



Therapeutics

# Unlocking the Potential of PSMA Therapy: A Next Generation Portfolio Approach

Scientific Update

April 2026

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# Presenters



**David N. Cade, MBBS**

Group Chief Medical Officer  
Telix Pharmaceuticals



**Louise Emmett, MD<sup>1</sup>**

Director of Theranostics and Nuclear Medicine  
St Vincent's Hospital, Sydney, Australia

# Agenda

- 1** Telix PSMA Portfolio
- 2** Experience with TLX597-Tx:  
OPTIMAL-PSMA
- 3** Summary and Q&A

1. Prof. Emmett is an independent expert speaker and is not an employee or consultant of Telix. Views expressed are the speaker's own.



# Telix PSMA Portfolio

**Dr. David N. Cade**

# Executive Summary

## A next generation portfolio overcomes limitations of first generation RLTs

1.  $^{177}\text{Lu}$ -PSMA small molecule radioligand therapy (RLT) is established in **advanced prostate cancer** (e.g. PSMA-617/I&T)
2. However, use of first generation RLT in **early prostate cancer** has proven challenging, due to worsened **quality of life (QOL)** and **renal toxicity** (e.g. PSMAAddition<sup>1</sup> and SPLASH<sup>2</sup> trials)

**Telix has two advanced-stage PSMA-targeting programs with distinct MOAs, tailored to the disease state**

- **TLX591-Tx in mCRPC:** Radio antibody-drug conjugate (rADC)
  - Antibody advantage is selectivity for tumor-expressed PSMA and long retention / residualization times
  - Two-dose regimen intended to be combined with standard of care (SOC) (Phase 3 ProstACT Global trial<sup>3</sup>)
- **TLX597-Tx in mHSPC:** Highly targeted “next generation” small molecule RLT with favorable dosimetry
  - Minimal salivary gland and kidney uptake suggests best-in-class small molecule profile
  - Biodistribution supports dose intensification, improved efficacy, and potentially QOL in mHSPC

**Proof-of-concept data from OPTIMAL-PSMA<sup>4</sup> Ph 2 RCT reported at ICPS 2026, Lugano, Switzerland**



NOTES:

PSMA = prostate-specific membrane antigen.

MOA = mode of action.

mHSPC = hormone-sensitive prostate cancer.

mCRPC = metastatic castration-resistant prostate cancer.

RCT = randomized controlled trial.

SOURCES:

1. ClinicalTrials.gov ID NCT04720157.

2. ClinicalTrials.gov ID NCT04647526.

3. ClinicalTrials.gov ID: NCT06520345.

4. Australian New Zealand Clinical Trials Registry ID: ACTRN12625000971437.

# Key considerations as PSMA RLT moves into earlier settings

## Quality of life and tailored dosing are critical

### Treatment algorithm for metastatic prostate cancer<sup>1</sup>

Estimated U.S. incidence<sup>2</sup>, 2026



**QOL & renal toxicity considerations increase in earlier, healthier patients**

- **First generation <sup>177</sup>Lu-PSMA-617 / I&T** established as a treatment for advanced prostate cancer
- **Emerging concerns as first generation agents attempt to move up treatment lines to earlier, healthier patients**
  - Risk from radiation to salivary glands and kidneys leading to **dry mouth** and **renal toxicity**<sup>4</sup>
  - **Over-treatment with fixed 6-dose regimen** (PSMAddition trial)<sup>5</sup>

### Long-Term Nephrotoxicity of <sup>177</sup>Lu-PSMA Radioligand Therapy

Lisa Steinhelfer\*<sup>1,2</sup>, Lukas Lunger\*<sup>3</sup>, Lisena Cala<sup>1</sup>, Christian H. Pfob<sup>4</sup>, Constantin Lapa<sup>4</sup>, Philipp E. Hartrampf<sup>5</sup>, Andreas K. Buck<sup>5</sup>, Hannah Schäfer<sup>6</sup>, Christoph Schmaderer<sup>6</sup>, Robert Tauber<sup>3</sup>, Julia Brosch-Lenz<sup>1</sup>, Bernhard Haller<sup>7</sup>, Valentin H. Meissner<sup>3</sup>, Karina Knorr<sup>1</sup>, Wolfgang A. Weber<sup>1</sup>, and Matthias Eiber<sup>1</sup>

### Assessment of nephrotoxicity following lutetium-177 PSMA I&T radioligand therapy: a comparative study with docetaxel chemotherapy

Florian P Kirchhoff<sup>1</sup> · Lisa Steinhelfer<sup>2,3</sup> · Christian H. Pfob<sup>4</sup> · Constantin Lapa<sup>4</sup> · Philipp E. Hartrampf<sup>5</sup> · Andreas K. Buck<sup>5</sup> · Robert Tauber<sup>1</sup> · Hannah Schäfer<sup>6</sup> · Christoph Schmaderer<sup>6</sup> · Cornelia Fütterer<sup>7</sup> · Bernhard Haller<sup>7</sup> · Matthias Jahn<sup>1</sup> · Karina Knorr<sup>2</sup> · Jürgen E. Gschwend<sup>1</sup> · Wolfgang A. Weber<sup>2</sup> · Matthias Eiber<sup>2</sup> · Lukas Lunger<sup>1</sup>

1. Adapted from Calais J. UCLA 2023 EANM 2023; NCCN Guidelines Version 5.2026 Category 1 Preferred.  
 2. Clarivate Market Forecast, published July 2025.  
 3. ClinicalTrials.gov ID: NCT03511664.  
 4. Steinhelfer et al. J Nucl Med. 2024; Kirchloff et al. EJNM 2026.  
 5. Azad, *Discussant – Phase III Trial of [<sup>177</sup>Lu]Lu-PSMA-617 Combined with ADT + ARPI in Patients with PSMA-Positive Metastatic Hormone-Sensitive Prostate Cancer (PSMAddition)*, presented at ESMO 2025. ClinicalTrials.gov ID: NCT04720157.

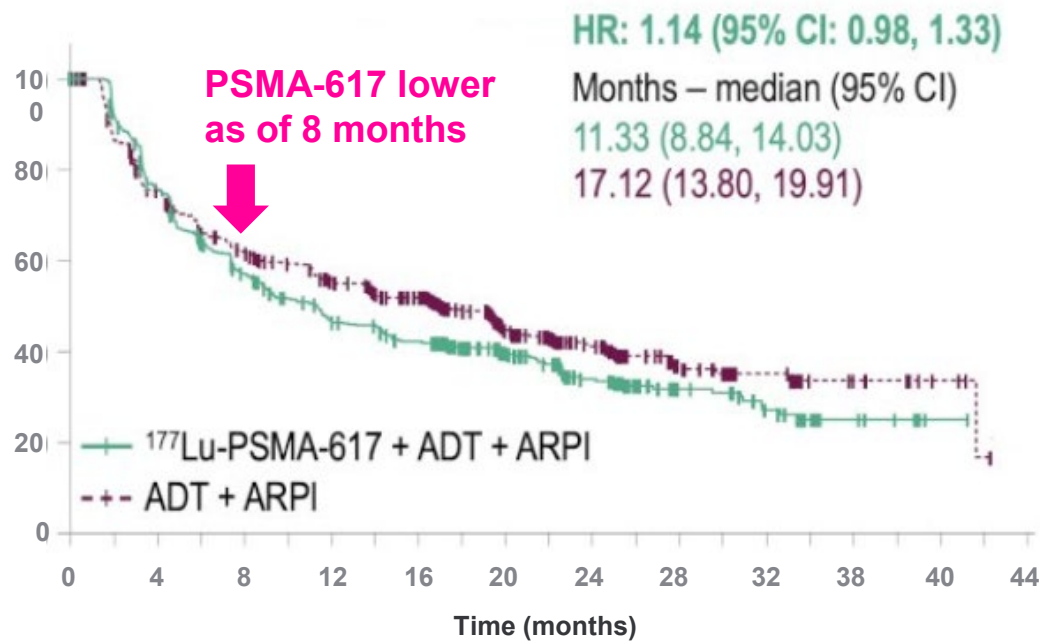
# QOL learnings from <sup>177</sup>Lu-PSMA-617 in hormone sensitive setting

## Challenges in healthier patients may limit potential clinical utility

PSMAddition Ph 3 showed limited improvement in QOL with PSMA-617<sup>1</sup>...

... leading to clinicians expressing concern about utility and level of adoption<sup>2</sup>

### FACT-P Total Score (QOL metric)



### Concluding thoughts from Prof Azad's discussion of PSMAddition at ESMO 2025

- The goal of any anti-cancer treatment is to make patients live longer and live better
  - This goal has not been achieved in PSMAddition
- I would not recommend widespread use of Lu-PSMA-617 in mHSPC at this stage
  - Would consider using if "bad" disease (e.g. de novo high volume) or "bad" scans (e.g. very high PSMA SUVmean and/or total tumour volume)
  - I have concerns about patient selection, overtreatment and impact of toxicity



SOURCES:

1. Tagawa, Phase III Trial of [<sup>177</sup>Lu]Lu-PSMA-617 Combined with ADT + ARPI in Patients with PSMA-Positive Metastatic Hormone-Sensitive Prostate Cancer (PSMAddition), presented at ESMO 2025. ClinicalTrials.gov ID NCT04720157.

1. Azad, Discussant – Phase III Trial of [<sup>177</sup>Lu]Lu-PSMA-617 Combined with ADT + ARPI in Patients with PSMA-Positive Metastatic Hormone-Sensitive Prostate Cancer (PSMAddition), presented at ESMO 2025.

# What does the “next generation” need to look like to succeed?

## Moving the needle on PSMA theranostics

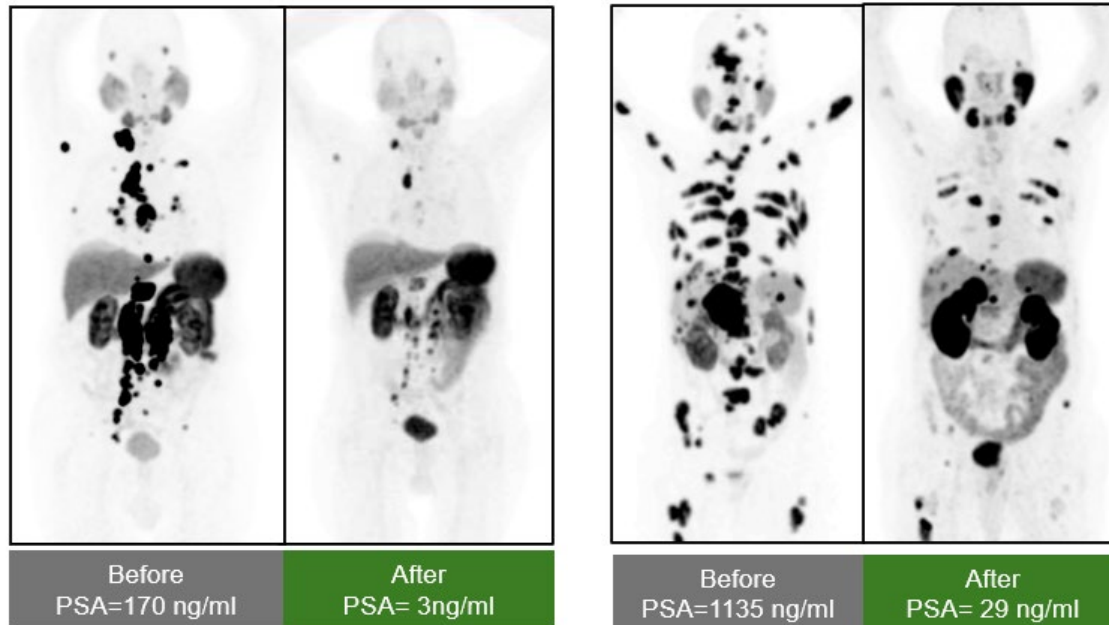
- Greater consideration around clearance organ dosimetry (hepatic clearance or very low renal imparted dose)
- Avoidance of exocrine gland irradiation
- Higher tumor retention / residualization, especially given the typically short retention and pharmacokinetics of small molecules
- Dosing regimens that maximize patient benefit
- More intensive treatment regimens that may benefit patient compliance
- Better integration with standard of care
- Potential to flexibly incorporate alpha-emitters



# TLX597-Tx (<sup>177</sup>Lu-DOTA-HYNIC-panPSMA)

## Highly targeted small molecule agent optimized for early prostate cancer

Representative images from 2 different patients who achieved ≥85% decrease from baseline PSA level following treatment with TLX597-Tx<sup>1</sup>



Patient representative scans – individual results may vary.

- **Current status:**

- Exploratory Phase 1 investigator-initiated trial (IIT) with adjusted formulation showed promising dosimetry (low kidney, salivary gland irradiation) and PSA reduction<sup>1</sup>
- OPTIMAL-PSMA<sup>2</sup> Phase 2 study with over 85 patients dosed trialing novel dosing regimen, promising efficacy signals
- Early access in select geographies

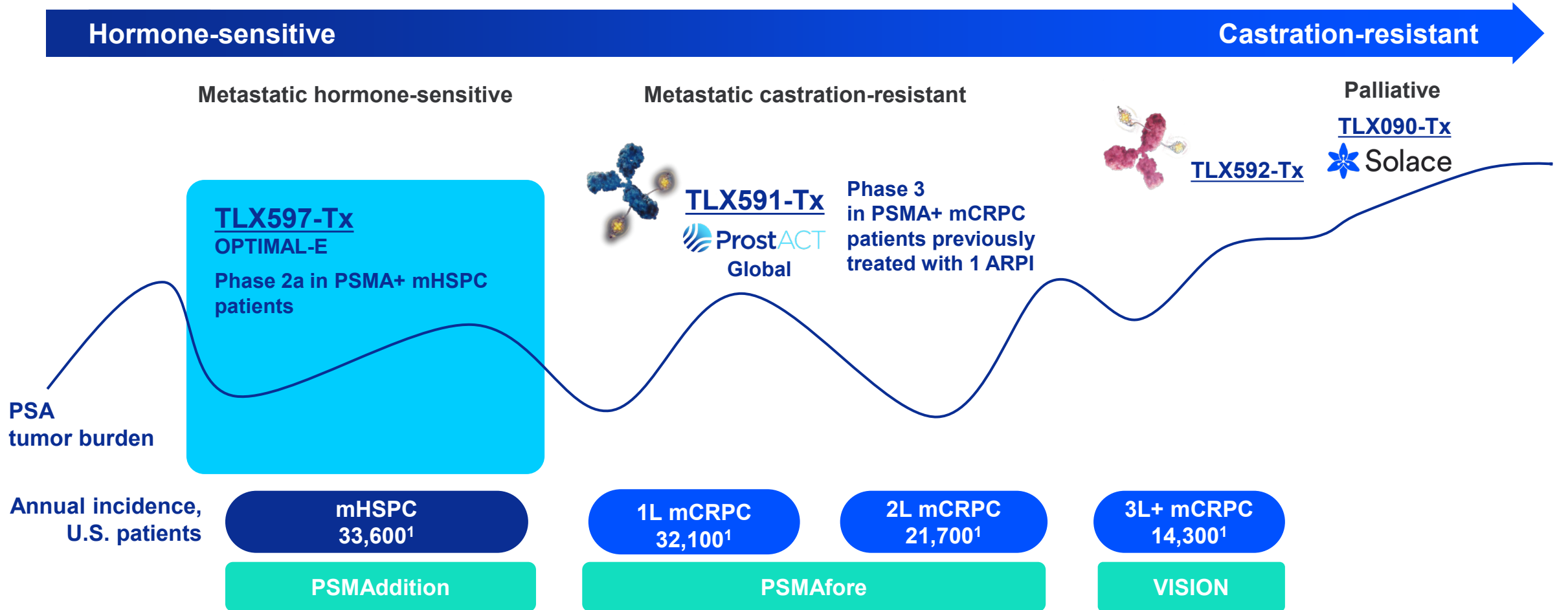
- **Highly targeted biodistribution with minimal salivary gland and kidney uptake supports**

- Dose intensification to improve efficacy
- Potential suitability in earlier prostate cancer (mHSPC)<sup>2</sup>

SOURCES:

1. Omar et al, [<sup>177</sup>Lu]Lu-DOTA-PSMA radioligand therapy for patients with metastatic castration-resistant prostate cancer, presented at EANM 2025.
2. Crumbaker et al. Dose Optimisation and PSMA Receptor intensification with <sup>177</sup>Lu-PSMA-597 in metastatic castration-resistant prostate cancer, the Randomised Phase II OPTIMAL-PSMA trial, presented at ASCO GU 2026; data on file. Australian New Zealand Clinical Trials Registry ID: ACTRN12625000971437.

# Portfolio to address early and late stage prostate cancer





Therapeutics

# Experience with TLX597-Tx: OPTIMAL-PSMA

Prof. Louise Emmett

# OPTIMAL-PSMA: POC for novel dosing with next gen agent

Phase 2 IIT at St Vincent's Hospital has dosed over 85 patients with TLX597-Tx

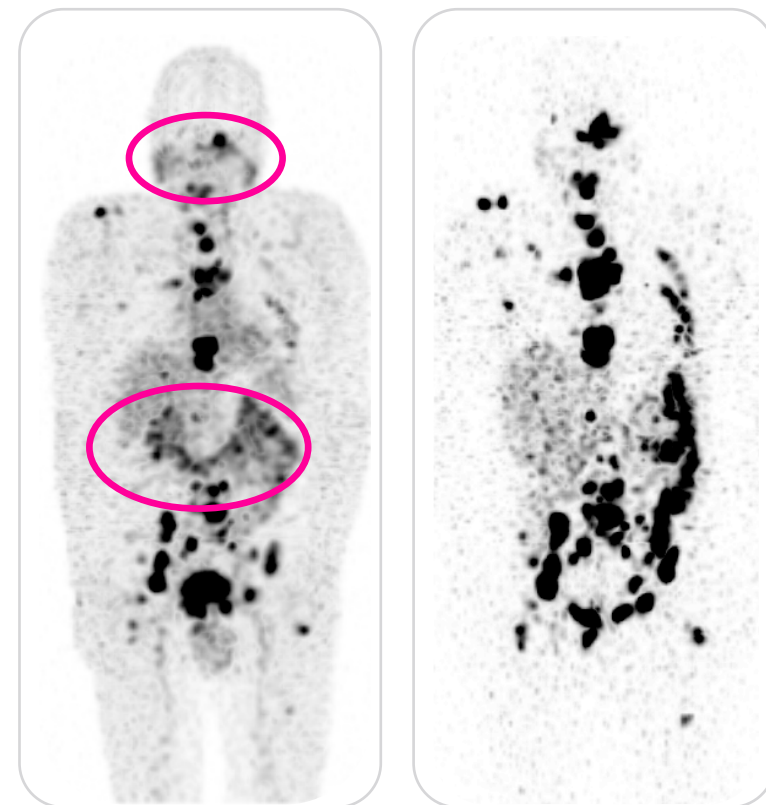
- VISION<sup>1</sup> and TheraP<sup>2</sup> trials demonstrated that <sup>177</sup>Lu-PSMA-617 improves QOL, but OS benefit is modest
- Evidence suggests underdosing of patients with PSMA therapy
  - Standard 7.5GBq (200mCi) dosing based on external beam radiation limits to kidneys
  - Clinical experience shows patients can tolerate higher doses
  - SPLASH<sup>3</sup> trial of PSMA-I&T suggested decreasing administered activity reduces tumor dose and efficacy
- OPTIMAL-PSMA<sup>4</sup> aims to improve response and survival by
  - 1) Using agent with highly favorable biodistribution enabling dose intensification, TLX597-Tx
  - 2) Optimizing dosing by intensifying administered activity to maximize radiation dose when the cancer cell is most vulnerable to damage

# TLX597-Tx dosimetry: Favorable profile vs available agents

Dosimetry enables dose intensification

Organs	TLX597-Tx (Gy/GBq) (n = 12) <sup>1</sup>	PSMA-617 <sup>2</sup> (Gy/GBq) (n = 297)	PSMA-I&T <sup>2</sup> (Gy/GBq) (n = 153)
Kidneys	0.28	0.58	0.71
Lacrimal	0.35	1.58	2.83
Submandibular	0.25	0.74	0.64
Lesions (bone)	9.74	3.57	4.1
Lesions (soft tissue)	9.57	4.19	2.94

TLX597-Tx SPECT scan, 5 and 120 hr



Patient representative scans – individual results may vary.

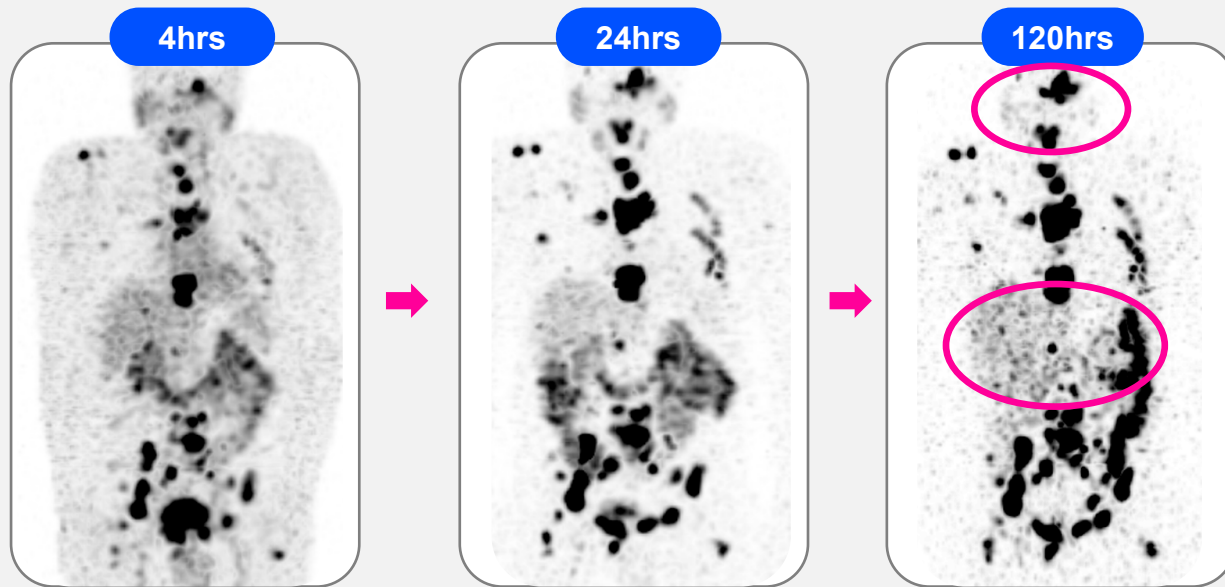
SOURCES:

1. Final dosimetry report for PSMA-597 (Ascinta Technologies)
2. Ellis et al Dosimetry of [177Lu]Lu-PSMA-Targeted Radiopharmaceutical Therapies in Patients with Prostate Cancer: A Comparative Systematic Review and Meta analysis. JNM 2024; 65:1264–1271.

# TLX597-Tx uptake profile compared to PSMA-617

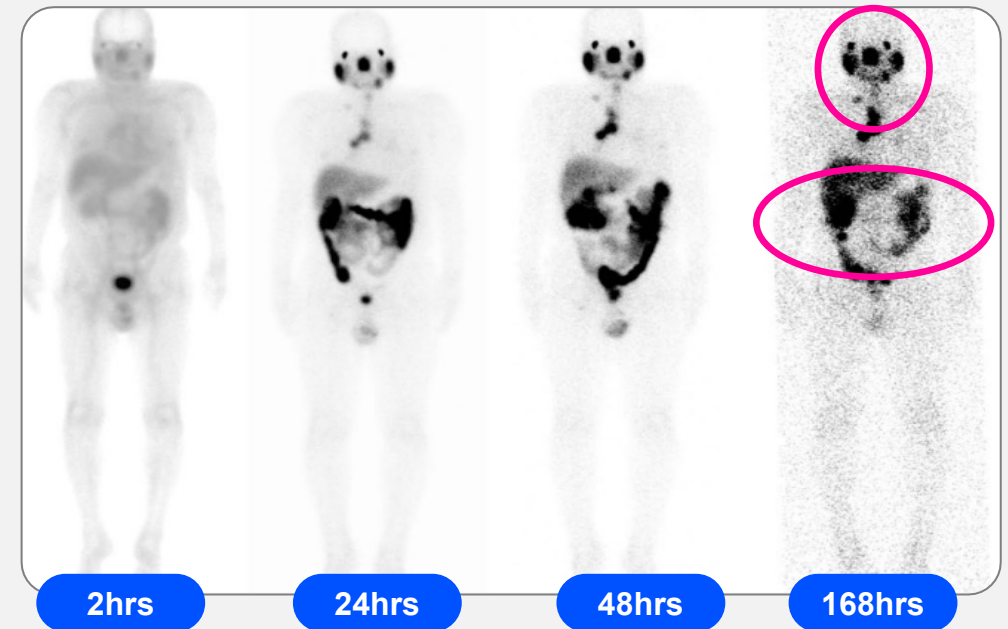
Long tumor retention even at 120 hours, limited salivary gland and kidney uptake

## TLX597-Tx SPECT biodistribution<sup>1</sup>



Dosimetry demonstrates low salivary gland and renal doses, high persistence of tumor radiation activity on the 120-hour imaging. The dose delivered to salivary glands is 0.25Gy/GBq (2.15Gy/7.4Gq), to kidneys is 0.28Gy/GBq (2.05Gy/7.4Gq) and to tumor is 9.74Gy/GBq (72Gy/7.4Gq). Patient representative scans – individual results may vary.

## PSMA-617 SPECT biodistribution<sup>2</sup>



Patient representative scans – individual results may vary.

### SOURCES:

1. Crumbaker et al. *Dose Optimisation and PSMA Receptor intensification with 177Lu-PSMA-597 in metastatic castration-resistant prostate cancer, the Randomised Phase II OPTIMAL-PSMA trial*, presented at ASCO GU 2026
2. *Annals of Nuclear Medicine* (2025) 39:1201–1212

# TLX597-Tx proof-of-concept: Phase 2 OPTIMAL-PSMA study

## Exploring safety, dosimetry, and efficacy of short-interval dose intensification

Aim: To see whether giving <sup>177</sup>Lu-PSMA more frequently at the start of treatment can overcome early resistance and improve outcomes.

### Part B: Pt 41-120

#### Eligibility

- Confirmed mCRPC
- Progressed on prior ARPI
- Baseline <sup>68</sup>Ga-PSMA-11 ENZA-p criteria (SUV max >15 at single site and >10 at larger sites)

Majority of patients received prior taxane

**TLX597-Tx\*  
Dose Intensified**

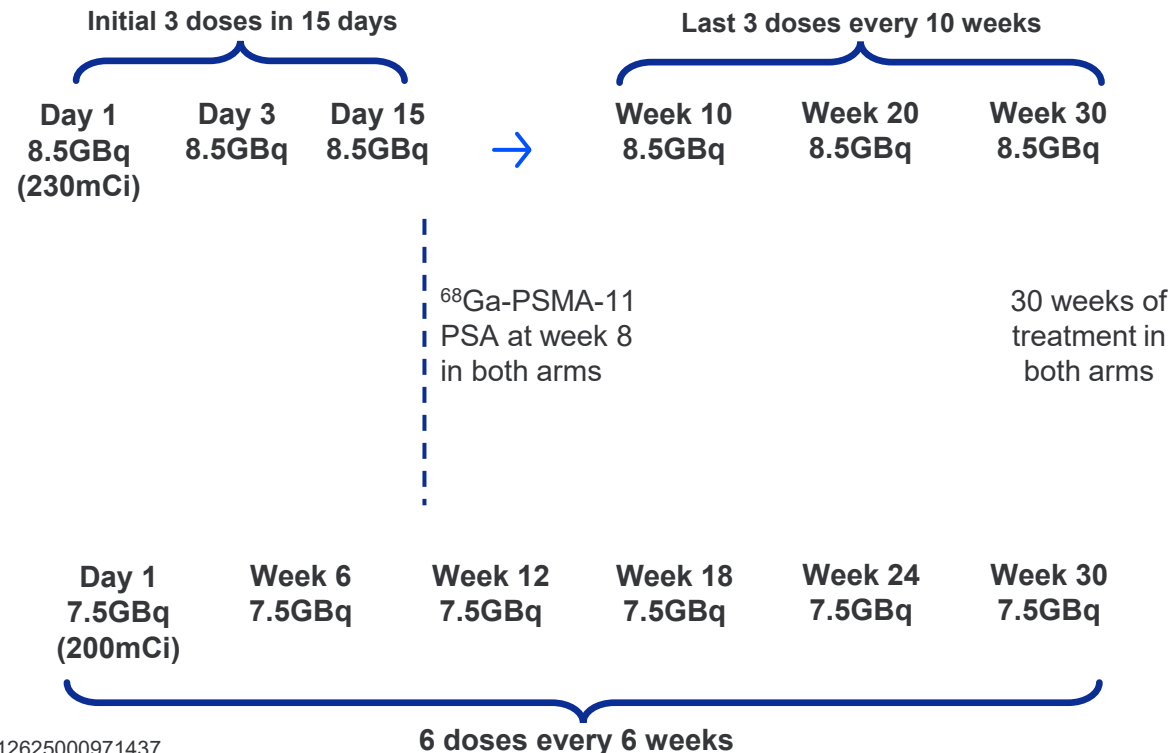
**ARM 1  
N = 80**

**TLX597-Tx  
Standard of Care**

**ARM 2  
N = 40**

2:1

Investigator Initiated Trial (PI: Prof Louise Emmett, St Vincent's Hospital Sydney)



#### Primary EP

- PSA90 RR

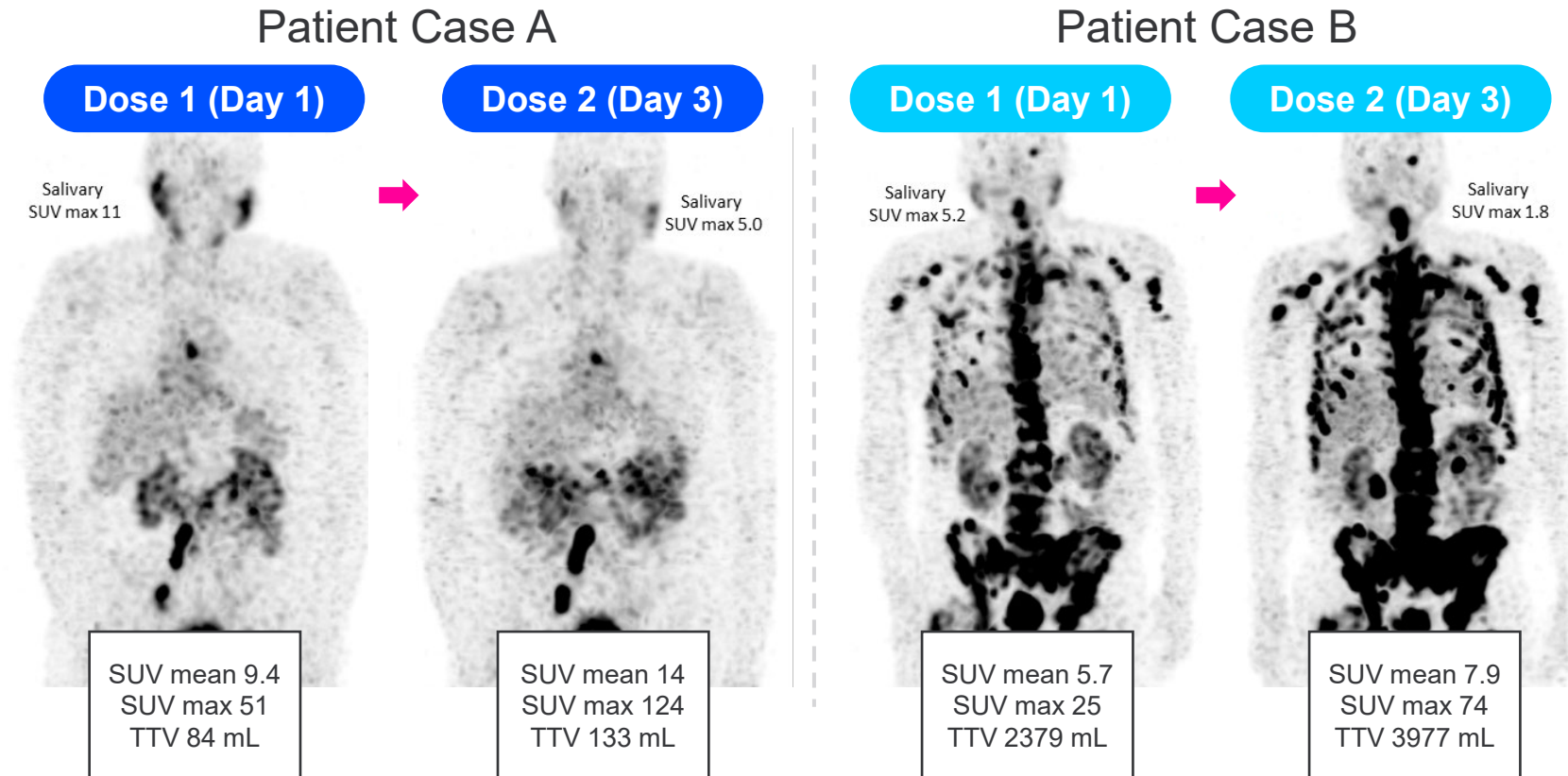
#### Secondary EPs

- PSA50 RR
- PSA-PFS
- rPFS
- OS
- ORR
- QoL
- Safety
- Dosimetry

# Why is up-front dose intensification effective?

Dose 1 induces PSMA expression in tumors, potentially increasing uptake of doses 2 and 3

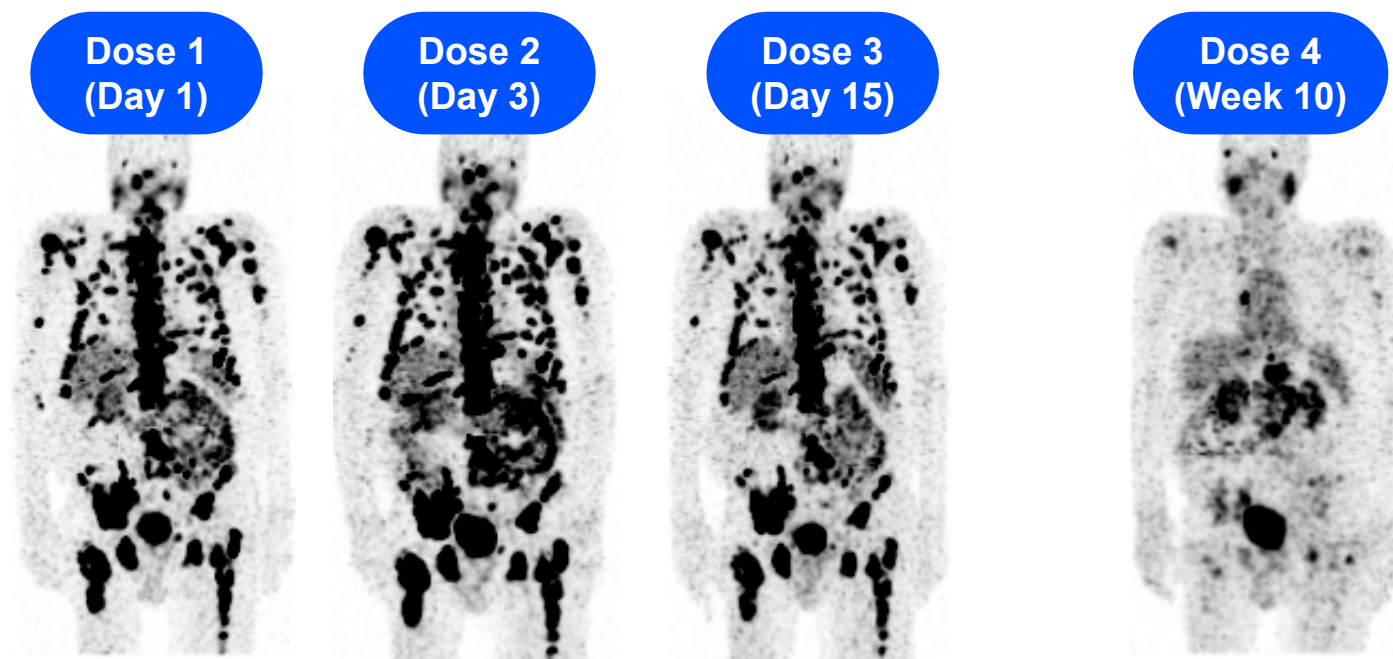
Day 3 scans show increase in TTV from higher PSMA expressions



NOTES:  
Patient representative scans - individual results may vary.  
Data from ASCO-GU 2026; Megan Crumbaker.

- 3 doses upfront maximize cell kill effect when PSMA expression is the highest
- Initial dose induces PSMA up-regulation (increased tumor volume on day 3 imaging), doses 2-3 increase radiation dose rate in cancer cells

# Patient case: TLX597-Tx post-chemo (2 lines), post-ARPI



**71-year-old patient with diffuse bone metastases**

- Blood platelets lower but stable
- Normal kidney function
- Substantial shrinkage of lesions
- 97% PSA response at week 10

	Day 1	Day 3	Day 15	Week 6	Week 10
PSA	1380	1480	828	131	40
Hb	112	111	117	116	106
PLT	201	198	217	190	208
eGFR	90	90	90	90	89

# Early data warrants exploring TLX597-Tx in the mHSPC setting

Biodistribution, flexible dosing regimen, favorable safety suggest promising profile

## ✓ Safety profile

Low renal and salivary gland uptake, limited AEs

## ✓ Pharmacokinetic (PK) profile

Long tumor retention, high lesion dose vs other small molecules

## ✓ Biodistribution

Enables intensified regimen to maximize efficacy

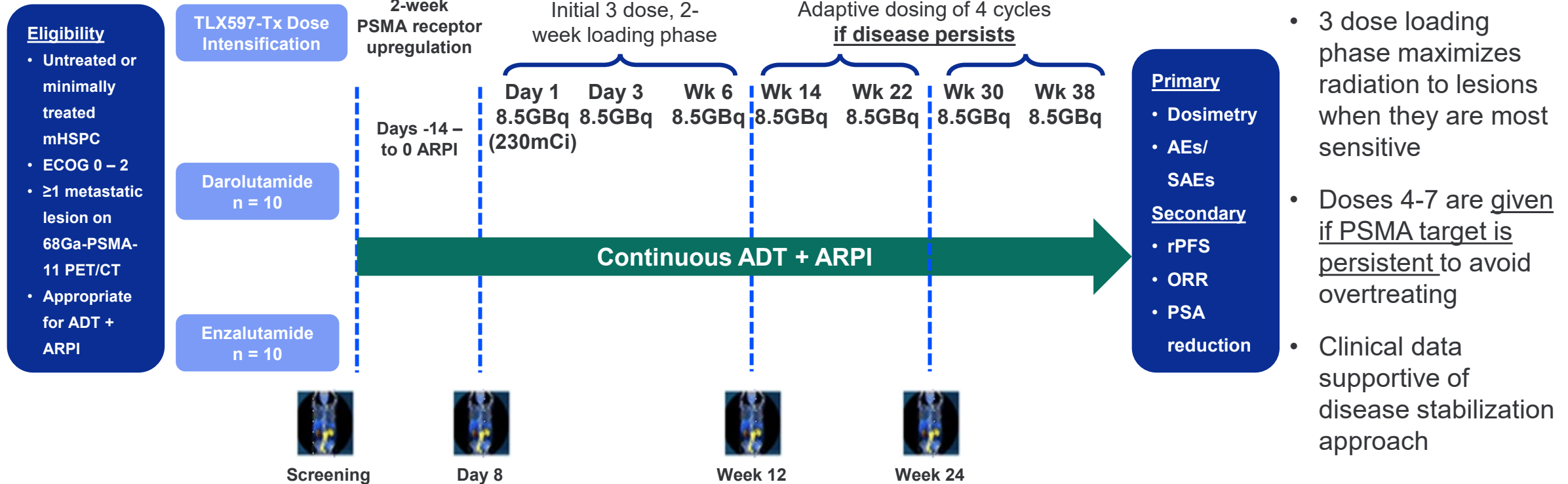
## ✓ Adaptive dosing

Maximize therapeutic effect in strong responders

- **Quality of life characteristics suggest high potential in mHSPC**
- **Additional future potential with novel isotopes e.g., alpha emitters including <sup>225</sup>Actinium**

# OPTIMAL-E: TLX597-Tx proof-of-concept in mHSPC (n=20)

Ph 2a exploring adaptive dosing with 3, 5, or 7 doses depending on response



ADT in the neo-adjuvant setting and / or up to 45 days of ADT/ARPI for metastatic disease allowed before study entry | Any ARPI with one switch allowed | BRIC, blinded independent review committee; ECOG PS, Eastern Cooperative Oncology Group performance status; mHSPC, metastatic hormone-sensitive prostate cancer; OS, overall survival; PET/CT, positron-emission tomography / computed tomography; rPFS, radiographic progression free survival.



# Summary



# Q&A

## Telix Contacts:

Kyahn Williamson (Global)  
SVP Investor Relations and Corporate Communications  
[kyahn.williamson@telixpharma.com](mailto:kyahn.williamson@telixpharma.com)

Telix Investor Relations (U.S.)  
Ms. Annie Kasparian  
Director Investor Relations and Corporate  
Communications  
[annie.kasparian@telixpharma.com](mailto:annie.kasparian@telixpharma.com)

Telix Investor Relations (Australia)  
Ms. Charlene Jaw  
Associate Director Investor Relations  
[charlene.jaw@telixpharma.com](mailto:charlene.jaw@telixpharma.com)

Crystal structure of prostate-specific  
membrane antigen

