



Therapeutics

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

Scientific Update

April 2026

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Presenters



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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}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. PSMAAddition¹ and SPLASH² 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 trial³)
- **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-PSMA⁴ 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 RNT moves into earlier settings

Quality of life and tailored dosing are critical

Treatment algorithm for metastatic prostate cancer¹

Estimated U.S. incidence², 2026



QOL & renal toxicity considerations increase in earlier, healthier patients

- **First generation ¹⁷⁷Lu-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**⁴
 - **Over-treatment with fixed 6-dose regimen** (PSMAddition trial)⁵

Long-Term Nephrotoxicity of ¹⁷⁷Lu-PSMA Radioligand Therapy

Lisa Steinhelfer^{*1,2}, Lukas Lunger^{*3}, Lisena Cala¹, Christian H. Pfob⁴, Constantin Lapa⁴, Philipp E. Hartrampf⁵, Andreas K. Buck⁵, Hannah Schäfer⁶, Christoph Schmaderer⁶, Robert Tauber³, Julia Brosch-Lenz¹, Bernhard Haller⁷, Valentin H. Meissner³, Karina Knorr¹, Wolfgang A. Weber¹, and Matthias Eiber¹

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

Florian P Kirchhoff¹ · Lisa Steinhelfer^{2,3} · Christian H. Pfob⁴ · Constantin Lapa⁴ · Philipp E. Hartrampf⁵ · Andreas K. Buck⁵ · Robert Tauber¹ · Hannah Schäfer⁶ · Christoph Schmaderer⁶ · Cornelia Fütterer⁷ · Bernhard Haller⁷ · Matthias Jahn¹ · Karina Knorr² · Jürgen E. Gschwend¹ · Wolfgang A. Weber² · Matthias Eiber² · Lukas Lunger¹

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 [¹⁷⁷Lu]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.

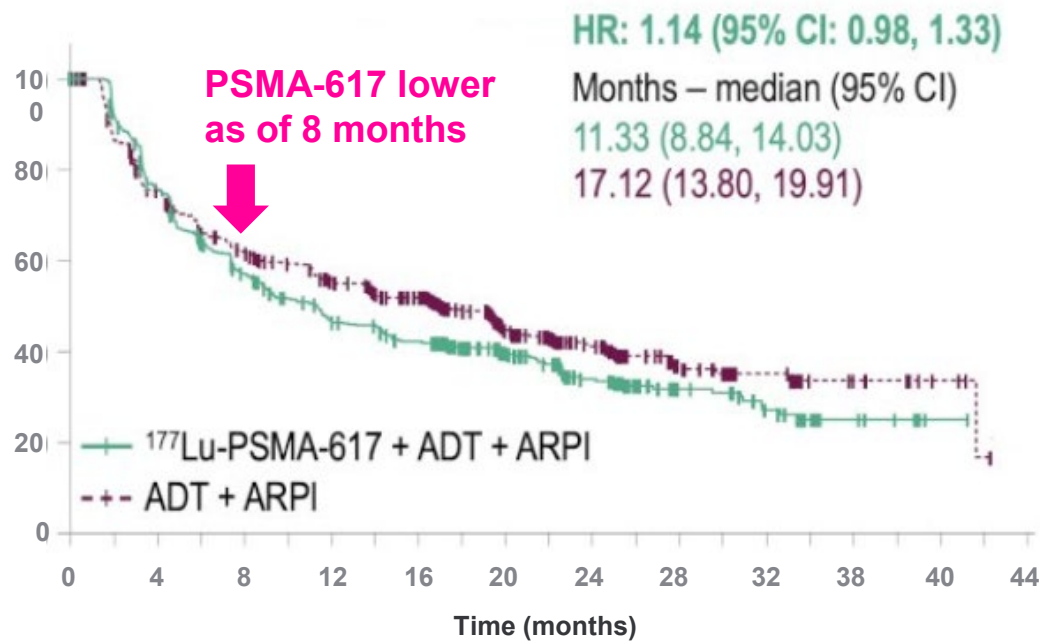
QOL learnings from ¹⁷⁷Lu-PSMA-617 in hormone sensitive setting

Challenges in healthier patients may limit potential clinical utility

PSMAddition Ph 3 showed limited improvement in QOL with PSMA-617¹...

... leading to clinicians expressing concern about utility and level of adoption²

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 [¹⁷⁷Lu]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 [¹⁷⁷Lu]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

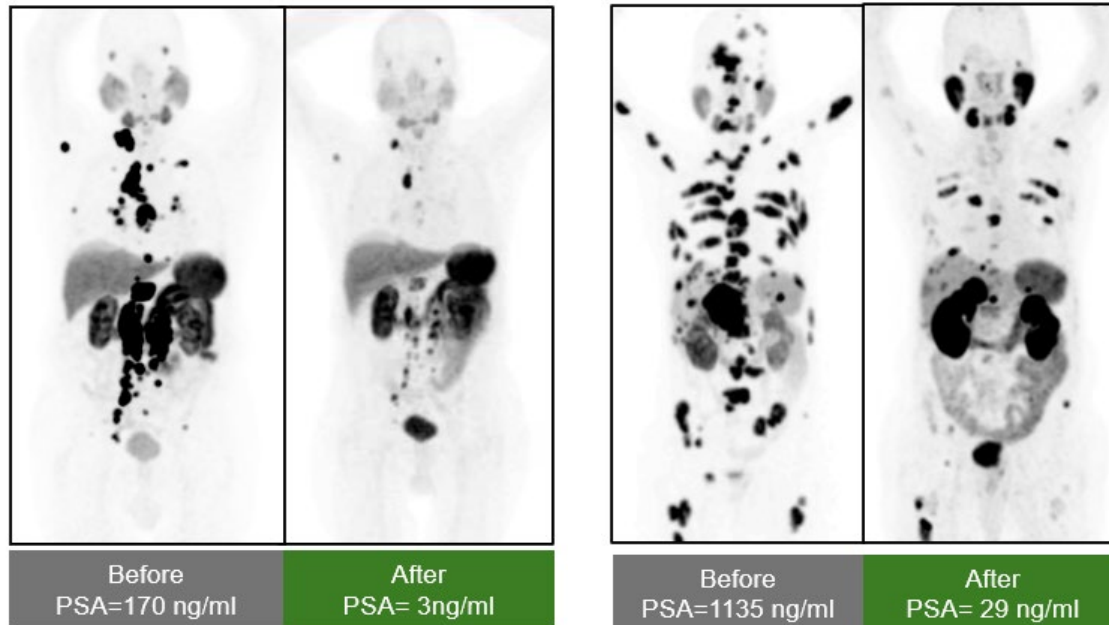
- Greater consideration around clearance organ dosimetry (hepatic clearance or very low renal imparted dose)
- Avoidance of exocrine gland irradiation
- Higher tumor retention / residualization, especially given the typically short retention and pharmacokinetics of small molecules
- Dosing regimens that 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 (¹⁷⁷Lu-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-Tx¹



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 reduction¹
- OPTIMAL-PSMA² Phase 2 study with over 85 patients dosed trialing novel dosing regimen, promising efficacy signals
- Early access in select geographies

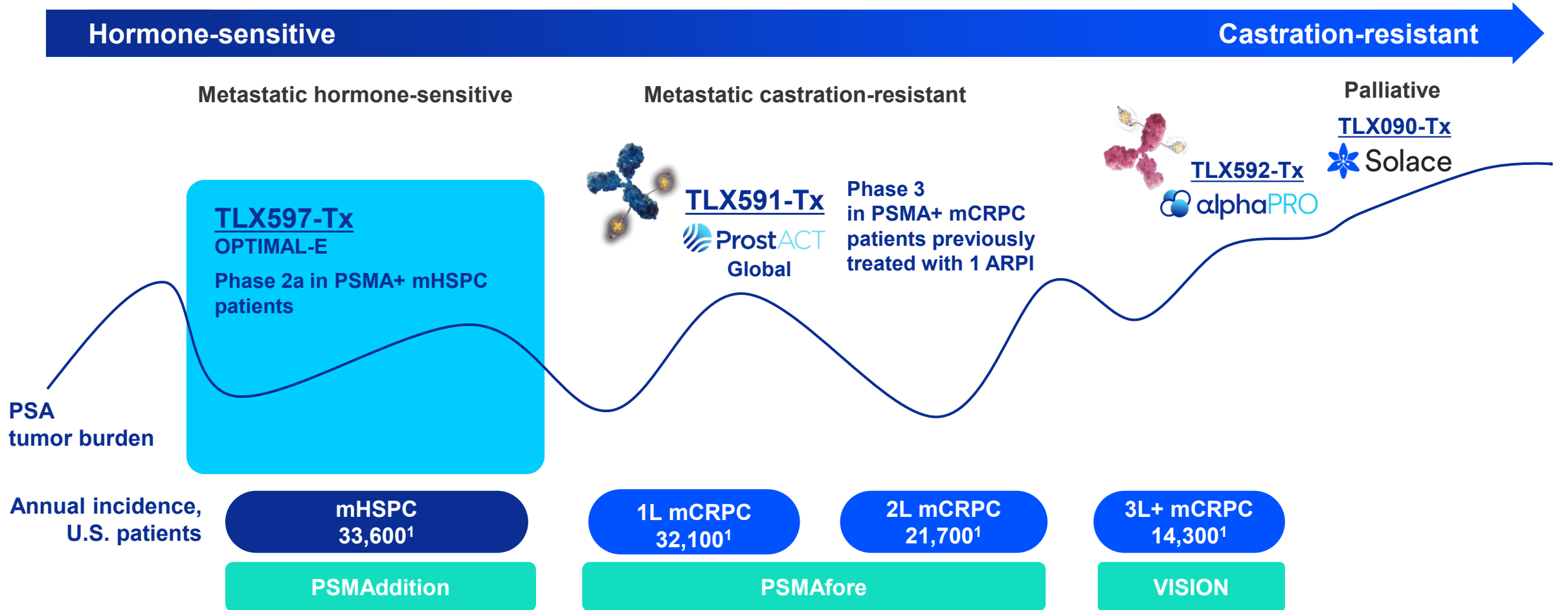
- **Highly targeted biodistribution with minimal salivary gland and kidney uptake supports**

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

SOURCES:

1. Omar et al, [¹⁷⁷Lu]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 ¹⁷⁷Lu-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

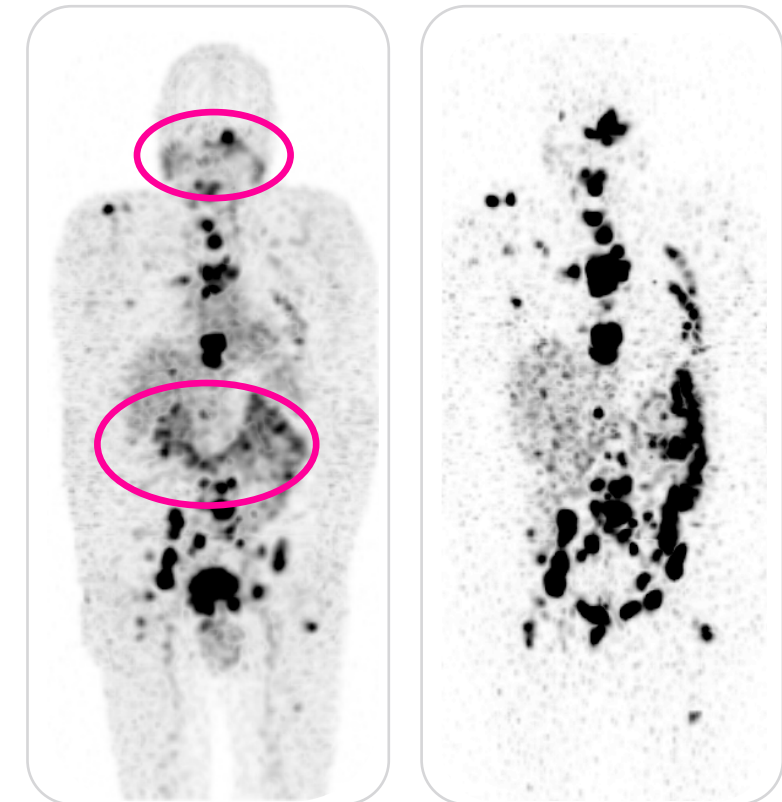
- VISION¹ and TheraP² trials demonstrated that ¹⁷⁷Lu-PSMA-617 improves QOL, but OS benefit is modest
- Evidence suggests underdosing of patients with PSMA therapy
 - Standard 7.5GBq (200mCi) dosing based on external beam radiation limits to kidneys
 - Clinical experience shows patients can tolerate higher doses
 - SPLASH³ trial of PSMA-I&T suggested decreasing administered activity reduces tumor dose and efficacy
- OPTIMAL-PSMA⁴ 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) ¹	PSMA-617 ² (Gy/GBq) (n = 297)	PSMA-I&T ² (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.

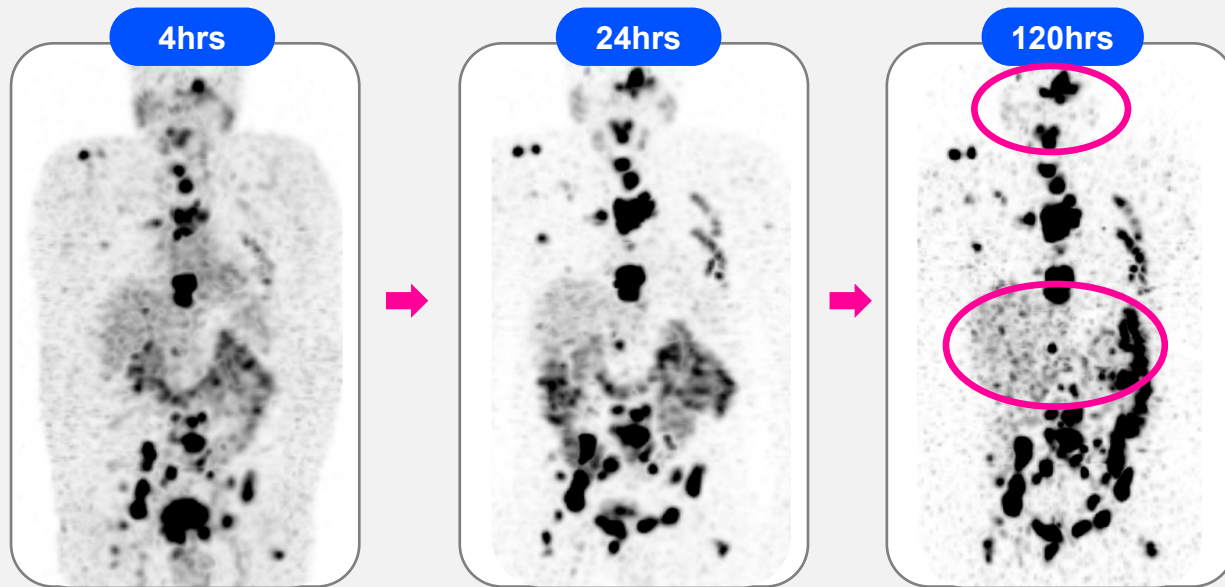
SOURCES:

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

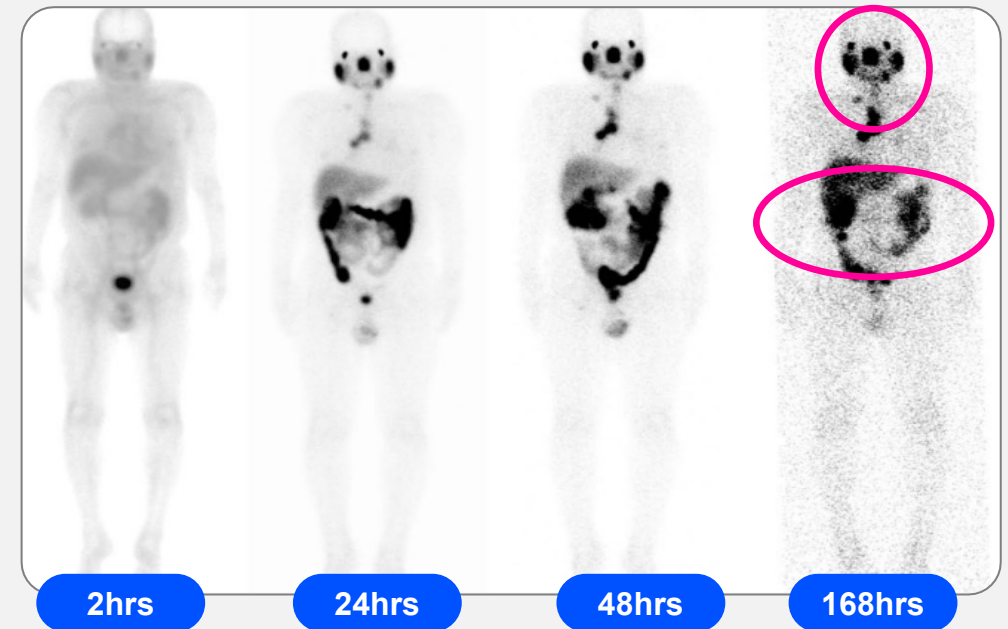
Long tumor retention even at 120 hours, limited salivary gland and kidney uptake

TLX597-Tx SPECT biodistribution¹



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 biodistribution²



Patient representative scans – individual results may vary.

SOURCES:

1. Crumbaker at 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 ¹⁷⁷Lu-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 ⁶⁸Ga-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**

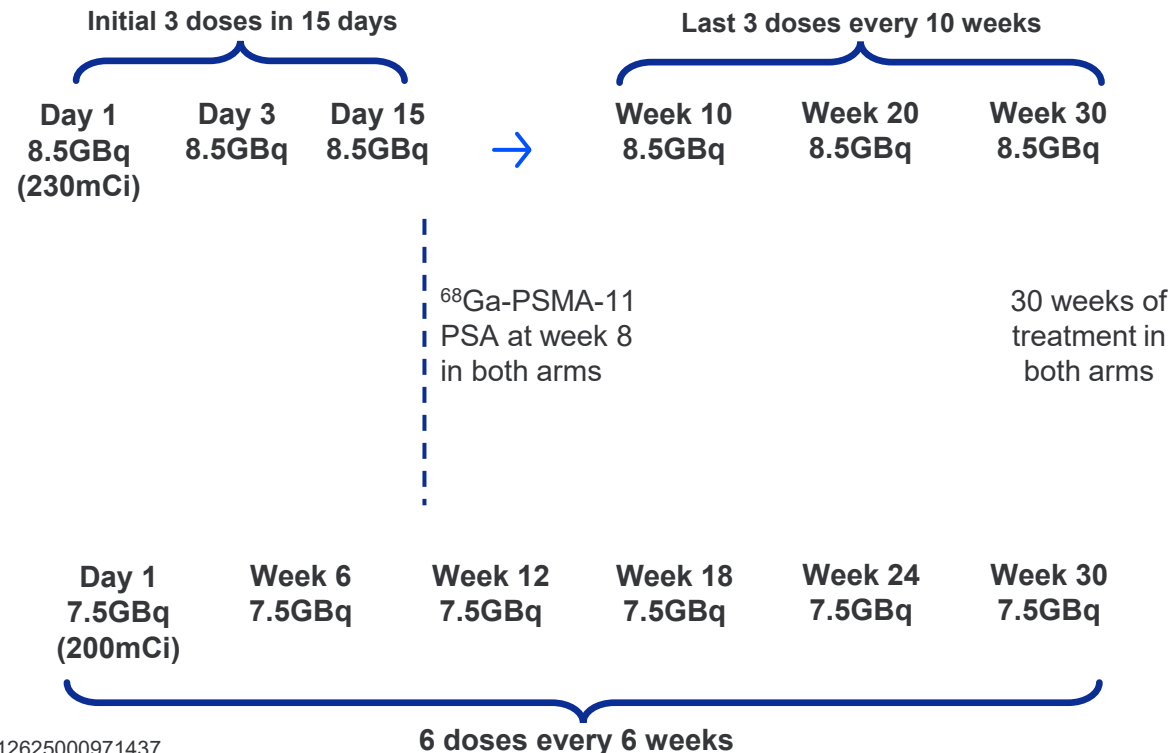
**ARM 1
N = 80**

**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

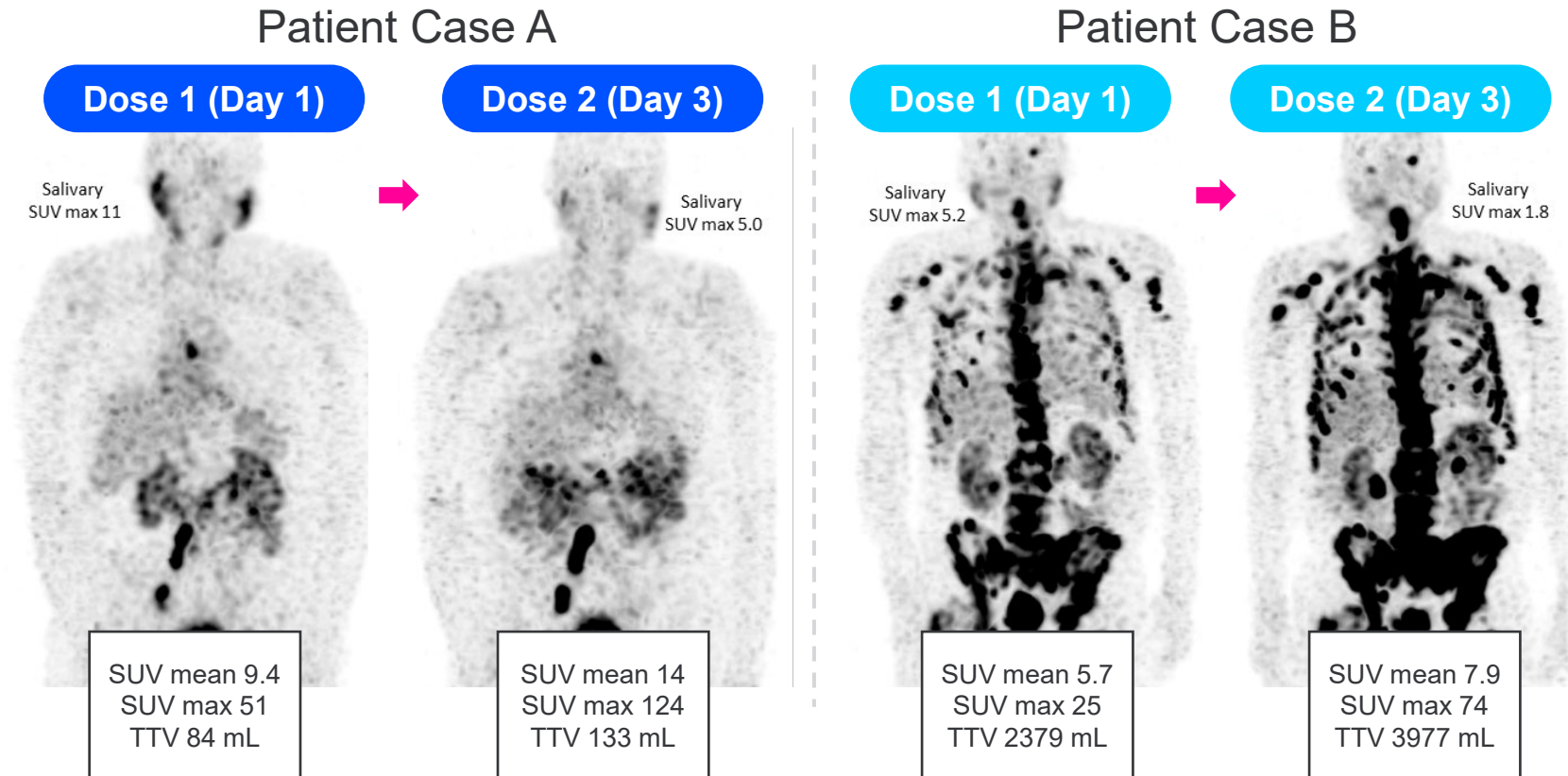
Secondary EPs

- 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

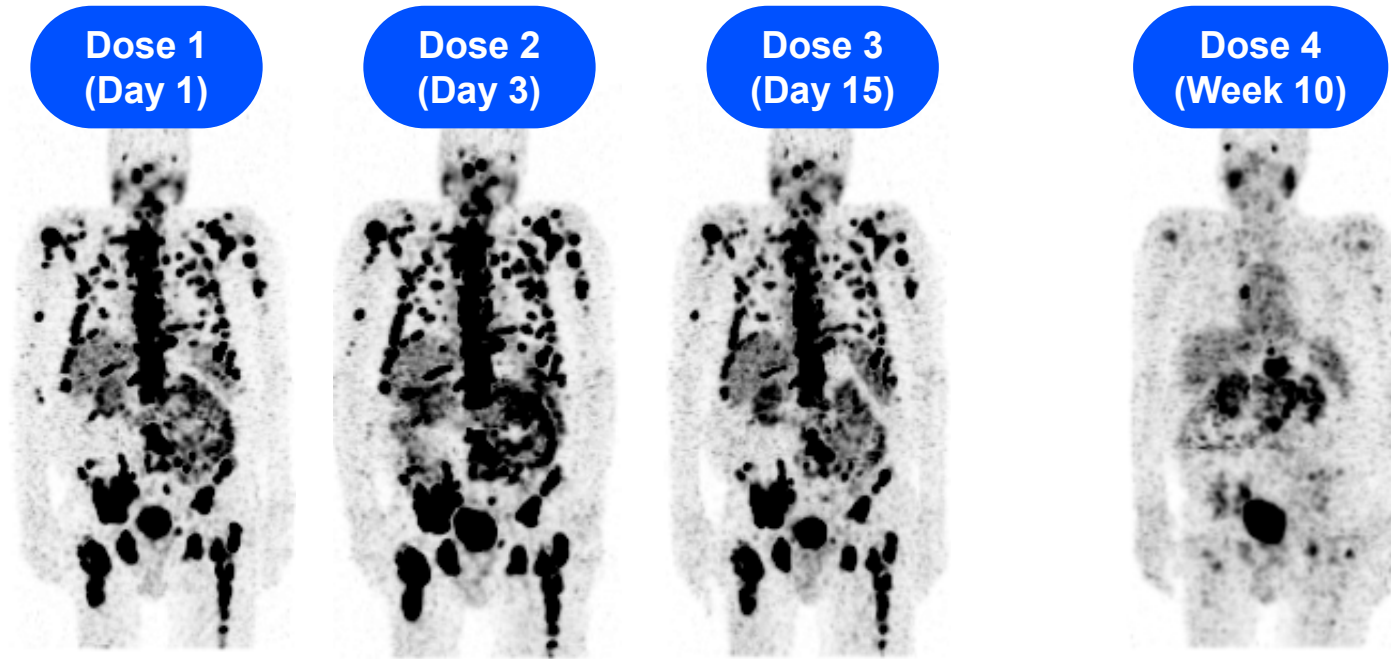
Day 3 scans show increase in TTV from higher PSMA expressions



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

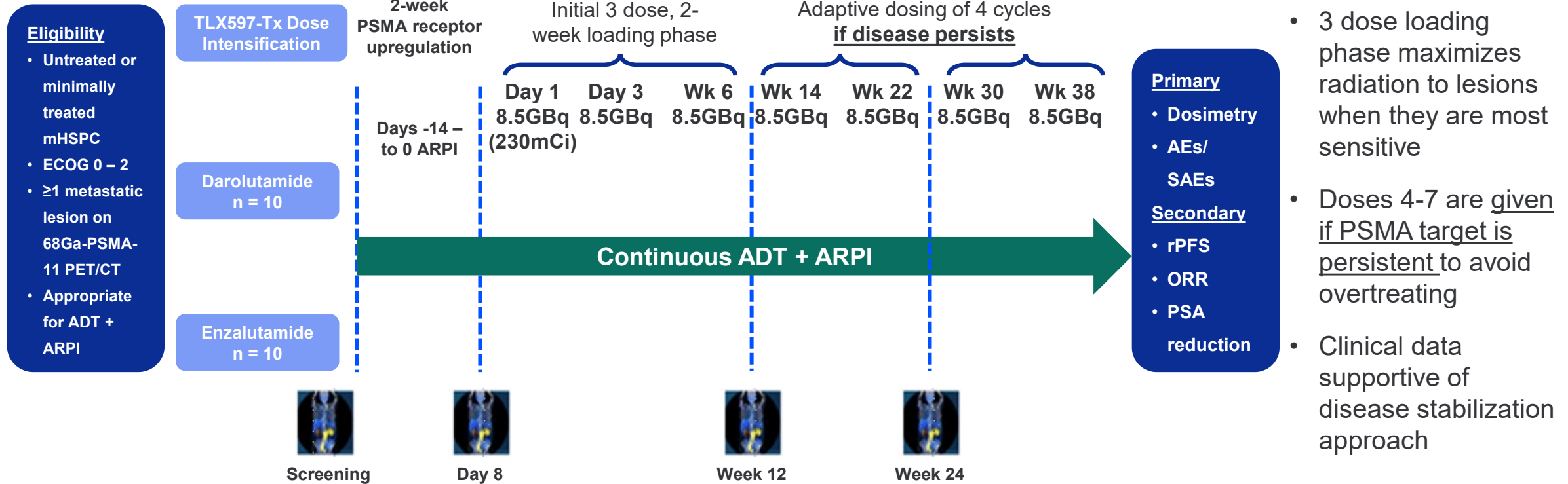
✓ Adaptive dosing

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 ²²⁵Actinium**

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

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Crystal structure of prostate-specific
membrane antigen

