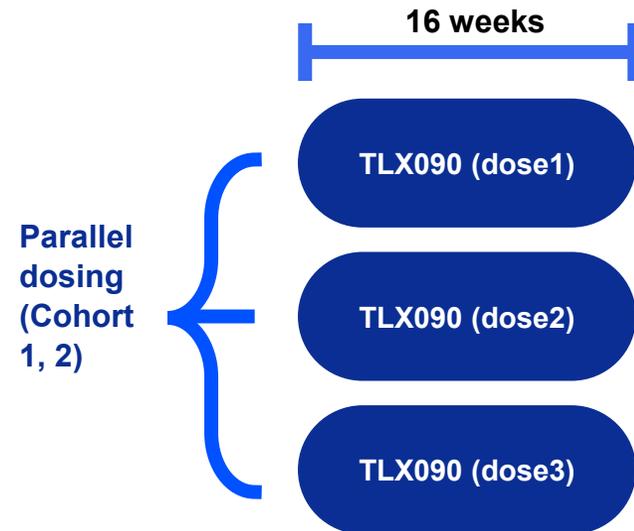
# TLX090 SOLACE trial: Metastatic bone pain



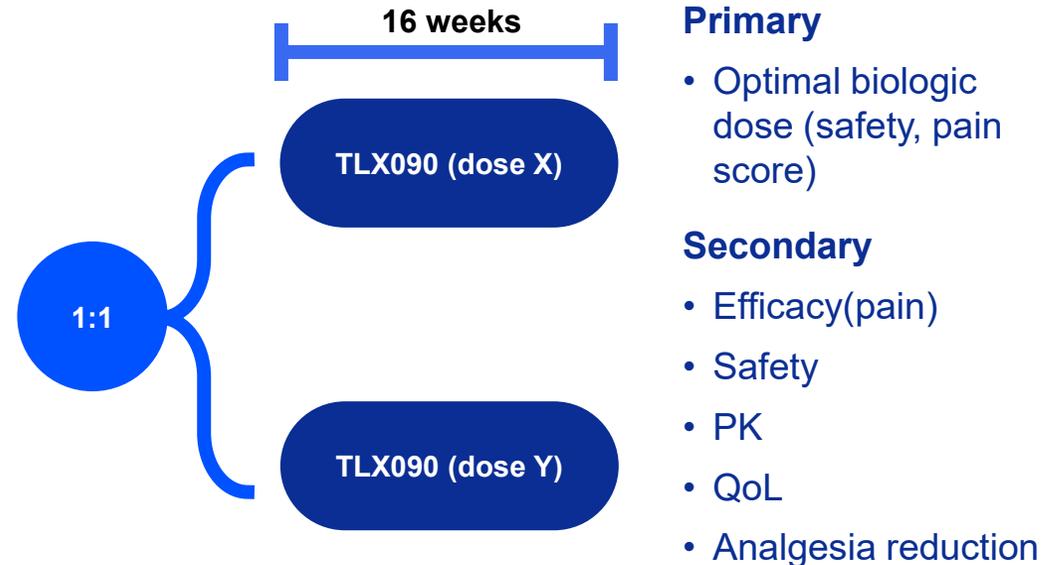
Phase 1 bridging study planned to commence in 2025<sup>1</sup>

Single dose 153-Sm-DOTMP for treatment of metastatic bone pain

**Part A: Dose Escalation**  
Dosimetry/Safety; (n = 9-12)



**Part B: Dose Selection** (n = 18)



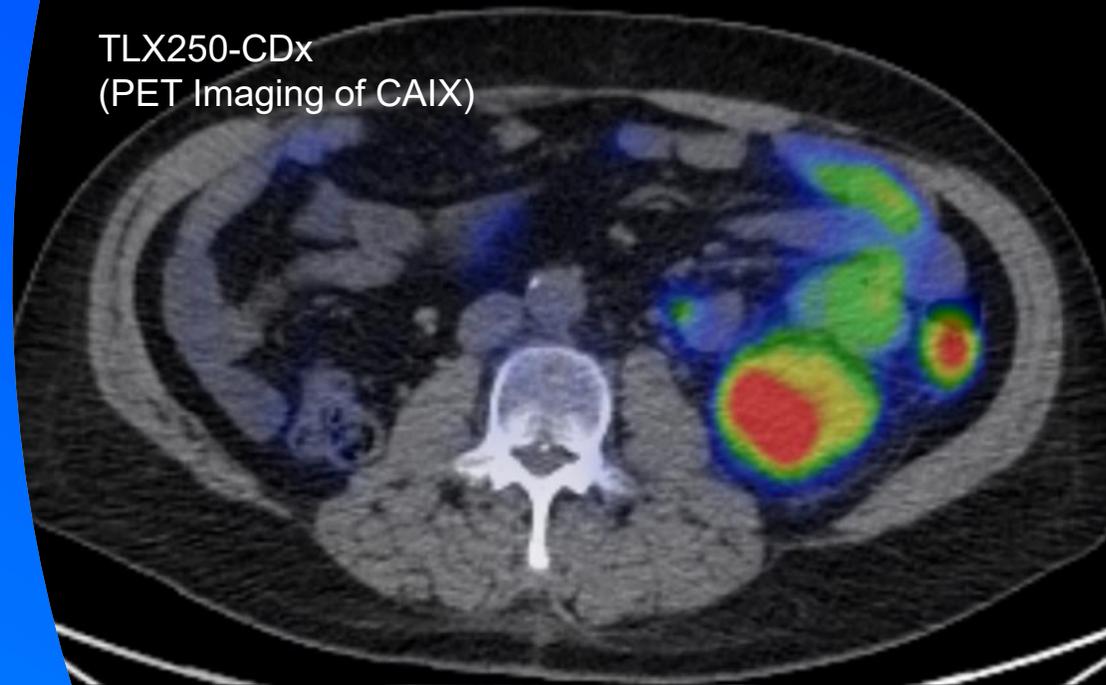
- **Phase 1 bridging study** links to first-generation product
- Objectives to confirm favorable safety profile, efficacy, and optimal dosing
- IND submission planned H2 2025



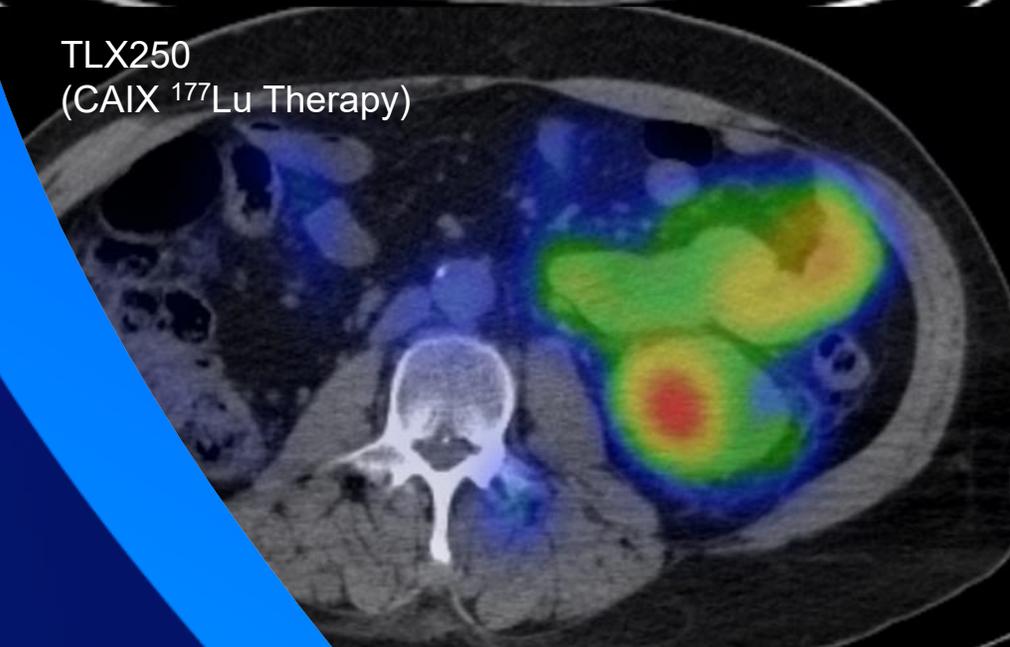
1. Proposed trial design, subject to regulatory approval.

# TLX250

TLX250-CDx  
(PET Imaging of CAIX)



TLX250  
(CAIX  $^{177}\text{Lu}$  Therapy)



# TLX250: First-in-class rADC for kidney cancer

Large opportunity across ccRCC and other CAIX-expressing tumors

## Product candidate

TLX250 ( $^{177}\text{Lu}$ -DOTA-girentuximab)

## Targeting molecule / target

Antibody /

Carbonic anhydrase IX (CAIX)

## Indication

Clear cell renal cell carcinoma

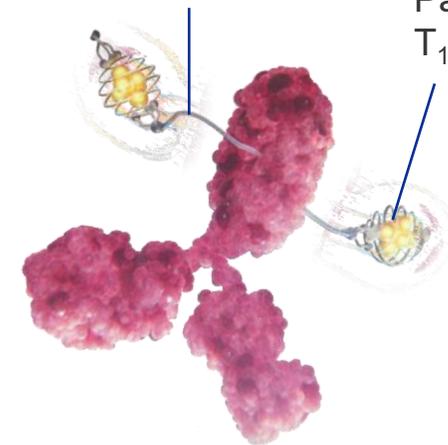
## Clinical experience to date

- Demonstrated potential for disease stabilization in 2 trials
  - **Phase 1:** Dose escalation to identify safety & MTD in 23 patients with advanced ccRCC
  - **Phase 2:** Dosed patients at maximum tolerated dose to evaluate efficacy in 14 patients with progressive mcrRCC

## Clinical trials

- STARLITE-1 (Phase 1b/2) – enrolling patients<sup>1</sup>
- STARLITE-2 (Phase 2) – enrolling patients<sup>2</sup>
- STARSTRUCK (Phase 1b) – enrolling<sup>3</sup>
- Planning pathway to pivotal study in ccRCC

Linker: DOTA



Payload:  $^{177}\text{Lu}$   
 $T_{1/2}$ : 6.7 days

## Darren R. Feldman, MD

Medical Oncologist at Memorial Sloan Kettering  
Cancer Center in New York



*“The selective targeting of TLX250 to CAIX delivers radiation therapy directly to ccRCC tumors. Combining this innovative approach with anti-PD-1/PD-L1 therapy could enhance existing immune-based treatments.”*



1. ClinicalTrials.gov ID: [NCT05663710](#).
2. ClinicalTrials.gov ID: [NCT05239533](#).
3. ClinicalTrials.gov ID: [NCT05868174](#).

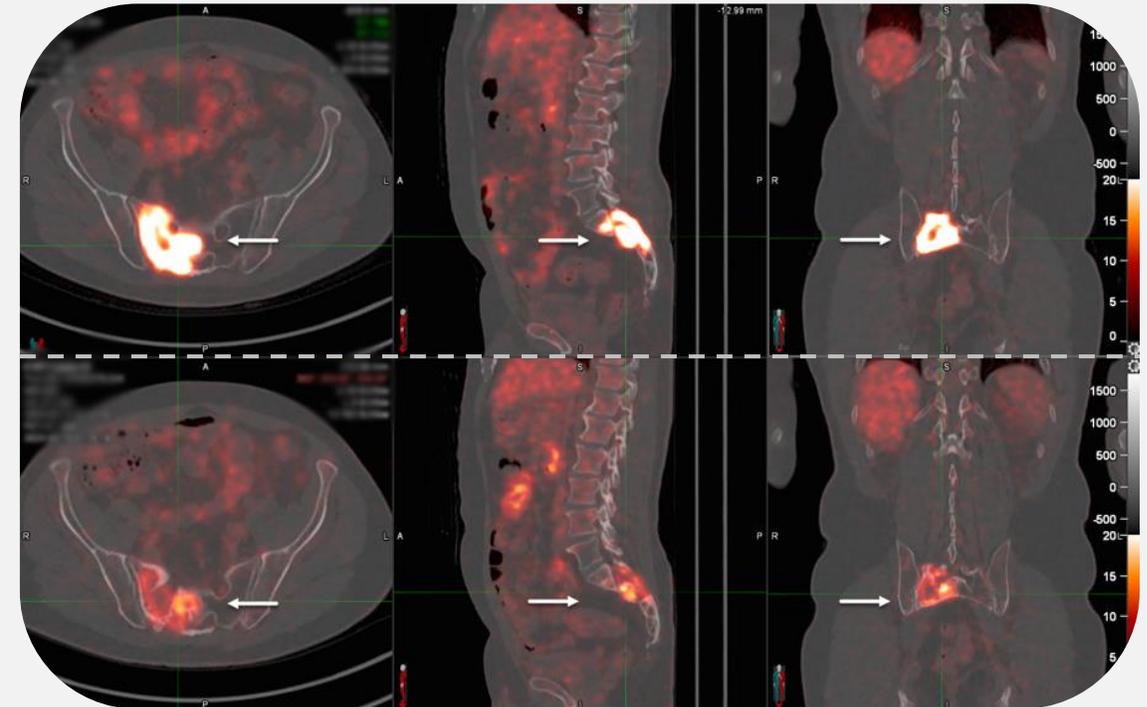
# TLX250: Validated in ccRCC, pan-cancer potential

Positioned to be first CAIX-targeting rADC to market

## TLX250 (<sup>177</sup>Lu-girentuximab)

- Monoclonal antibody targeting Carbonic Anhydrase IX (CAIX), a **validated target expressed in >90% of ccRCC and range of solid tumors**<sup>1</sup>
- **Ability to image CAIX with Zircaix<sup>2</sup>**, use of extensively studied 177-Lutetium payload de-risks clinical program<sup>3</sup>
- **Demonstrated durable disease control in a Phase 1 and a Phase 2 RCC study** with a manageable safety profile<sup>4,5</sup>
- **High unmet need in late-line RCC**, with expansion potential to other solid tumors

**TOP:** <sup>89</sup>Zr-girentuximab PET/CT at baseline showing uptake in a sacral metastatic lesion in a patient with ccRCC.



**BOTTOM:** <sup>89</sup>Zr-girentuximab PET/CT after three cycles of therapy.



1. Pastorekova S and Gillies RJ. *Cancer Metastasis Rev.* 2019;38:65-77.
2. Brand name subject to final regulatory approval.
3. Shuch et al. *Lancet Oncology* 2024.

4. Stillbroer et al. *European Urology.* 2013.
5. Muselaers et al. *European Urology.* 2015.

Images from Telix's STARSTRUCK study, data on file.  
Patient representative scans - individual results may vary.

# Established clinical proof of concept for renal cancer therapy

## Encouraging safety/tolerability profile, preliminary efficacy signal (monotherapy)

Previously studied in end-stage patients with advanced renal cell carcinoma:

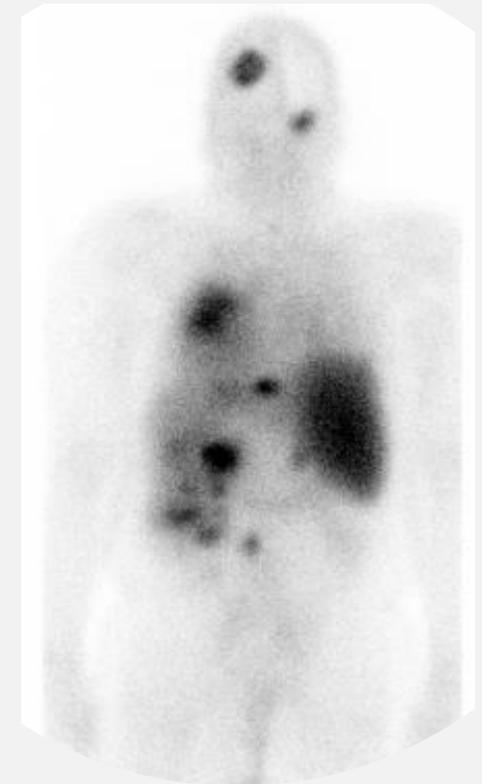
- Phase 1: Dose escalation study to identify safety & MTD in 23 patients with advanced ccRCC<sup>1</sup>
- Phase 2: Dosed at maximum tolerated dose (65 mCi/m<sup>2</sup>) to evaluate efficacy in 14 patients with advanced ccRCC<sup>2</sup>

Prior studies have demonstrated:

- Good safety profile<sup>1,2</sup>
- Potential to stabilize disease in metastatic ccRCC as a monotherapy
- Disease control rate: 74% (Phase 1 trial)
- Median PFS for all patients was 8.1 months – but different pre-treatment profile (VEGF-TKI) (Phase 2 trial)

### **<sup>177</sup>Lu-TLX250 SPECT Imaging**

SPECT image post <sup>177</sup>Lu-TLX250 treatment showing uptake of drug product in metastatic ccRCC tumors expressing CAIX



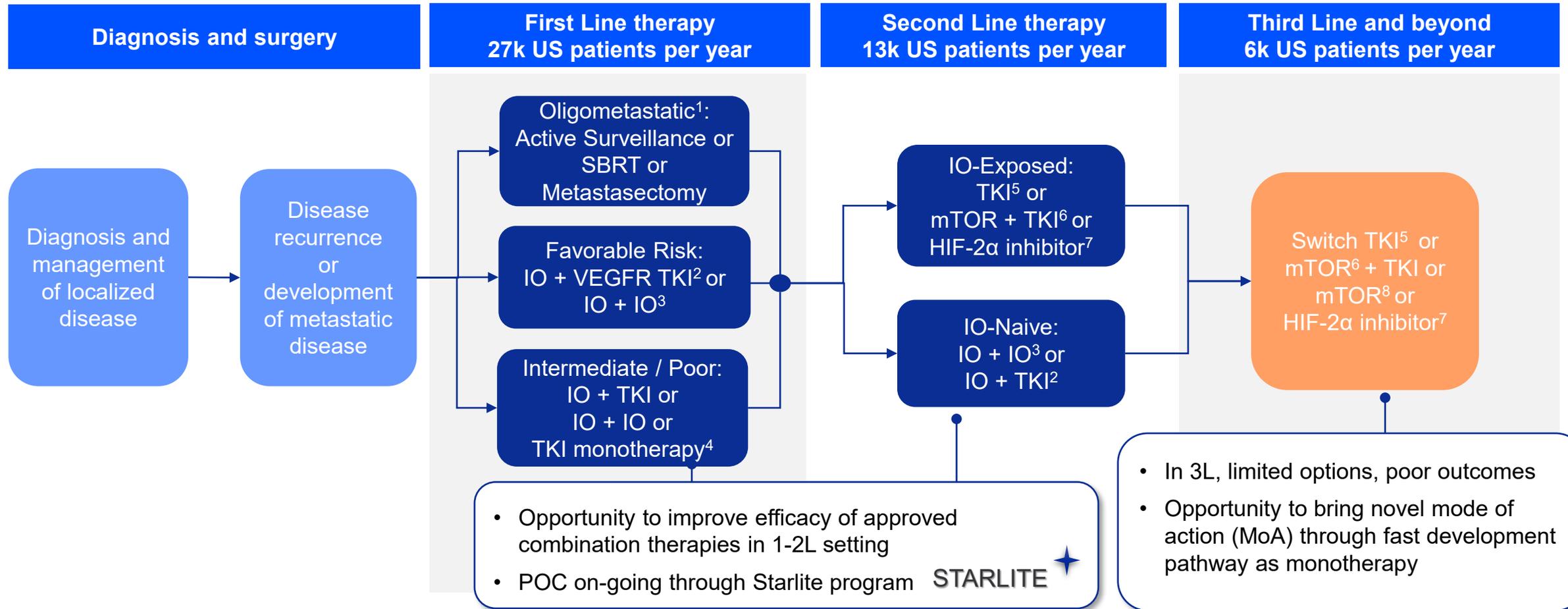
Phase 1 Radioimmunotherapy Study with Lutetium 177-labelled Anti-Carbonic Anhydrase IX Monoclonal Antibody Girentuximab in Patients with Advanced Renal Cell Carcinoma.

1. Stillbroer et al., European Urology 64 (2013) 478–48

2. Muselaers CHJ, et al. Phase 2 Study of Lutetium 177-Labeled Anti-Carbonic Anhydrase IX Monoclonal Antibody Girentuximab in Patients with Advanced Renal Cell Carcinoma. Eur Urol (2015)

# Typical patient journey for a metastatic kidney cancer patient

Major unmet needs include enhancing efficacy of combination treatments and late-line treatment



SOURCE: NCCN Guidelines, Kidney Cancer; PharmaIntelligence Patient-based Forecast Model, RCC

- |  |                                       |
|--|---------------------------------------|
| 1. Options only available for patients with select favorable disease features. | 5. Cabozantinib; Axitinib; Tivozanib. |
| 2. Axitinib/Pembrolizumab; Cabozantinib/Nivolumab; Lenvatinib/Pembrolizumab.   | 6. Lenvatinib/Everolimus.             |
| 3. Ipilimumab/Nivolumab.   | 7. Belzutifan.                        |
| 4. Cabozantinib only.  | 8. Everolimus.                        |



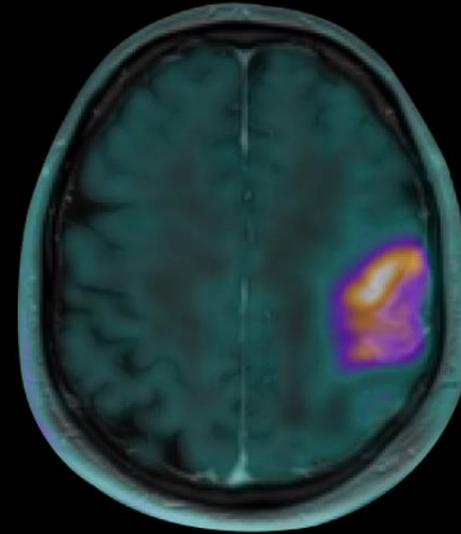
# TLX250: Development pathway

Study name	Indication	Phase	Status
 <b>STARLITE-1</b> ClinicalTrials.gov ID: <a href="https://clinicaltrials.gov/ct2/show/study/NCT05663710">NCT05663710</a>	Treatment-naïve advanced ccRCC	1b/2	<ul style="list-style-type: none"> <li>Enrolling patients</li> <li>TLX250 in combination with cabozantinib and nivolumab</li> </ul>
 <b>STARLITE-2</b> ClinicalTrials.gov ID: <a href="https://clinicaltrials.gov/ct2/show/study/NCT05239533">NCT05239533</a>	Advanced or metastatic ccRCC	2	<ul style="list-style-type: none"> <li>MTD of TLX250 established when administered in combination with nivolumab</li> <li>Enrolling an expansion cohort at the MTD</li> </ul>
 <b>STARSTRUCK</b> ClinicalTrials.gov ID: <a href="https://clinicaltrials.gov/ct2/show/study/NCT05868174">NCT05868174</a>	CAIX-expressing solid tumors	1b	<ul style="list-style-type: none"> <li>Enrolling patients</li> <li>TLX250 in combination with peposertib</li> </ul>
 <b>Pivotal study</b>	Unresectable, locally advanced or metastatic ccRCC	2/3	<ul style="list-style-type: none"> <li>In planning, expected to open in ex-U.S. sites in 2025</li> <li>Monotherapy</li> </ul>

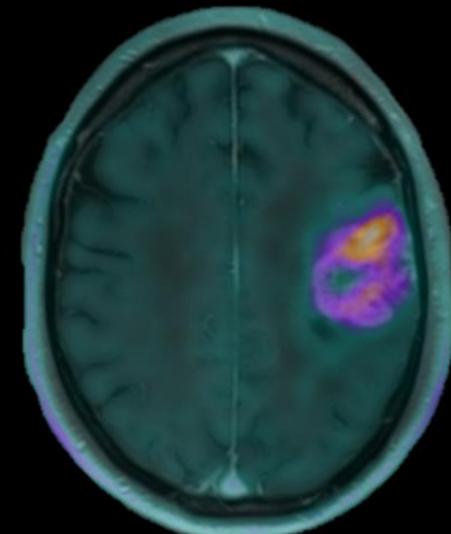
# Brain cancer

## TLX101

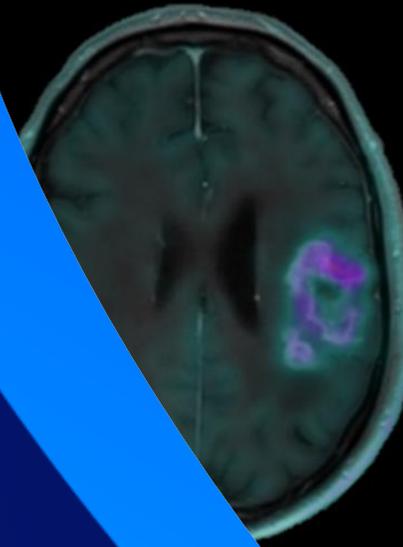
Glioblastoma patient (salvage) with clinically stable disease  
18 months from initiation of TLX101 therapy



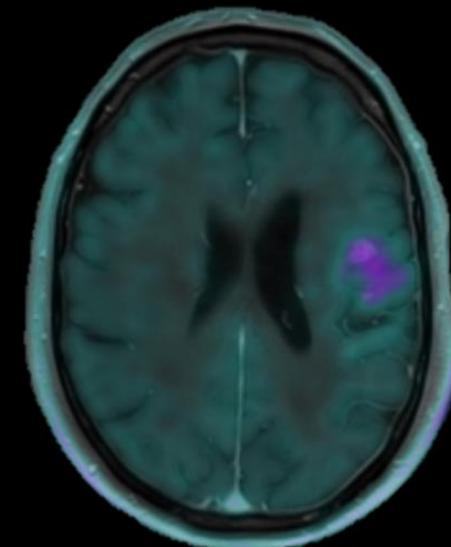
T = 0



10 months



16 months



18 months

# TLX101-CDx (Pixclara) for imaging glioma

## Unmet need for delineating progressive disease from treatment-induced changes

### Product candidate

TLX101-CDx (Pixclara<sup>1</sup>)

<sup>18</sup>F-floretyrosine or <sup>18</sup>F-FET

FDA Orphan Drug and Fast Track designations

### Targeting molecule / target

Small molecule /

L-Type amino acid transporters 1 and 2 (LAT1 & 2)

### Indication

Characterization of progressive or recurrent glioma

### Clinical experience to date

- Widely used in Europe and recommended in the EANM/EANO/RANO/SNMMI guidelines for PET imaging of gliomas<sup>2</sup>
- First PET-based response assessment criteria for diffuse gliomas issued by RANO in January 2024<sup>3</sup>

### Current status

- Preparing to re-file U.S. NDA
- Expanded access program active in the U.S.

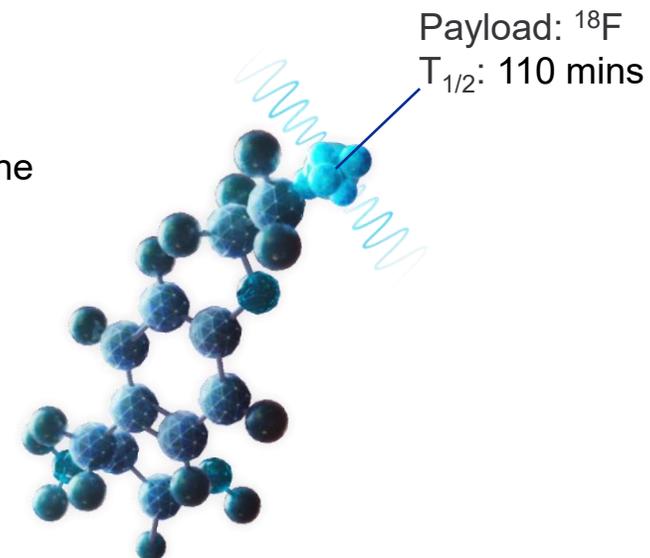
### Upcoming milestones

- Targeted global regulatory filings, opportunities in select markets where access is currently restricted



**Patrick Wen, MD**, Professor, Neurology, Harvard Medical School and Director, Center for Neuro-Oncology, Dana-Farber Cancer Institute

*“TLX101-CDx (<sup>18</sup>F-FET-PET) shows potential to provide a more rapid and conclusive diagnosis, inform treatment decisions and deliver a new standard for the management of gliomas in the U.S.”*



1. Brand name subject to final regulatory approval.
2. Joint European Association of Nuclear Medicine//European Association of Neurooncology/Response Assessment in Neurooncology practice guidelines/Society for Nuclear Medicine and Molecular Imaging procedure standards for the clinical use of PET imaging in gliomas.
3. Albert et al. *Lancet Oncol.* 2024.

# TLX101: Potential first systemic radiotherapy in glioblastoma

Promising therapeutic profile, simple IV administration solves major challenge in GBM treatment

## Product candidate

TLX101 (<sup>131</sup>I Iodofalan)

FDA and EU Orphan Drug designation

## Targeting molecule / target

Small molecule /

L-Type amino acid transporter 1 (LAT1)

## Indication

Glioblastoma

## Clinical experience to date

### Phase 2 IPAX-Linz<sup>1</sup>:

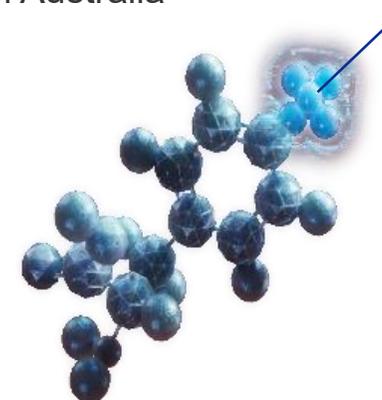
- Median overall survival (OS) of 12.4 months from initiation of TLX101 dosing
- mOS of 32.2 months from initial diagnosis
- No serious adverse events (AEs)

**Phase 1 IPAX-1<sup>2</sup>:** mOS 23 months from initial diagnosis

## Planned clinical activity

- Planned initiation of pivotal trial in Australia in 2025

Payload: <sup>131</sup>I  
T<sub>1/2</sub>: 8.02 days



**Professor Josef Pichler, Kepler University Hospital, Austria**

*“TLX101 continues to show significant potential to improve outcomes for patients living with high-grade glioma. These results also potentially support higher therapeutic doses in subsequent prospective controlled studies.”*



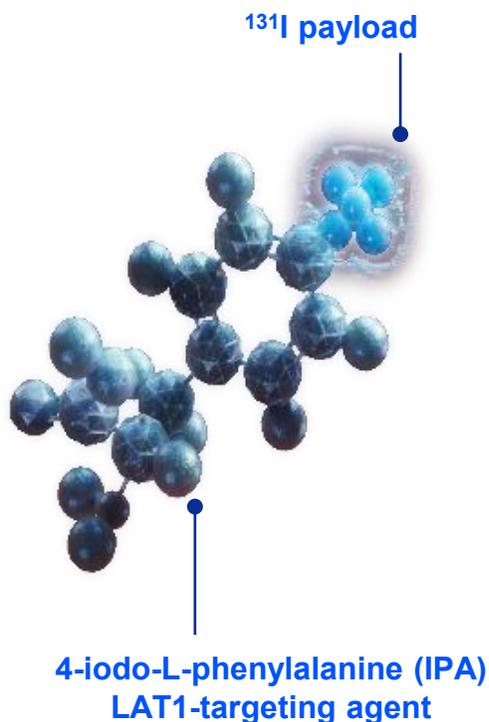
1. Telix ASX disclosure 16 April 2025.

2. Telix ASX disclosure 21 September 2022. Pichler et al. *Neurooncol Adv.* 2024. ClinicalTrials.gov ID: [NCT03849105](https://clinicaltrials.gov/ct2/show/study/NCT03849105).

# TLX101: Novel treatment candidate for glioblastoma (GBM)

Promising therapeutic profile, IV delivery addresses a challenge in GBM

## TLX101: Iodofalan ( $^{131}\text{I}$ )



TLX101 is an iodine-labelled small molecule, Iodofalan ( $^{131}\text{I}$ ), targeting the L-Type amino acid transporter 1 (LAT1)

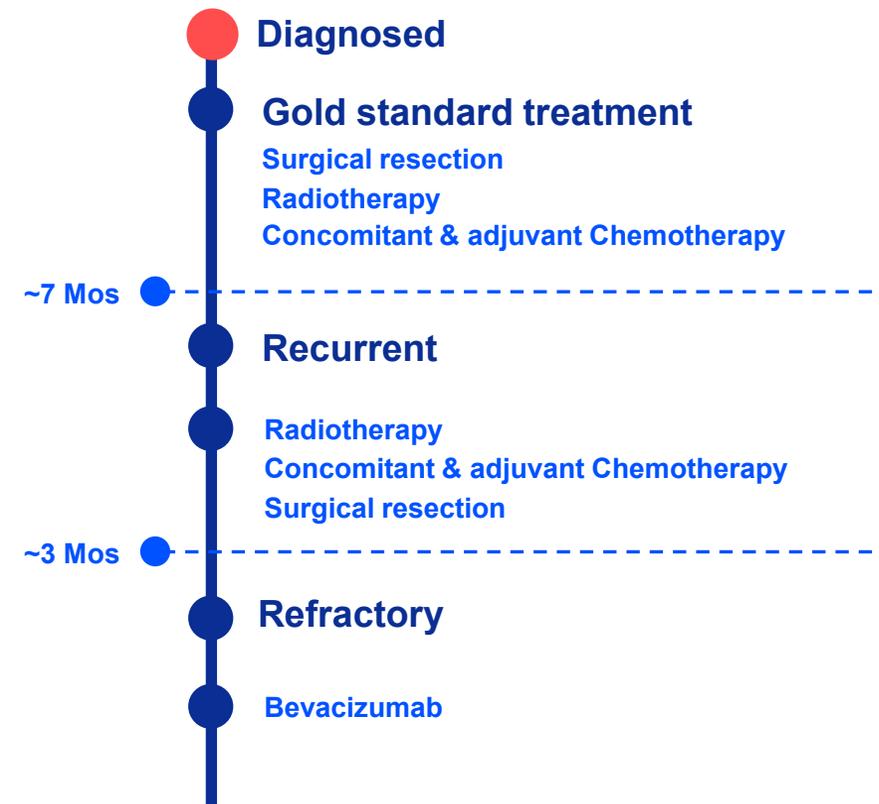
- **Validated target highly expressed in a wide variety of solid tumors**, including malignancies of the central nervous system (CNS)
- **Intravenous delivery with ability to cross the blood-brain barrier**; MOA synergistic to external beam radiation therapy (EBRT)
- **Early safety profile and tolerability in combination with EBRT confirmed in glioblastoma (GBM) Phase 1 trial**, along with encouraging preliminary efficacy signal (via PET, OS)<sup>1, 2</sup>
- **Granted orphan drug designation** in the U.S. (10-3287) and EU (EU/2/06/363) for the treatment of gliomas

# Significant unmet need in glioblastoma

## Initial focus on recurrent GBM patients with limited treatment options

- **Most common and most aggressive primary brain tumor**
  - Over 14,500 U.S. patients diagnosed each year
  - Most patients progress after ~7 months
  - mOS of 12-15 months, 5-year survival of 4.7%<sup>1</sup>
  - Clinical trial as preferred option recommended by NCCN for recurrent patients<sup>2</sup>
- First line standard of care consists of surgery, chemotherapy, radiation w/ over 90% of patients experiencing recurrence
- **No established 2<sup>nd</sup> line standard of care**
- **Key challenge for treatments is crossing blood-brain barrier**, limiting potential of intravenous therapies

### Glioblastoma patient flow



# TLX101: Development pathway

	Study name	Indication (GBM)	Phase	Status
	<b>IPAX-1</b> ClinicalTrials.gov ID: <a href="https://clinicaltrials.gov/ct2/show/study/NCT03849105">NCT03849105</a>	First recurrence	1	<b>Completed</b> Demonstrated mOS of 13 months from the initiation of treatment, or 23 months from initial diagnosis <sup>1</sup>
	<b>IPAX-2</b> ClinicalTrials.gov ID: <a href="https://clinicaltrials.gov/ct2/show/study/NCT05450744">NCT05450744</a>	Newly diagnosed	1	<b>Recruiting</b>
	<b>IPAX-Linz</b>	First or second recurrence	2 (IIT)	<b>Study closed, topline data released<sup>2</sup></b> Demonstrated mOS of 12.4 months from the initiation of treatment, or 32.2 months from initial diagnosis.
	<b>IPAX-BriGHT</b>	First or second recurrence	Pivotal registration study	<b>Planned to commence dosing patients in 2025, ex-U.S. sites</b>



1. Picher et al. *Neurooncol. Adv.* 2024.
2. Telix ASX release 16 April 2025.

# Addressing brain malignancies with alpha and beta therapy candidates

## Two treatment candidates addressing distinct unmet needs

	<b>TLX101</b>	<b>TLX102</b>
<b>Targeting agent</b>	<b>Phenylalanine (targets LAT1 and 2)</b>	<b>Phenylalanine (targets LAT1 and 2)</b>
<b>Isotope</b>	<b>Iodine-131 (beta emitter)</b>	<b>Astatine-211 (alpha emitter)</b>
<b>Half life</b>	<b>8.02 days<sup>1</sup></b>	<b>7.21 hours<sup>2</sup></b>
<b>Administration method</b>	<b>IV administration (outpatient procedure)</b>	<b>IV or Intraarterial (IA) administration (outpatient procedure)</b>
<b>Lead indication</b>	<b>Recurrent GBM (~9k U.S. patients per year)</b>	<b>Follow-on to TLX101 (Indications Undisclosed)</b>
<b>Development stage and next step</b>	<b>Pivotal trial targeting commencement in 2025</b>	<b>First-in-human study targeting commencement in 2026</b>

- TLX101 and TLX102 are ideal to treat brain malignancies because they cross the blood-brain barrier, enabling IV administration and outpatient procedures
- TLX102 uses identical targeting agent, but is labelled with astatine-211, an alpha emitter which may help overcome radiation resistance commonly seen in CNS cancers
- Future potential: Exploring TLX101 and TLX102 beyond GBM into other neuro-oncology indications



1. <https://www.cdc.gov/radiation-emergencies/hcp/isotopes/iodine-131.html> 2. Guérard, François et al. "Production of [(211)At]-astatinated radiopharmaceuticals and applications in targeted  $\alpha$ -particle therapy." Cancer biotherapy & radiopharmaceuticals vol. 28,1 (2013): 1-20. doi:10.1089/cbr.2012.1292

# TLX102: $^{211}\text{At}$ labelled follow-on product

High potency isotope with shorter path length provides potential to expand adoption

## Product candidate

TLX102 ( $^{211}\text{At}$  astato-L-phenylalanine)

## Targeting molecule / target

Small molecule /

L-Type amino acid transporter 1 (LAT1)

## Indication

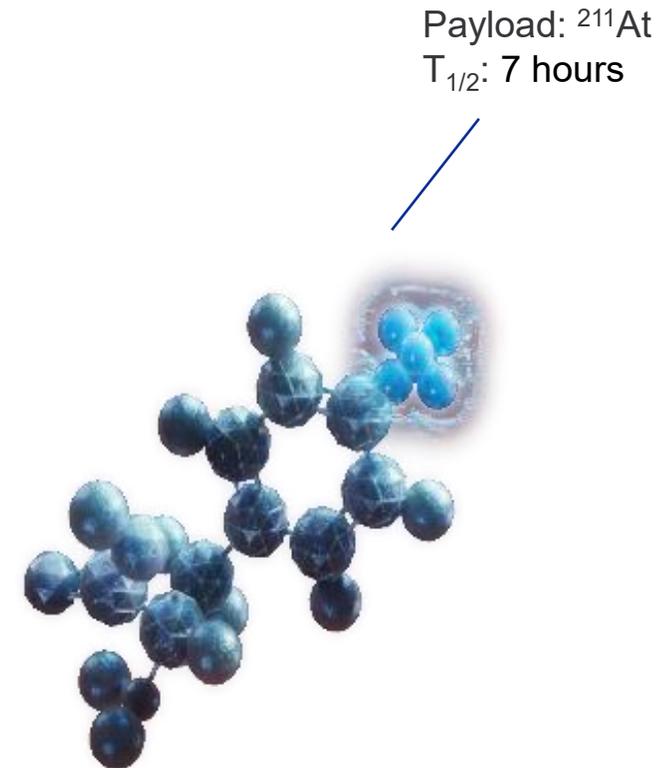
Undisclosed

## Pre-clinical experience to date

- Preclinical data in glioma models demonstrated tumor growth inhibition, acceptable safety profile (no observed weight loss)<sup>1</sup>
- TLX102 also permeates blood-brain barrier and enables simple intravenous administration

## Planned clinical activity

- First-in-human study targeting commencement in 2026



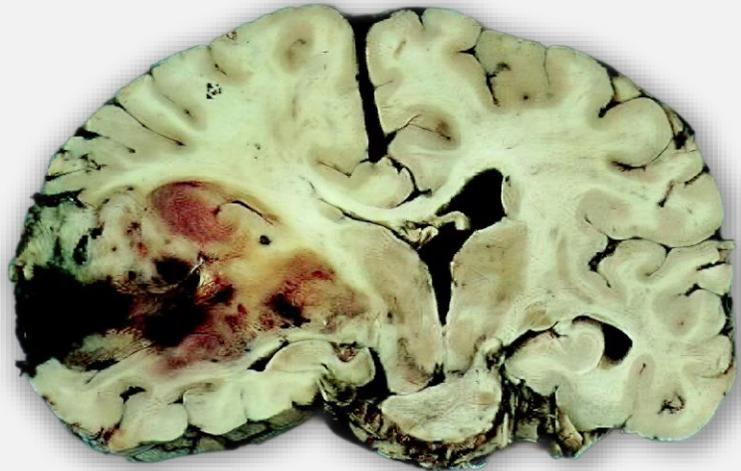
# **KOL** **perspective:** **TLX101**

**John de Groot, MD**

**Division Chief of Neuro-Oncology  
at University of California San  
Francisco**

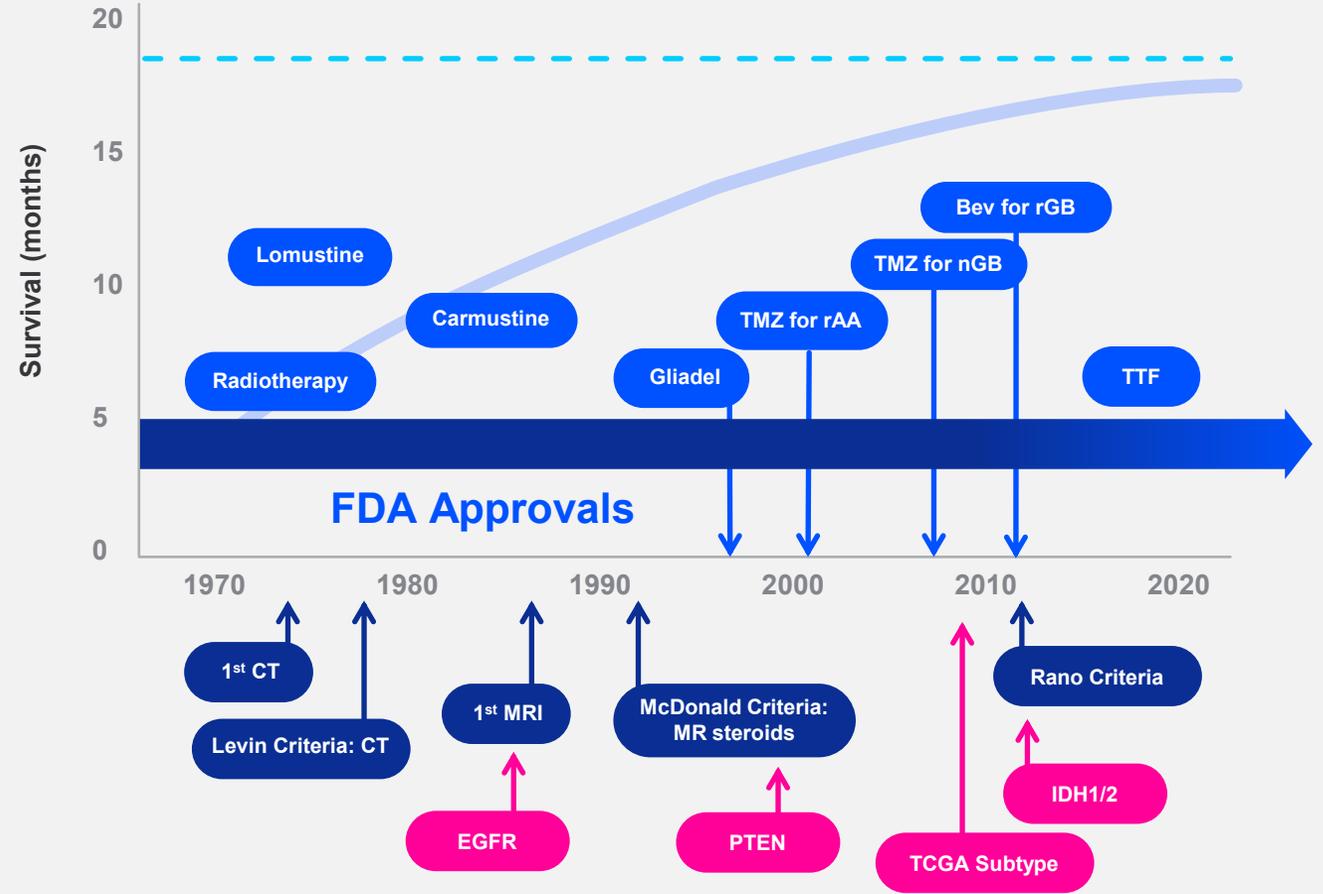


# Glioblastoma: where are we now?



339/78

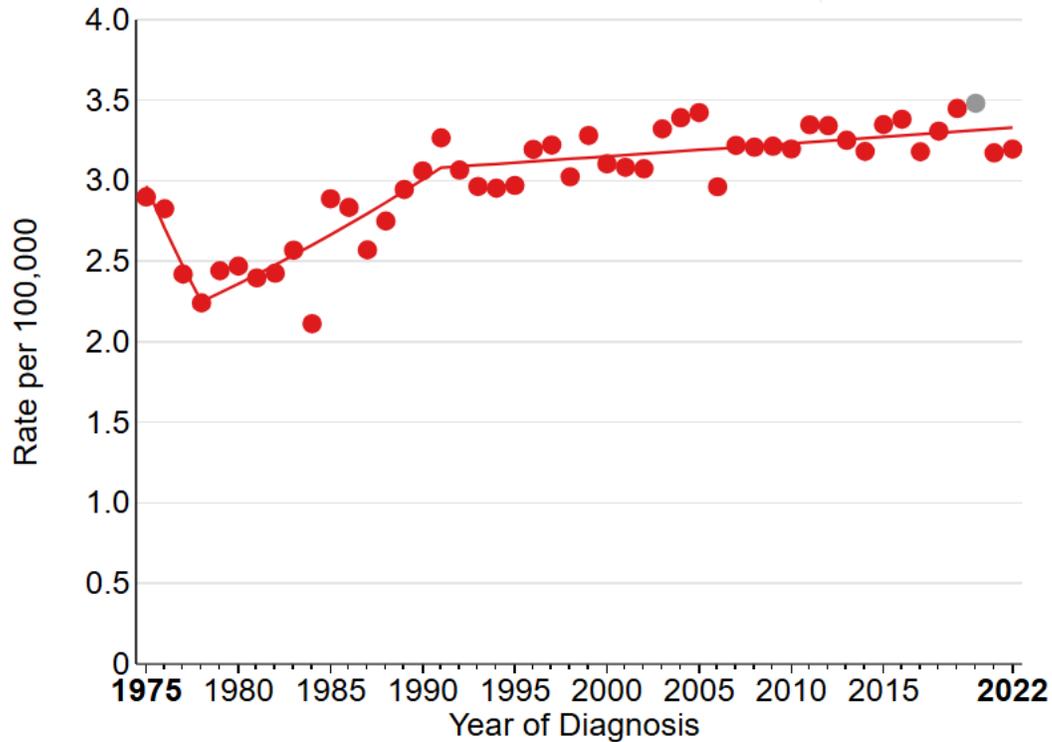
2 drug approvals  
in 25 years



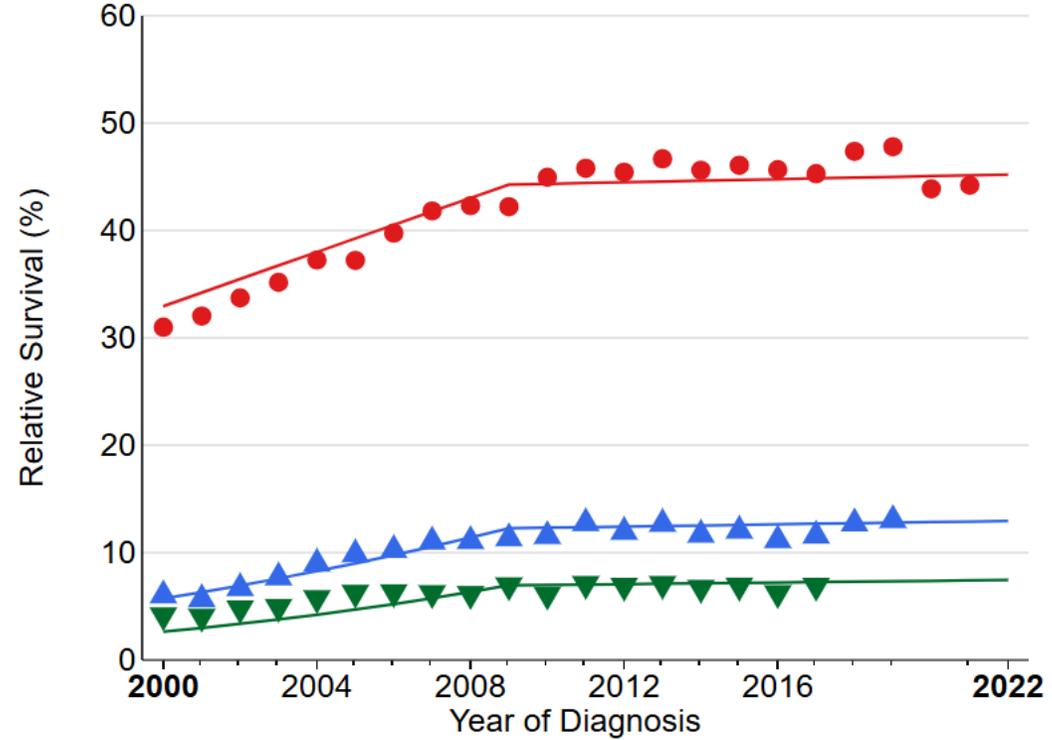
# Evidence-based management of adult glioblastoma

- Maximum safe resection
- Conventionally fractionated limited-field radiotherapy
- Chemotherapy
  - Concurrent daily temozolomide with radiotherapy
  - 6-12 cycles post-radiotherapy temozolomide
  - Single agent bevacizumab at recurrence
- Tumor treating fields
  - FDA approved in 2011 (recurrent disease) and 2015 (Newly diagnosed disease)

# Glioblastoma is increasing and overall survival rates remain low



Annual Incidence in US<sup>1</sup>



Average Survival (US)<sup>1</sup>

● 1-year survival, ▲ 3-year survival, ▼ 5-year survival



1. NCI SEER Database, 2025

# LAT1 is a validated target upregulated in brain malignancies

## Role in drug transport, cell proliferation, and survival

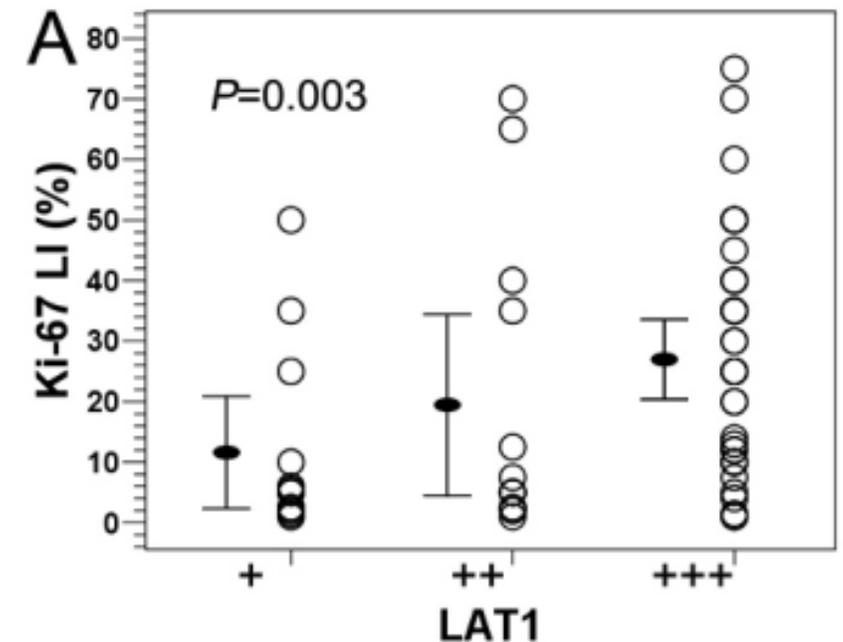
### LAT1 is a transmembrane transporter<sup>1</sup> that is

- Integral to the transport of large neutral amino acids across the blood-brain barrier, playing a crucial role in brain homeostasis and the delivery of therapeutic agents<sup>2</sup>
- Expressed on both the luminal (plasma-facing) and abluminal (brain-facing) membrane side of the capillary endothelial cells of the blood-brain barrier<sup>3</sup>
- Upregulated in gliomas<sup>1,3,4</sup> with negligible expression found in adjacent normal brain tissue<sup>4</sup>

### LAT1 plays a key role in cancer growth and survival<sup>1</sup>

- High expression in human gliomas associated with progression and poor prognosis<sup>4</sup>

### LAT1 Overexpression Is Correlated With Ki67, a Marker of Cell Proliferation, in Human Gliomas<sup>4</sup>



# TLX101: Potential first-in-class systemic radiotherapy for GBM

Novel approach passes blood-brain barrier, enabling effective treatment with IV administration

TLX101: Iodofalan ( $^{131}\text{I}$ )



## Mechanism of action

- **Radiolabelled IPA delivers systemic radiation** directly to tumor
  - Binds to LAT1 receptor, upregulated in cancerous lesions<sup>1</sup>, and internalized
  - Iodine-131 payload emits cytotoxic radiation to induce cell death
- **Potentially synergistic with external beam radiation** as a sensitizing agent<sup>1</sup>

## Benefits of the TLX101 approach

- **TLX101 readily passes blood-brain-barrier to reach tumors<sup>1</sup>**, solving major challenge in GBM treatment
  - Enables effective treatment with out-patient intravenous administration
  - Removes requirement for intra-cranial administration, in-patient procedure impacting quality of life
- **Safety and tolerability in combination with EBRT confirmed** in Phase 1 trial, with encouraging preliminary efficacy signal (via PET, OS)<sup>2</sup>
- Iodine-131 as extensively studied payload used to treat thyroid cancer for decades

# Why is TLX101 promising?

Compassionate use case of glioblastoma patient with durable partial response after four treatments (1/2)

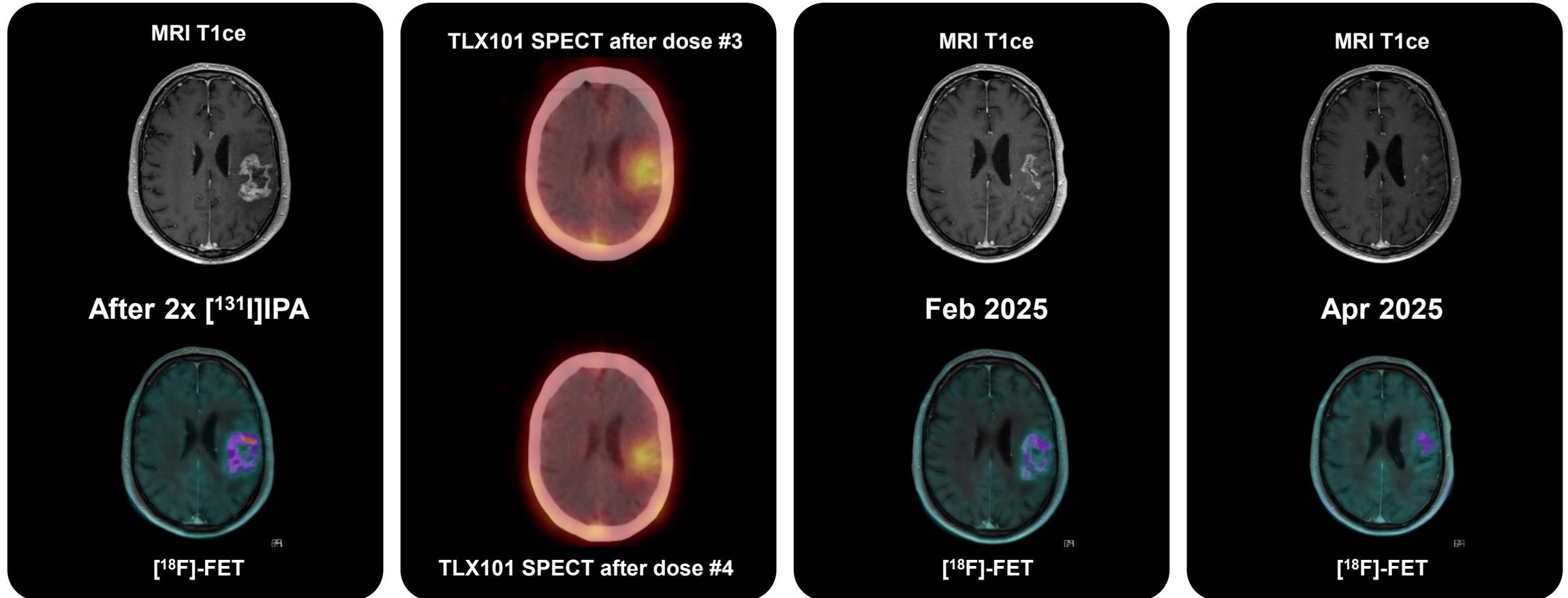
Courtesy of Dr. Braat  
UMC Utrecht



# Why is TLX101 promising?

Compassionate use case of glioblastoma patient with durable partial response after four treatments (2/2)

Courtesy of Dr. Braat  
UMC Utrecht



# Summary of IPAX-1 results

TLX101 plus EBRT was associated with acceptable safety profile and specific tumor targeting in patients with recurrent GBM



## Safety and tolerability profile

- All dosing regimens were well tolerated
- Organ-absorbed radiation doses confirmed no radiation-based toxicity



## Radiological tumor response (at 3-mo F/U, MRI)

- 44.4% patients had stable disease

## Metabolic tumor response (at 3-mo F/U, <sup>18</sup>F-FET PET)

- Based on peak uptake within the lesion, 66.7% patients had metabolic stable disease
- Based on mean lesion uptake, 77.8% patients had stable disease



## Survival outcomes

- Median PFS: 4.3 mo.
- Median OS: 23 mo. from initial diagnosis

# Summary of IPAX-Linz top line results<sup>1</sup>

Further substantiates safety profile and efficacy signal generated in IPAX-1



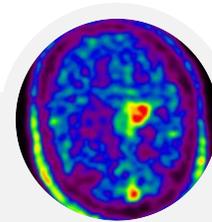
## Patient population

- 8 total rGBM patients treated
- 5 had MGMT unmethylated tumors which are associated with poor outcomes



## Safety profile and tolerability

- Adaptive dosing regimen of up to 6 GBq total was well tolerated
- No serious adverse events (SAEs) related to TLX101



## Survival outcomes

- Median OS: 32.2 mos from initial diagnosis
- Median OS from TLX101 + EBRT treatment: 12.4 mos

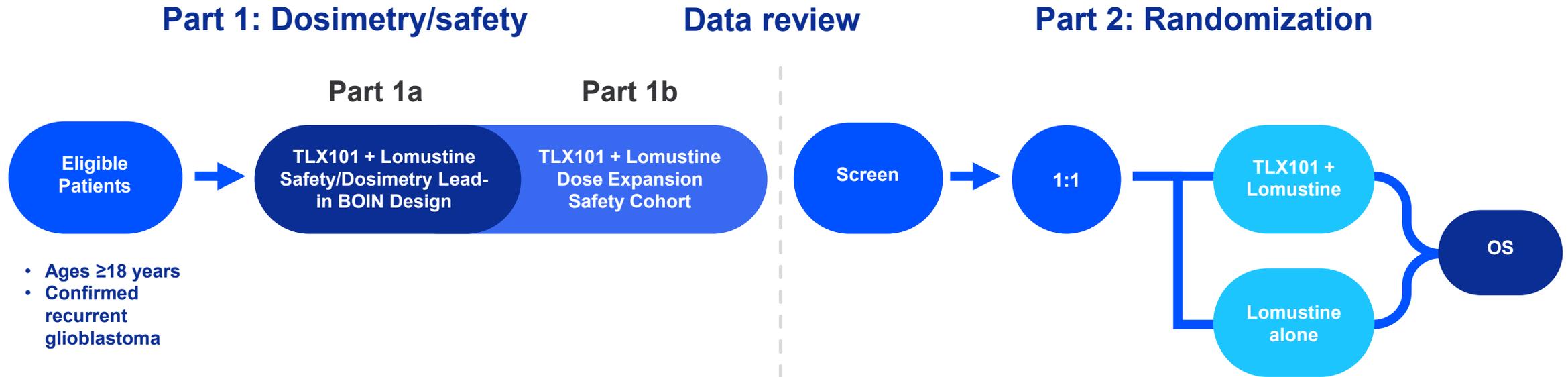


## Next steps

- 6 GBq total dose was well tolerated which supports increased dosing in follow on studies

# IPAX-BrIGHT: Study design

A pivotal, global registration enabling trial in recurrent glioblastoma



- IPAX-BrIGHT is currently under ethics review in Australia and CTA is under preparation for EU filing in 1H 2025. Telix will be seeking to commence enrolling patients in 2025 (subject to regulatory approval)<sup>1</sup>.

- <sup>18</sup>F-Floretyrosine will be used to select patients as well as assess response according to PET RANO



BOIN – Bayesian Optimal Interval

1. Telix ASX disclosure 16 April 2025.

# TLX66: Opportunity to improve outcomes for AML patients

## A potent, low morbidity option for bone marrow conditioning

### Product candidate

TLX66,  $^{90}\text{Y}$ -besilesomab  
FDA orphan drug designation

### Targeting molecule / target

Antibody / cluster of differentiation 66

### Indication

Bone marrow conditioning for allogeneic stem cell transplantation in acute myeloid leukemia (AML)

### Clinical experience to date

~100 patients treated in Phase 1 & 2 IITs in different hematological diseases (AML, multiple myeloma, systemic amyloid light chain amyloidosis) requiring autologous or allogeneic stem cell transplantation

### Current status / planned clinical activity

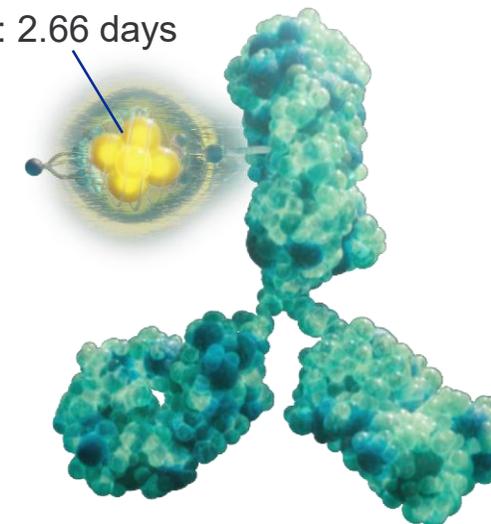
- Phase 2 investigator-initiated trial in pediatric high-risk leukemia dosing patients at Great Ormond Street Hospital in London
- U.S. FDA and EMA Orphan Drug Designation granted for TLX66 for bone marrow conditioning



**Dr. Kim Orchard, Consultant Hematologist at University Hospital Southampton**

*“Compared to the significant toxicity profile typically experienced with conventional chemotherapy-based regimens, molecularly targeted radiation with  $^{90}\text{Y}$ -besilesomab demonstrates a very benign toxicity profile. The very low toxicity but with demonstrable responses is very encouraging.”*

Payload:  $^{90}\text{Y}$   
 $T_{1/2}$ : 2.66 days



# TLX300: Radiolabelled olaratumab advancing to clinical trials

## Strong scientific, clinical and commercial rationale for development

### Product candidate

TLX300 (-olaratumab)

### Targeting molecule / target

Antibody /

PDGFR $\alpha$  (platelet-derived growth factor receptor alpha)

### Indication

Advanced metastatic soft-tissue sarcoma

### Clinical experience to date

- In-licensed from Eli Lilly and Company with exclusive rights to develop as a radiopharmaceutical<sup>1</sup>
- Established clinical safety profile, favourable toxicology dataset and advanced manufacturing

### Clinical trial

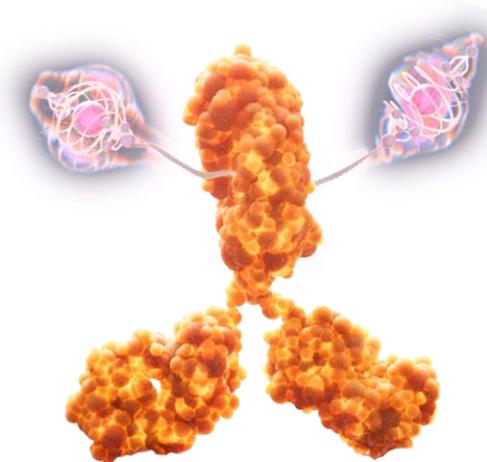
Phase 1 ZOLAR imaging study recruiting, trial aims to

- Evaluate the safety, pharmacokinetics, biodistribution and dosimetry,
- Establish the optimal dose of TLX300-CDx in patients with advanced STS, prior to therapeutic studies, based on a theranostic approach

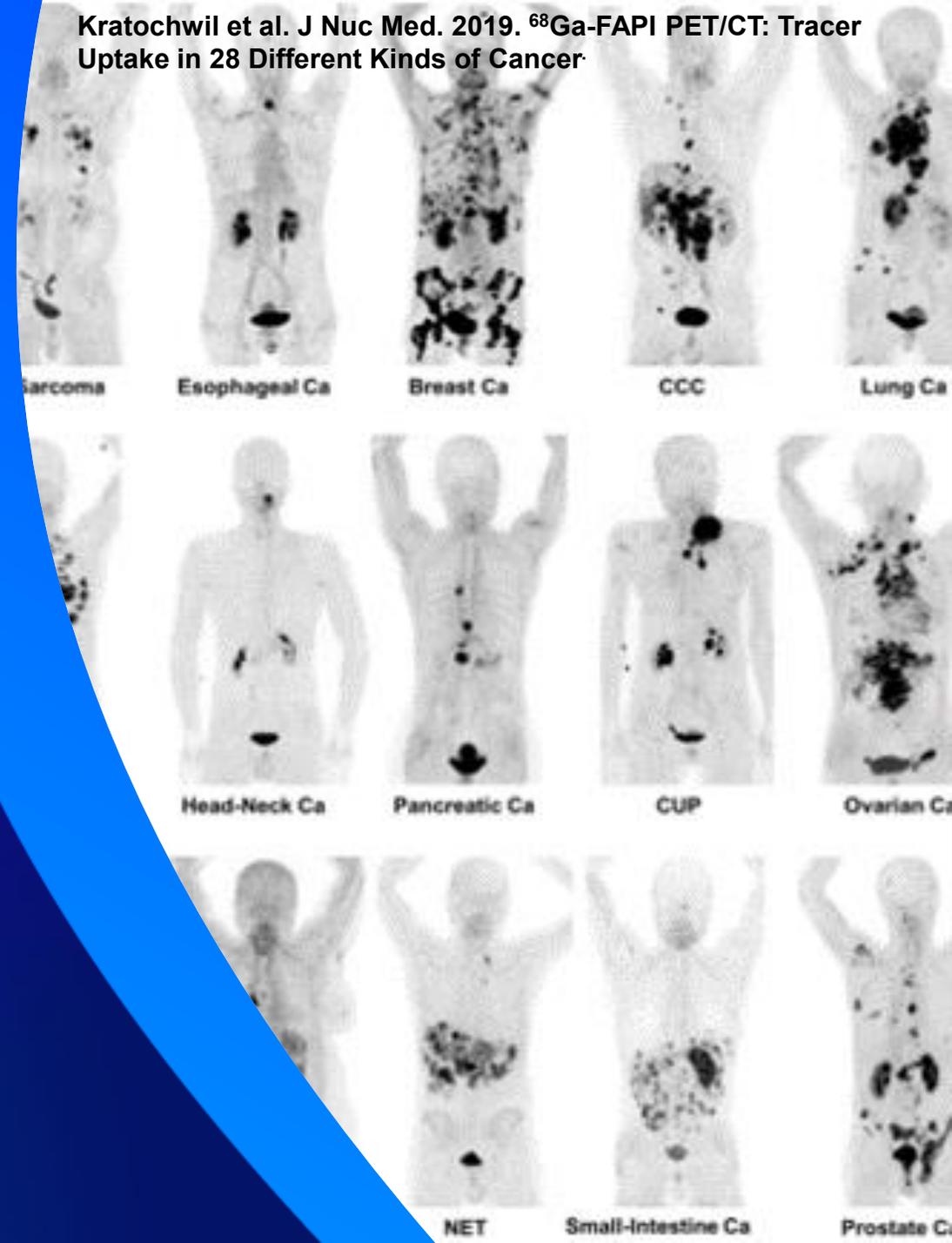


**Professor Rod Hicks AM, MD,  
Founder, Chair, and Chief Medical Officer at Melbourne  
Theranostic Innovation Centre**

*“While localized soft-tissue sarcoma generally responds to radiotherapy, it is challenging to treat once it has spread. Targeted radionuclide therapy, which targets cancer cells throughout the body, is therefore an attractive option to treat disseminated disease.”*



# Q&A



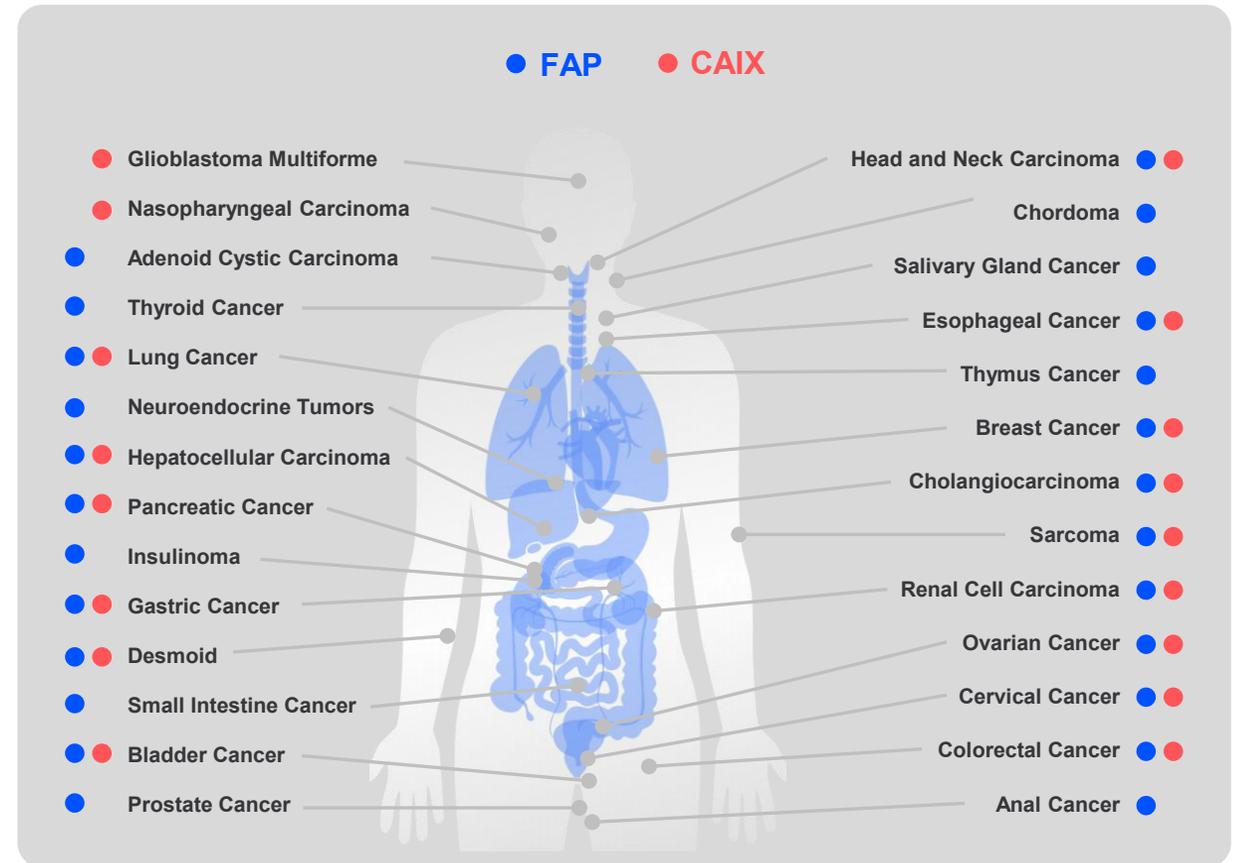
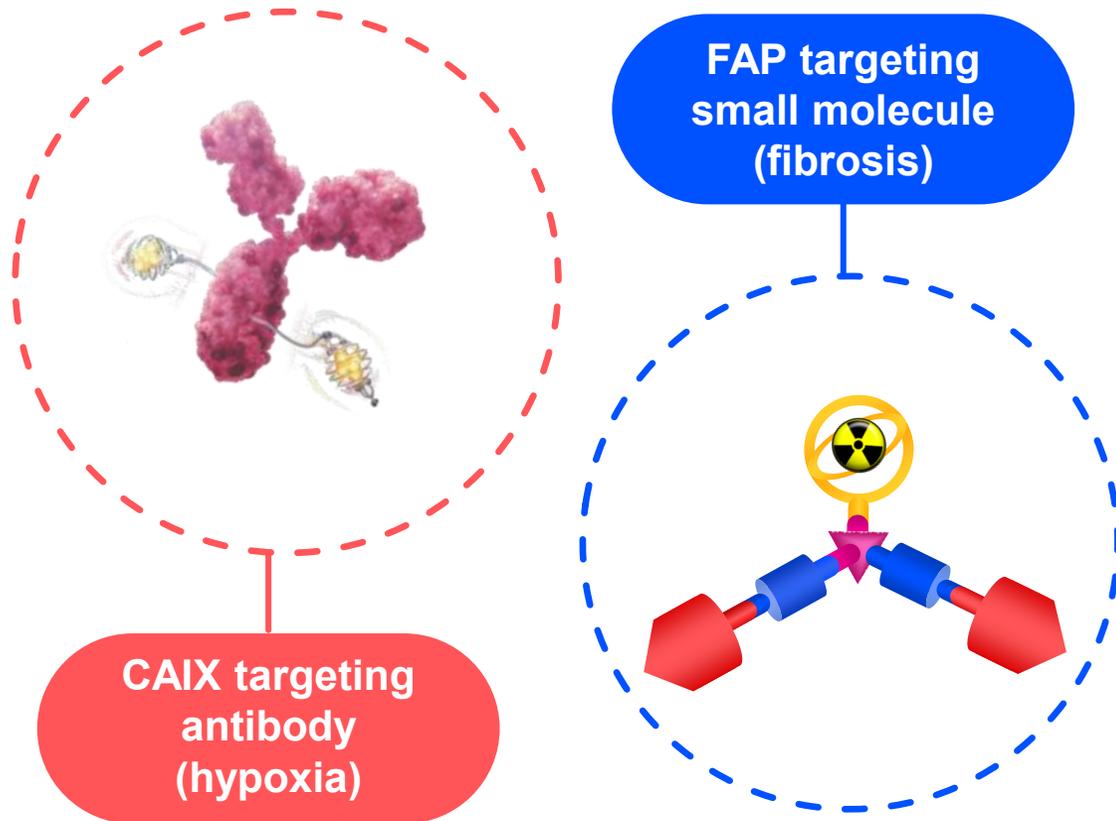
# Pan cancer:

Spotlight on two key targets  
(CAIX and FAP)

# CAIX + FAP: Potential multi-blockbuster opportunity

Exploring multi-indication asset strategies leveraging validated pan-tumor targets

Two well-validated targets with pan-cancer potential<sup>1, 2</sup>



1. Literature reports of CAIX expression.  
2. Giesel et al. *J Nucl Med.* 2019.

# TLX252: Next generation alpha emitter entering clinic

## CAIX-targeting $^{225}\text{Ac}$ -labelled rADC for the treatment of patients with advanced cancer

### Product candidate

TLX252 ( $^{225}\text{Ac}$ -DOTA-girentuximab)

### Targeting molecule / target

Antibody /

Carbonic anhydrase IX (CAIX)

### Indication

Clear cell renal cell carcinoma

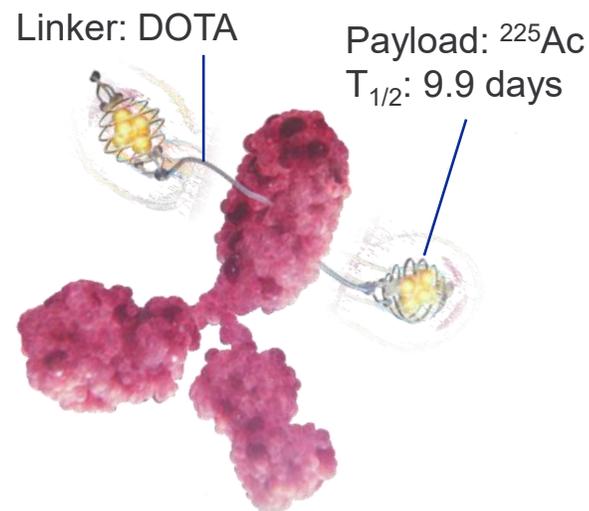
### Clinical experience to date

- Preclinical data in RCC models indicate approach may lead to tumor growth delay without short-term toxicity<sup>1</sup>
- Investigator-initiated trials demonstrated proof-of-concept for CAIX-targeted alpha therapy in triple-negative breast cancer, non-muscle-invasive bladder cancer<sup>2,3</sup>

### Planned clinical activity

Phase 1 study in CAIX positive cancers:

- Planning to commence patient enrolment at Australian sites in 2026, subject to regulatory approval



# Clinical utility of $^{225}\text{Ac}$ -TLX252

## Significant unmet medical need for patients with CAIX-expressing tumors and opportunity to overcome hypoxia-driven treatment resistance

- Patients with tumors expressing high levels of CAIX, a marker of tumor hypoxia, have significantly poorer overall survival, shorter disease-free survival, and greater risk of recurrence and metastasis<sup>1</sup>
- Overall, approximately 30-70% of patients have CAIX-high tumors across solid cancer types.
- CAIX is a broad indicator of aggressive, treatment-resistant disease in most solid tumors. For example, high CAIX expression is linked to:
  - **Chemoresistance:** Including in breast cancer<sup>2</sup>, ovarian cancer<sup>3</sup> and bladder cancer<sup>4</sup>
  - **Resistance to immunotherapy:** In head and neck cancer, CAIX-positive, hypoxic tumors show impaired immune-cell function, with lower CAIX levels associated with better PD-1 inhibitor responses<sup>5</sup>
  - **Radioresistance:** Hypoxia (often associated with CAIX expression) induces radioresistance through a number of molecular pathways<sup>6</sup>
- The use of an  $\alpha$ -emitter like  $^{225}\text{Ac}$  for CAIX-targeted radiation may help overcome treatment resistance in these aggressive tumors given the unique properties of  $\alpha$ -particles, which make this treatment modality impervious to conventional cellular resistance mechanisms<sup>7</sup>

1. van Kuijk et al. *Front Oncol.* 2016.

2. Betof, et al. *Br J Cancer.* 2012.

3. Williams et al. *Virchows Arch.* 2012.

4. Leite et al. *Clin Genitourin Cancer.* 2022.

5. Zandberg et al. *J Immunother Cancer.* 2021

6. Pastorekova, S., Gillies, R.J. *Cancer Metastasis Rev.* 2019.

7. Sgouros G. *Cancer Research.* 2019.

# TLX252 Phase 1 study in CAIX-positive cancers

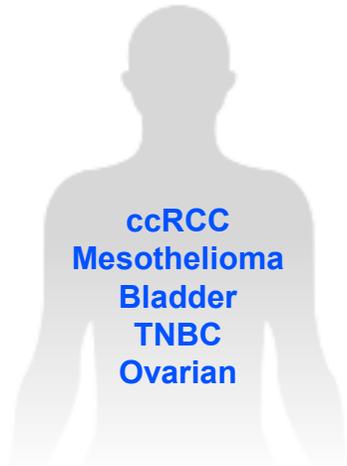
Utilizing the theranostic pairing of imaging and alpha therapy to personalize treatment

Patient population → Patient selection & treatment planning → Truly personalized patient treatment

CAIX-expressing tumors

Telix's  $^{89}\text{Zr}$ -Girentuximab (TLX250-CDx) imaging agent used to select patients and estimate therapeutic dose

Imaging with TLX250-CDx allows prediction of tumor uptake and therefore enables ALL patients to receive comparable doses of  $^{225}\text{Ac}$ -TLX252 irrespective of cancer type



$^{89}\text{Zr}$ -TLX250  
predictive  
dosimetry



Cohort 1  
Initial dose

Dose escalation

Cohort 2  
Higher dose



Planning to commence patient enrolment at Australian sites in 2026, subject to regulatory approval



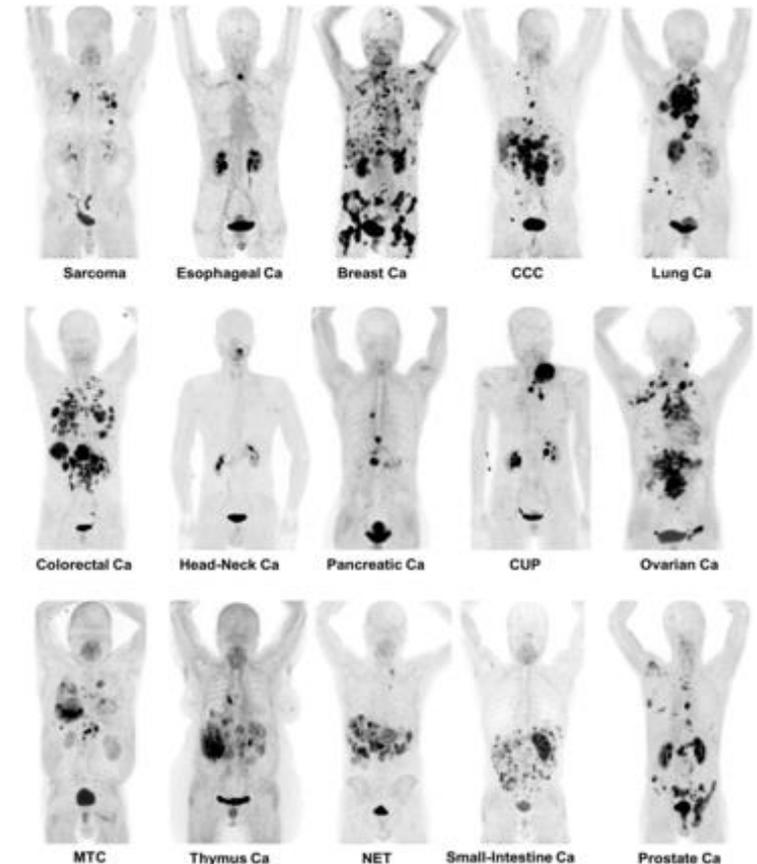
# FAP expression suggests potential target for pan-cancer theranostic

## Opportunity to treat spectrum of tumors with single target

- FAP present on more than 90% of epithelial cancers, **identified as a potential target for molecular imaging and therapy**
- **Broad expression on tumor stroma across solid tumors** (including pancreatic, colorectal, breast, bladder) suggests pan-tumor potential
- In certain cancers (e.g., sarcoma, ovarian, pancreatic) FAP also expressed on cell surface, potentially enhancing efficacy
- **Not expressed in most normal adult tissues**
- This prevalence, along with the druggability of the target, is what makes FAP a potential Achilles' heel of cancer

### SNMMI Image of the Year 2019

#### <sup>68</sup>Ga-FAPI PET/CT: Tracer Uptake in 28 Different Kinds of Cancer<sup>1</sup>



Maximum-intensity projections of <sup>68</sup>Ga-FAPI PET/CT in patients reflecting 15 different histologically proven tumor entities (sorted by uptake in descending order). Ca = cancer; CCC = cholangiocellular carcinoma; CUP = carcinoma of unknown primary; MTC = medullary thyroid cancer; NET = neuroendocrine tumor.

# TLX400: Next generation FAPi therapy with pan-tumor potential

## Product candidate

$^{177}\text{Lu}$ -DOTAGA.Glu.(FAP)<sub>2</sub>

## Targeting molecule / target

Fibroblast Activation Protein (FAP)

## Indication

Pan-cancer

## Clinical experience to date

The diagnostic and therapeutic compounds have been clinically validated in over 700 patients across a variety of solid tumors and are the subject of multiple peer-review publications<sup>1</sup>

## Planned clinical activity

Planned to commence clinical development program in 2026: Pan-cancer basket study + lead indication (undisclosed)

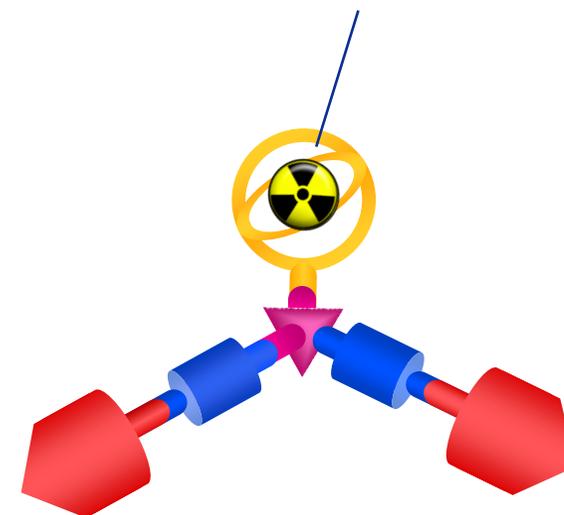


### Prof. Dr. Frederik L. Giesel

Chair of Dept of Nuclear Medicine at Uni Düsseldorf

*“FAP-targeting is very exciting. In the past, we have been successful in treating primarily one cancer type with a certain asset or therapeutic agent. Here we have opened a new door to treat a variety of cancer subtypes – a pan tumor target and even beyond.”*

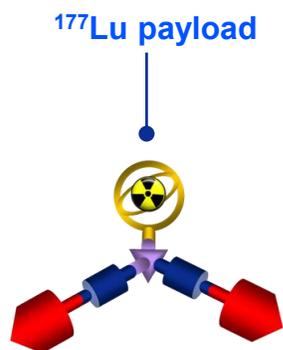
Payload:  $^{177}\text{Lu}$   
 $T_{1/2}$ : 6.7 days



# TLX400: FAP-targeting candidate with pan-tumor potential

Next generation asset designed to overcome historical limitations of FAP therapy

TLX400:  
 $^{177}\text{Lu}$ -  
DOTAGA.Glu.(FAP)<sub>2</sub>



## Clinically-validated therapeutic and companion diagnostic

- Designed to overcome limitations of current (first generation) FAP targeted radiotherapies e.g., short tumor residence and non-target organ uptake<sup>1</sup>
- Engineered for prolonged tumor retention, delivering a substantial radiation dose to the tumor while minimizing off-target organ uptake and enhancing systemic clearance
- Therapeutic candidate: Clinical data in ~150 patients including sarcoma, breast, thyroid cancers, three published datasets and extensive peer-reviewed pre-clinical research<sup>2</sup>
- Complementary diagnostic agent enables patient selection and extension into bladder cancer
  - Significant clinical experience with over 550 patients dosed

**Planned to commence clinical development program in 2026: Pan-cancer basket study + lead indication for accelerated approval (undisclosed) as well as IITs**

# Telex is leading the next generation of radiopharmaceuticals

We have multiple drivers of value creation

## Commercial execution

- ✓ Proven track record of commercial delivery with Illuccix
- ✓ Now differentiated as the only provider with two FDA-approved PSMA-PET imaging agent for U.S.
- ✓ Global expansion as Illuccix launches in Europe

## Pipeline Development

- ✓ Multiple near-term catalysts in Precision Medicine (Zircaix, Pixclara)
- ✓ Key therapeutic assets progressing to pivotal trials (TLX591, 250, 101)
- ✓ Advancing the next-generation assets and R&D platform

## Industry-leading manufacturing and supply chain

- ✓ Manufacturing, isotope and distribution capabilities and partnerships
- ✓ Global delivery and patient access

Zircaix and Pixclara brand names and marketing authorization subject to regulatory approval.

## Contact:

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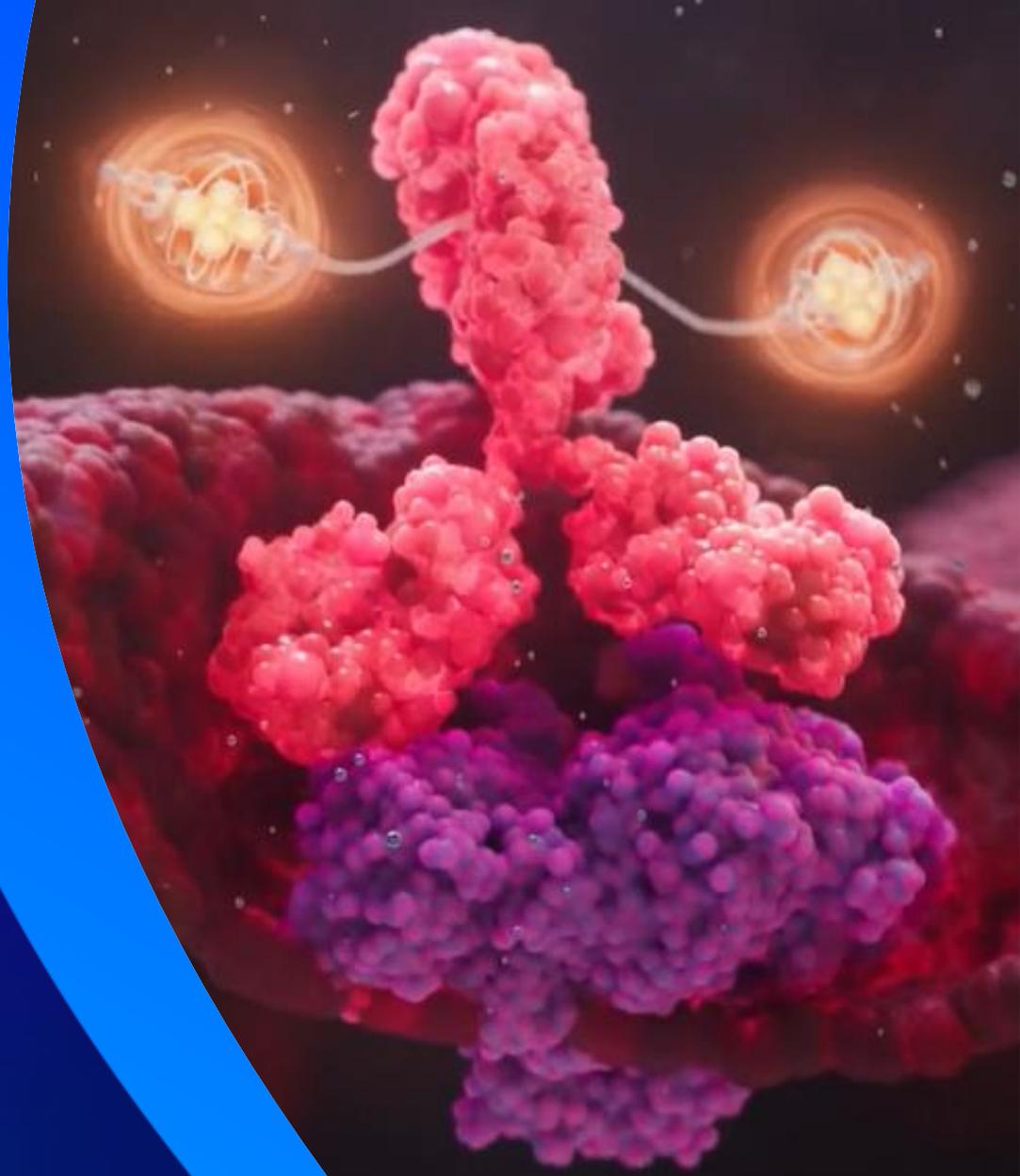


Illustration showing TLX250 binding to carbonic anhydrase IX and internalization