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ProstACT Global

TLX591-Tx
ProstACT Global Phase 3 study (NCT06520345)

Part 1 results: Safety and dosimetry

March 10, 2026

ASX: TLX | NASDAQ: TLX

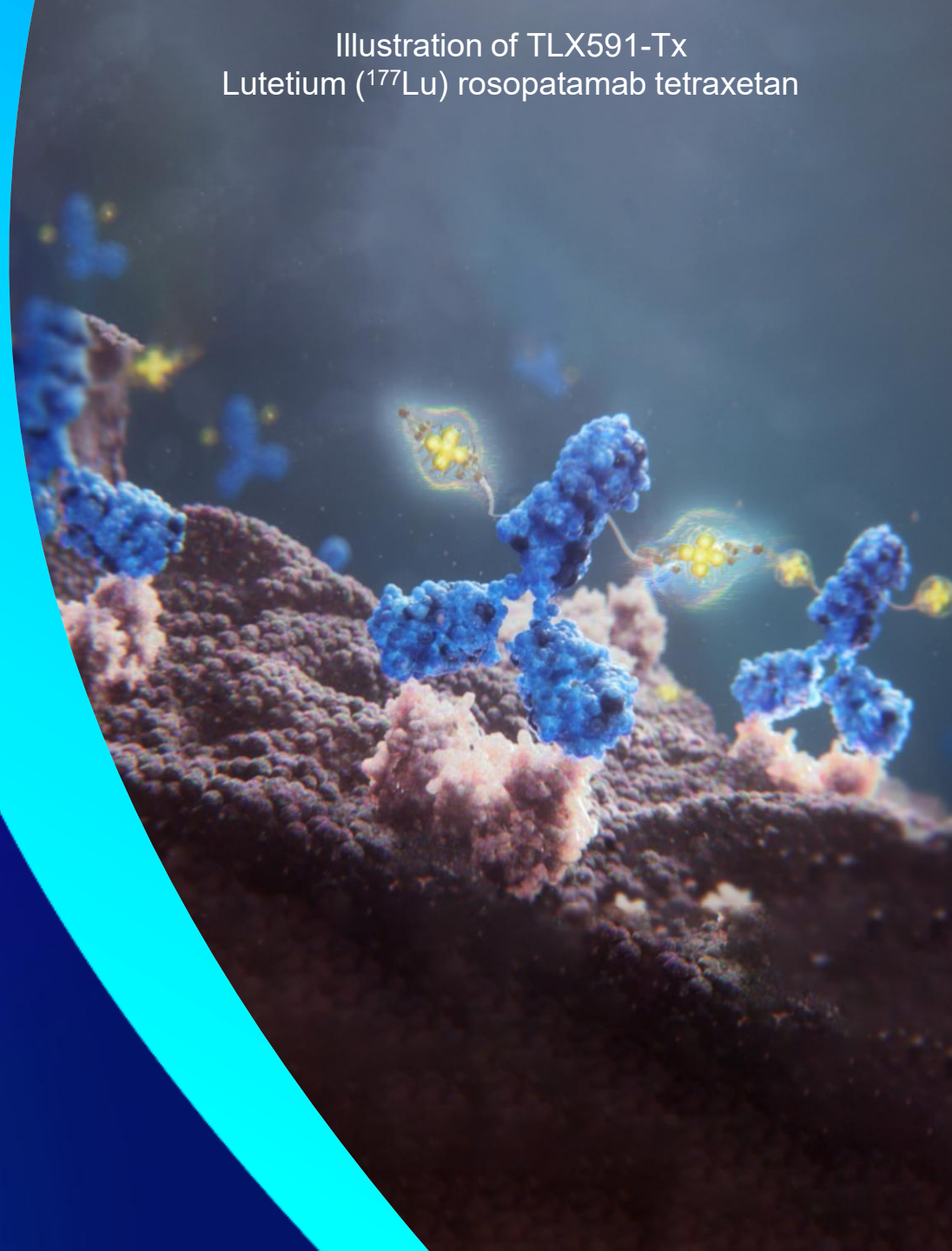

Illustration of TLX591-Tx
Lutetium (^{177}Lu) rosopatamab tetraxetan

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*Independent expert speaker, not an employee of Telix. Views are speaker's own.

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Introductory remarks

ProstACT Global Phase 3 (Part 1 Lead-in): Key findings

Primary and secondary endpoints: Safety and dosimetry

- **Study objectives met:** Confirmed safety, pharmacokinetics, dosimetry across cohorts
- **No new safety signals:** Hematologic events transient and manageable
- **Tolerability profile** supported by dosimetry and low-grade non-hematologic events
- Lesion dosimetry indicates no difference in **absorbed dose profile** across cohorts
- **No adverse drug-drug interactions** observed in TLX591-Tx combinations

Demonstrates feasibility of integrating TLX591-Tx with contemporary, global standards of care

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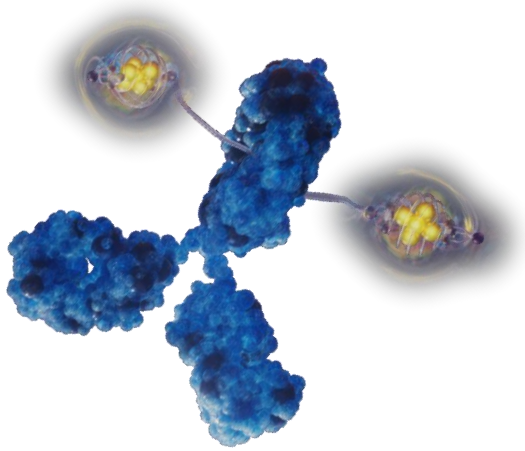
1. Source: ProstACT Global Part 1 data on file.

TLX591-Tx is a novel therapy candidate for prostate cancer

Differentiated radiopharmaceutical using an antibody (mAb) to target PSMA[1]

TLX591-Tx:
Lutetium (^{177}Lu) rosopatamab tetraxetan



Radio antibody-drug conjugate (rADC) approach addresses key unmet needs[2-5]

1. **Patient friendly two-dose regimen:** Supports compliance to treatment and ease of integration with standard of care (SOC)
2. **Safety and tolerability profile:** Low radiation to salivary glands and kidneys, transient and manageable hematologic profile
3. **Internalization and prolonged retention:** Delivering a payload to the tumor, potentially maximizing cell killing effect
4. **Supply, access, and radiation protection:** Potential real-world advantages from lower administered activity (76 mCi per dose)

Differences described are not derived from head-to-head clinical studies, cross-trial comparison should be interpreted as not being definitive.

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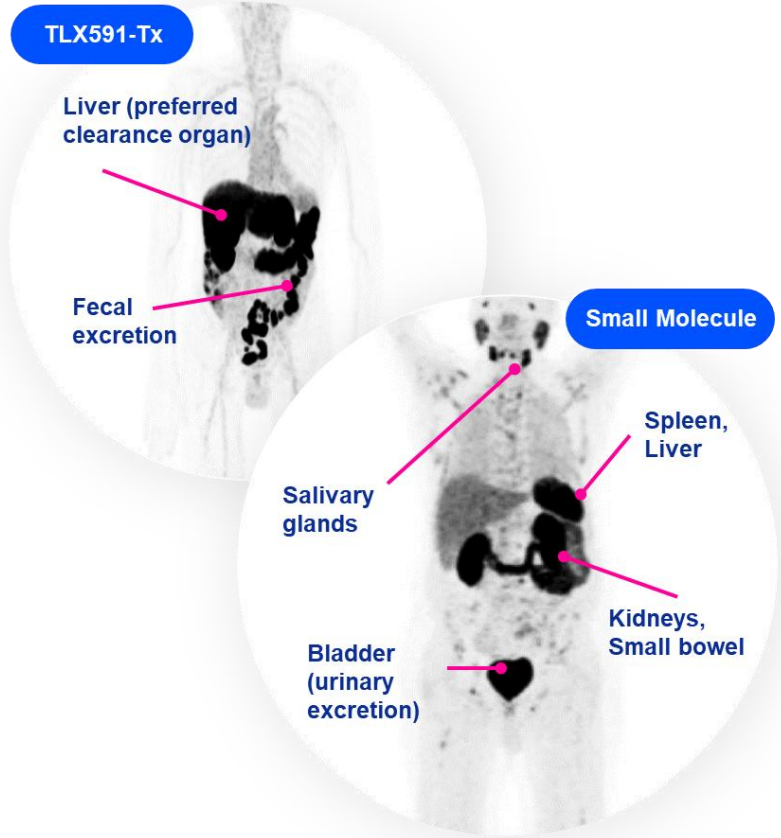
1. Prostate-specific membrane antigen.
2. Sartor O, et al. Presented at: American Society of Clinical Oncology Annual Meeting 2024; TPS5115.
3. Sun M, et al. *Curr Oncol Rep.* 2021.
4. ProstACT SELECT data on file. Clinical Study Report December 2025.
5. Tagawa ST, et al. *Cancer.* 2019.

TLX591-Tx rADC versus 1st generation small molecule RLT

Key differences underpin PSMA tumor targeting, internalization, and prolonged retention

	rADC	1st generation RLT[5]
Radiopharmaceutical description	TLX591-Tx[1-4]	Small Molecule
Recommended dose	2 x 76 mCi (14 days apart)	6 x 200 mCi (6 weeks apart)[6]
Molecular weight (MW)	Antibody Large (mw ~150,000)	Small molecule (mw ~1,200)
Terminal half-life ($t_{1/2}$)	5.6 days	1.7 days
Off-target organ exposure	Liver, spleen	Salivary glands, kidneys, GI[7] tract, other sites
Route of excretion	Hepatobiliary (liver)	Renal (kidneys)



Differences described are not derived from head-to-head clinical studies, cross-trial comparison should be interpreted as not being definitive.

Patient representative scans – individual results may vary.

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1. Sartor O, et al. Presented at: American Society of Clinical Oncology Annual Meeting 2024; TPS5115.
2. Sun M, et al. *Curr Oncol Rep.* 2021.
3. Data on file. Telix Pharmaceuticals Limited.
4. Tagawa ST et al. *Cancer.* 2019.
5. Radio-ligand therapy.
6. Lu177-PSMA617. Prescribing information. 2022. Novartis Pharmaceuticals AG. Administered every 6 weeks for up to 6 treatments, solution for injection contains 200 mCi (7.4 GBq) at time of use.
7. Gastrointestinal.

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Study design and patient population

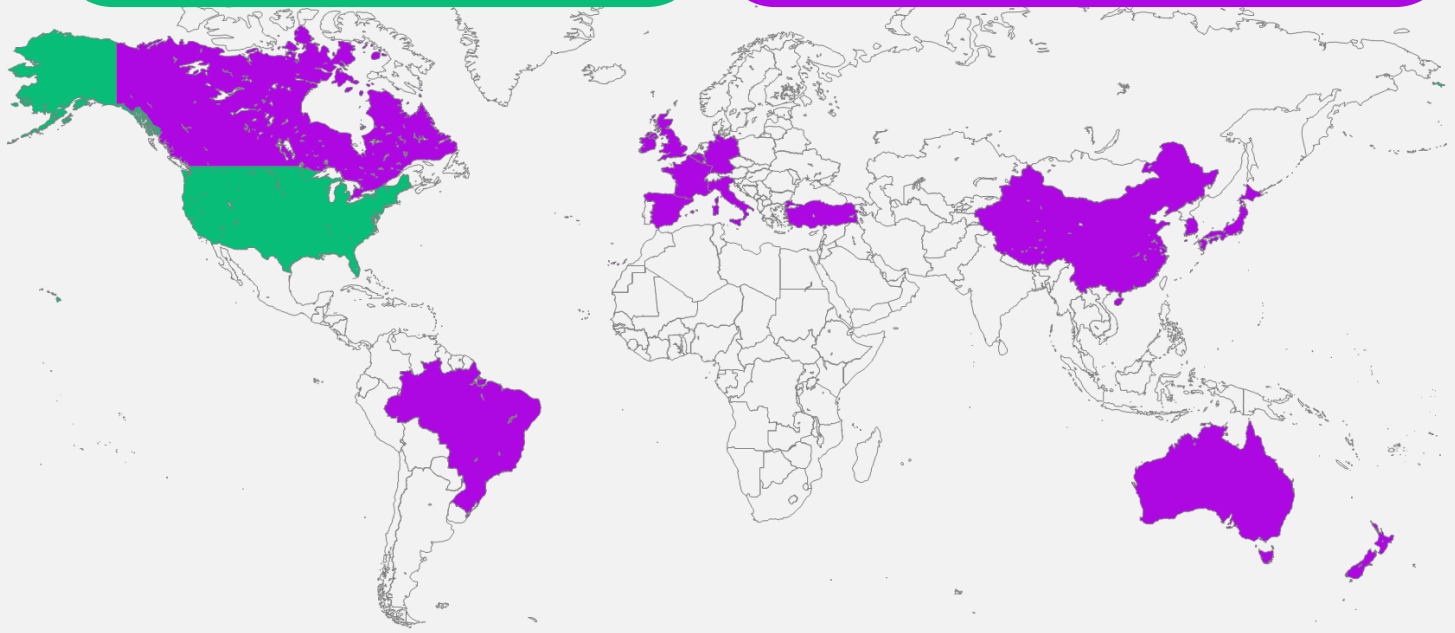
ProstACT Global study design reflects global clinical practice

Allows investigator to combine TLX591-Tx with ARPI or docetaxel

Typical clinical practice following disease progression on first ARPI

Predominantly ARPI Switch[2]

Predominantly Docetaxel[3,4,5,6,7,8]



U.S.

- Largest prostate cancer market[1]
- NCCN Guidelines® allow either ARPI or docetaxel[9]
- **Real-world analysis indicates 57% of patients** receive another ARPI as next therapy[2]

Rest of World

- Guidelines support docetaxel post-progression on first ARPI

1. Clarivate Prostate Cancer Market Forecast, July 2025.
2. Narayan V. et al, Treatment Patterns and Survival Outcomes Among Androgen Receptor Pathway Inhibitor- Experienced Patients with Metastatic Castration Resistant Prostate Cancer, *Clin Genitourin Cancer.* 2024.
3. 2025 Canadian Urological Association-Canadian Uro-oncology Group Guideline: Metastatic castration-resistant prostate cancer.
4. 2025 ESMO Treatment Guidelines / EAU Prostate Cancer Guidelines.
5. 2025 Chinese Society of Clinical Oncology Guideline.
6. Korean Guidelines for the Management of Metastatic Prostate Cancer.
7. Japanese Clinical Practice Guidelines for Prostate Cancer 2023.
8. Fontes et al. Treatment Patterns Among Patients with advanced Prostate Cancer in Brazil: An Analysis of a Private Healthcare System Database, *World J. Oncology* 2022.
9. National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology for Prostate Cancer V3.2026.

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ProstACT Global Phase 3 current status

Part 2 approved in select jurisdictions and enrolling patients
Part 1 complete, prerequisite for progression to Part 2 in U.S.[1]

- Enrolling in Australia, New Zealand, & Canada following IDMC[4] review
- Regulatory approvals obtained allowing study start in China, Singapore, South Korea, Japan[5], Türkiye, & UK

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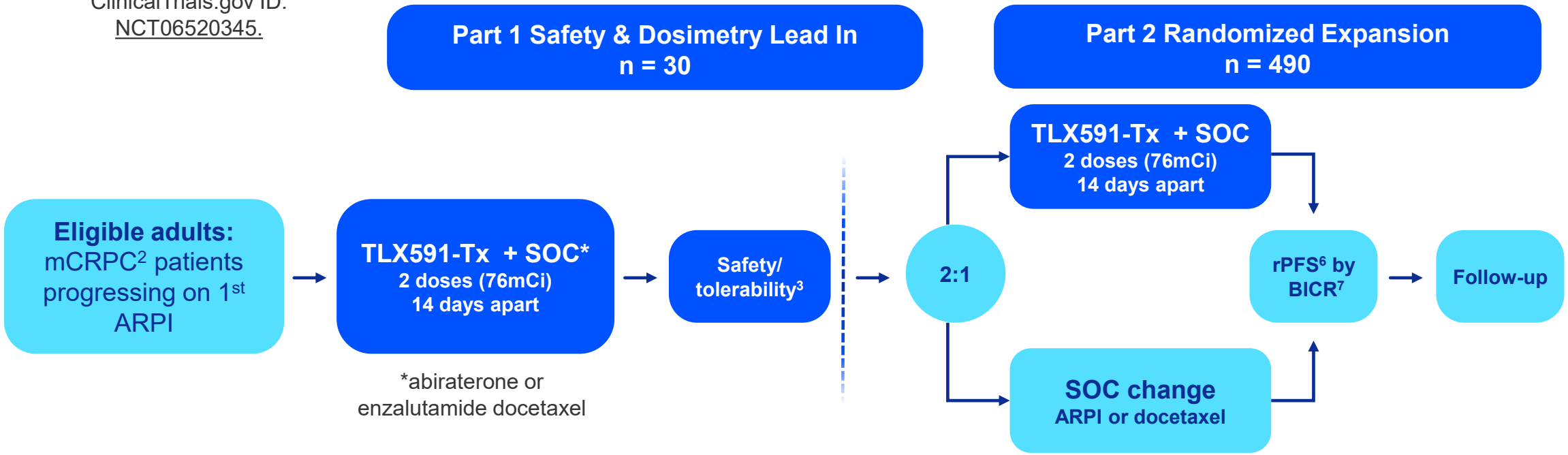
ClinicalTrials.gov ID: NCT06520345.



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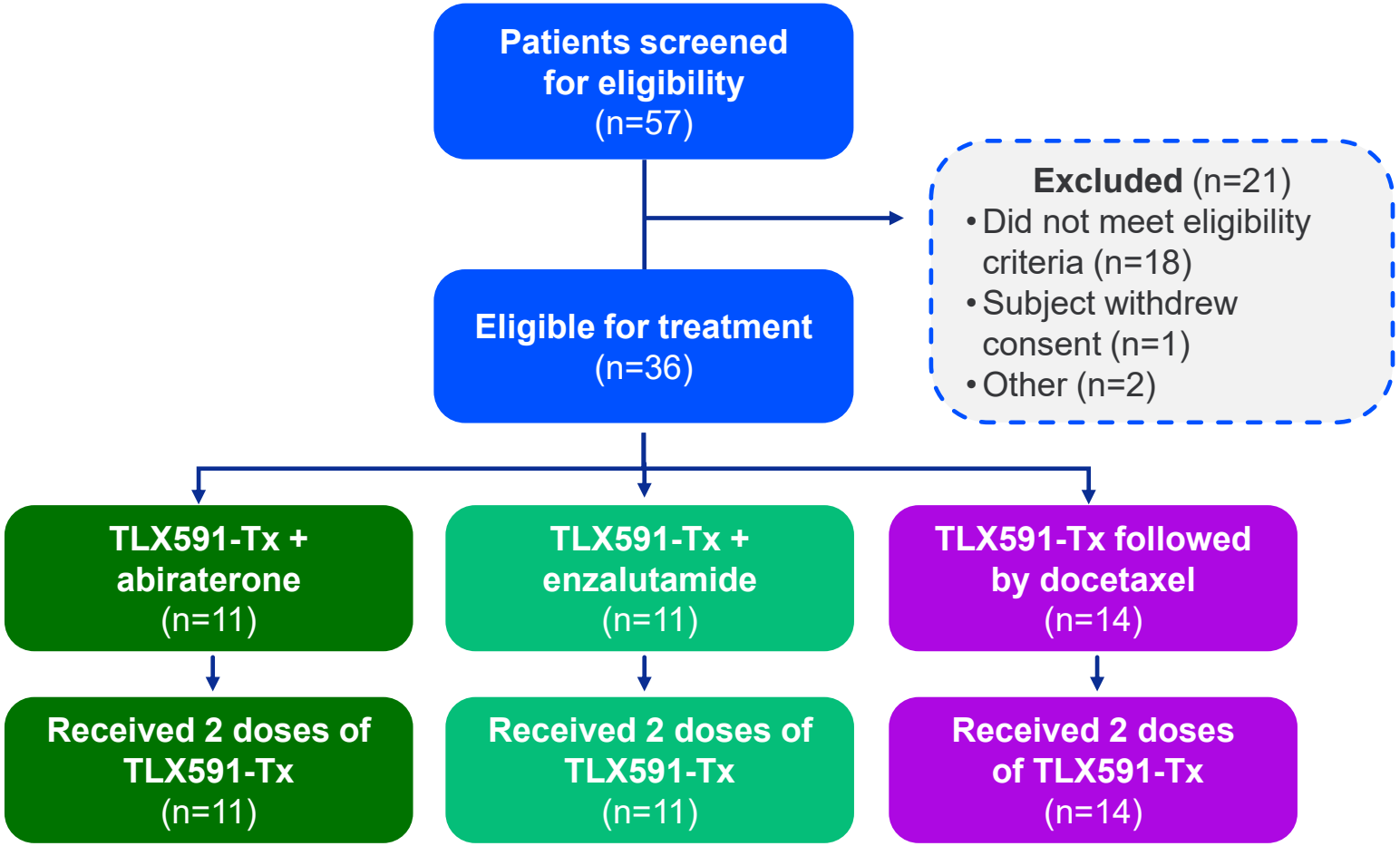
1. Data to be submitted to FDA to seek IND amendment/Part 2 clearance.
2. Metastatic castration resistant prostate cancer.
3. Safety & tolerability reported as adverse events.
4. Independent Data Monitoring Committee review, October 2025.
5. Japanese regulator has granted approval for a Japan-specific Part 1 in nine patients, prior to commencing Part 2.
6. Radiographic progression-free survival.
7. Blinded independent central review.

Part 1 enrolled 36 patients each with one prior ARPI treatment

All patients received two doses of TLX591-Tx

Key observations

- No treatment-related deaths
- 32 patients remain alive
- 26 patients continuing on the study



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Part 1: Baseline demographics and prior treatments[1]

Majority of patients (n=36) are 2L mCRPC

Baseline age demographics

Slightly older patient population compared to other ^{177}Lu-PSMA trials[2]

- Mean age: 75 years
- Median age: 77 years
- Age range: 59 – 88 years

Prior treatments	
Setting of 1st ARPI indication, n (%)	
mCSPC[3]	10 (28)
mCRPC 1L	26 (72)
Prior ARPI therapy, n (%)	
Abiraterone	10 (28)
Apalutamide	3 (8)
Darolutamide	6 (17)
Enzalutamide	17 (47)
Prior taxane treatment in mCSPC, n (%)	
Yes	9 (25)
No	27 (75)

Other prognostic factors	
PSA[4] (ng/dL) at baseline medium range, n	
Mean	60.3
Median	18.2
ECOG performance status, n (%)	
0	19 (53)
1	17 (47)
Sites of metastases, n (%)	
Lymph Node	14 (39)
Bone (Skeletal)	17 (47)
Viscera	13 (36)

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1. ProstACT Global Part 1 data on file. Telix Pharmaceuticals.
2. Morris et al. *Lancet* 2024.
3. Metastatic castration sensitive prostate cancer.
4. Prostate-specific antigen.

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Safety

Acceptable safety profile confirmed with no new safety signals

Non-hematologic events were low grade, hematologic events were transient and manageable

Key observations

Treatment emergent adverse events (TEAE)

- Most prevalent non-hematologic adverse events were fatigue (53%), nausea (28%) and dry mouth (25%)
- Almost all TLX591-Tx related non-hematologic events were grade 1 or grade 2[2]

Hematologic events: In line with profile expected for this class of therapy

- **Grade 3** thrombocytopenia 5/36 (14%) and neutropenia 8/36 (22%) events in line with profile expected for this class of therapy; single Grade 3 anemia
- **Grade 4** thrombocytopenia 11/36 (31%) and neutropenia 9/36 (25%)

ProstACT Global Part 1 (safety TEAE)[1]

Adverse Event	Grade 1	Grade 2	Grade 3	Grade 4	Total (n)	% of N=36
Non-hematologic events						
Fatigue	10	7	2	0	19	53
Nausea	5	4	1	0	10	28
Dry mouth	9	0	0	0	9	25
Diarrhea	5	3	0	0	8	22
Back pain	4	3	1	0	8	22
Headache	4	1	0	0	5	14
Hematologic events						
Thrombocytopenia	6	6	5	11	28	78
Neutropenia	2	4	8	9	23	64
Anemia	5	10	1	0	16	44
WBC[3] decrease	0	4	6	5	15	42
Lymphopenia	0	5	8	7	20	56

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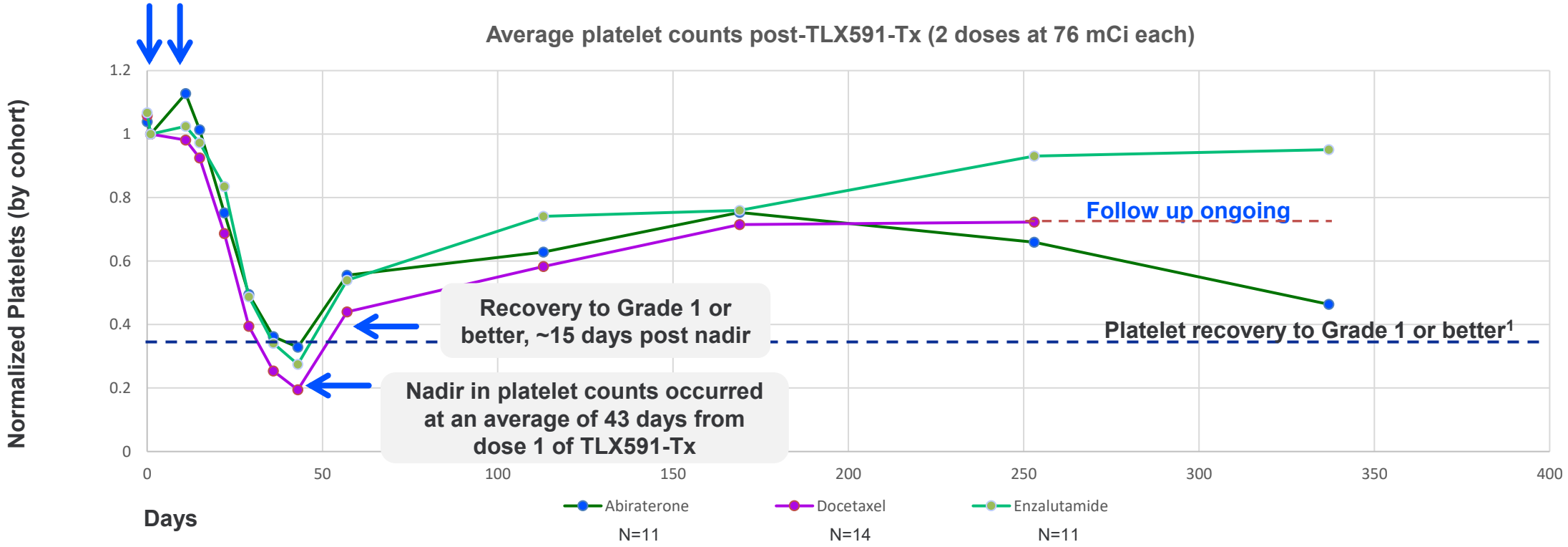
1. ProstACT Global Part 1 data on file. Telix Pharmaceuticals.
2. One grade 3 dizziness was considered treatment-related.
3. White blood cell.

Hematological profile transient and consistent across cohorts

Platelet counts recovered consistently in all three cohorts at ~15 days post nadir

TLX591-Tx (2 doses at 76 mCi each)



1. G1 platelets 75,000/µL to 150,000 /µL

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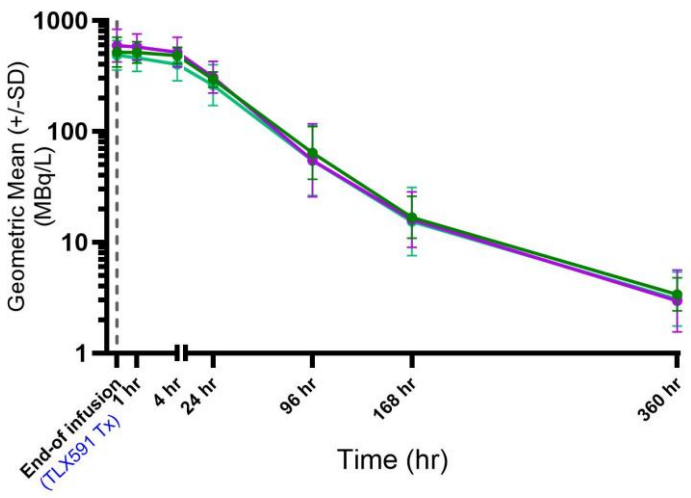
Dosimetry

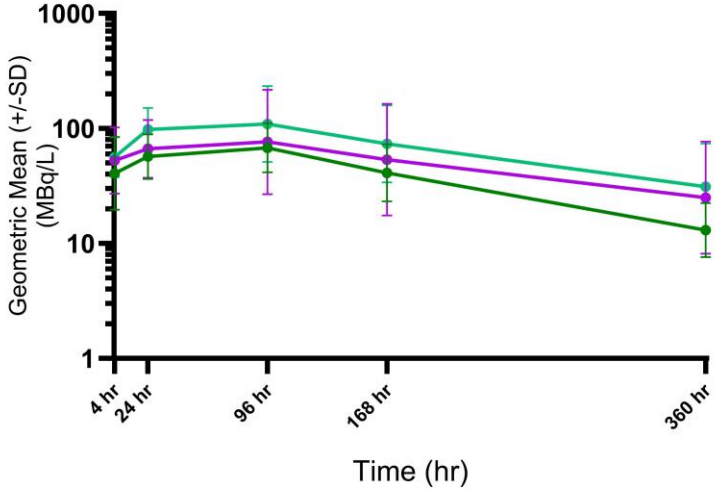
Pharmacokinetic profile driven by TLX591-Tx residence time

Demonstrates sustained activity, consistent across cohorts[1]

Blood radioactivity
Concentrations-Time Profile



Lesion activity
Concentrations-Time profile



Abiraterone[2,3] Docetaxel[2,3] Enzalutamide[2,3]

Key observations

- **Predictable PK profile:** Low inter-patient variability supports reliable dosing, streamlined clinical development
- **No evidence of drug–drug interaction**: Exposure and washout kinetics were consistent across cohorts
- **Sustained tumor retention**: Lesion activity concentrations remained detectable through 15 days, demonstrating prolonged radiation exposure to the tumor

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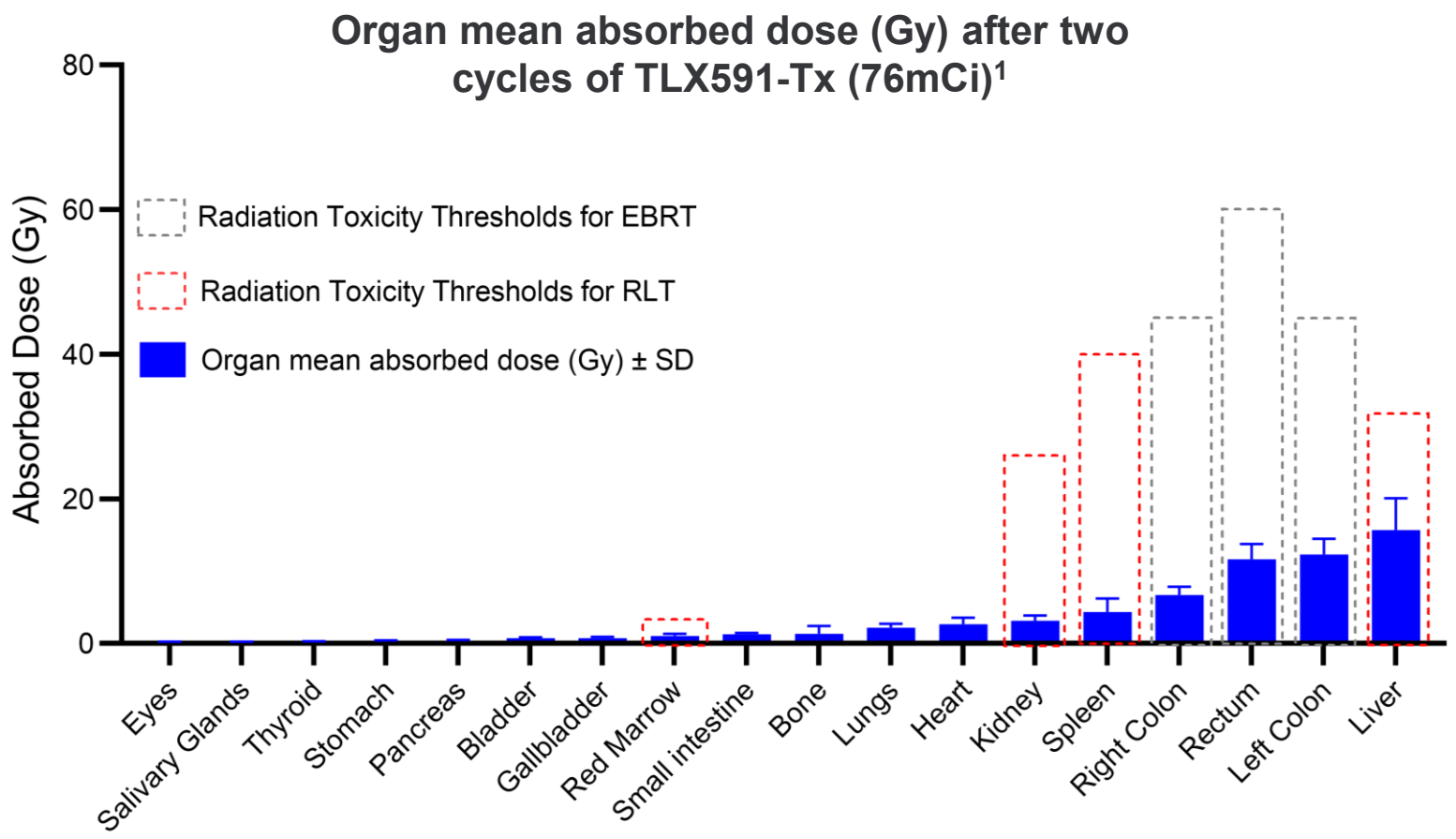
1. ProstACT Global Part 1 data on file. Telix Pharmaceuticals.
2. Lesion and blood activity concentrations were measured following the first TLX591-Tx dose (2.8 GBq; ~76 mCi).
3. Number of patients in abiraterone cohort (n = 11), Docetaxel (n = 13), Enzalutamide (n = 10).

PK and lesion activity analyses are based on imaging datasets provided by the imaging CRO. Demographic and safety summaries are derived from the iQVIA clinical database; differences in patient numbers reflect data availability across datasets

Organ radiation exposure is well below established safety limits

Low radiation to salivary glands and kidneys supports tolerability profile



Key observations

- Liver (clearance organ), colon, rectum, spleen, kidney and red marrow mean absorbed dose (Gy) below the threshold for known radiation injury[2,3]
- Dose to organs at risk consistent with Phase 1 SELECT data

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1. ProstACT Global Part 1 data on file. Telix Pharmaceuticals. Organ mean absorbed dose reported in (n = 33) patients. Red Marrow dose determined from blood-based assay, 1.03 ± 0.31 Gy for 2 cycles of 76 mCi.
2. Wahl RL, Normal-Tissue Tolerance to Radiopharmaceutical Therapies, the Knowns and the Unknowns, *J Nucl Med* Vol. 2021.
3. Emami et al. Tolerance of normal tissue to therapeutic irradiation. *Int J Radiat Oncol Biol Phys.* 1991.

Lesion dosimetry confirmed TLX591-Tx uptake in tumors

Meaningful absorbed dose across lesion locations and consistent across cohorts[1]

Tumor dose (Gy) after the administration of TLX591-Tx in 2 doses of 2812 MBq (76 mCi) 14 days apart

Tumor Sites	Mean	Median	Min	Max	SD
All lesions (n=132)	4.83	2.84	0.28	49.59	6.91
Bone (n=122)	5.00	2.92	0.28	49.59	7.14
Lymphatic nodes (n=8)	2.01	2.15	1.02	2.89	0.53
Soft tissue (n=2)	5.73	5.73	3.27	8.20	2.46

The mean tumor volume by site was 13.47 ± 16.22 mL for bone, 13.52 ± 15.21 mL for lymphatic tissue and 9.87 ± 0.15 mL for soft tissue lesions.

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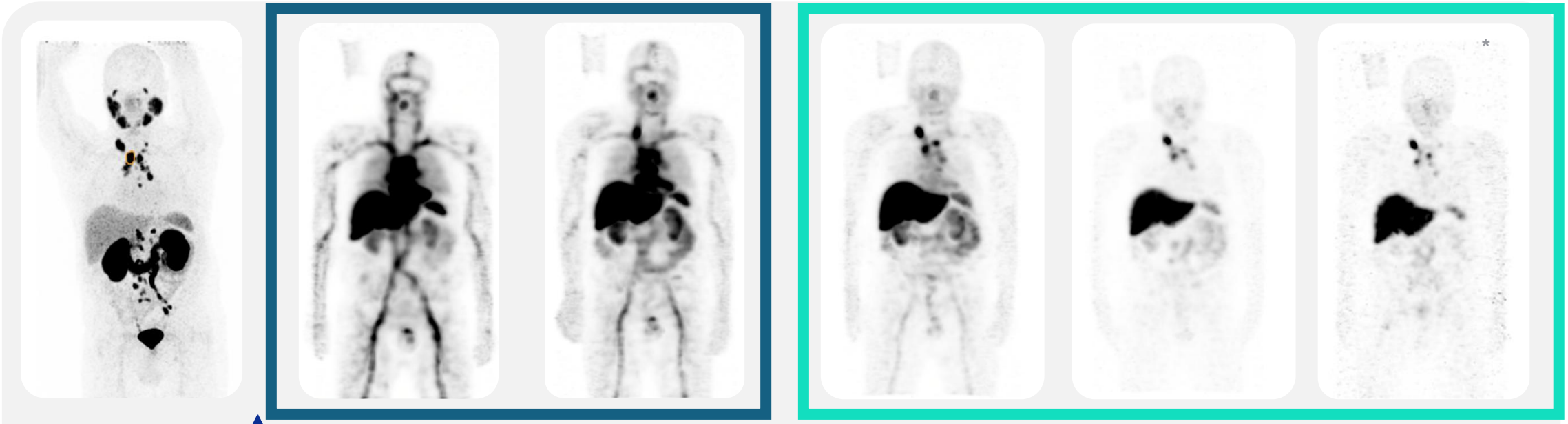
1. ProstACT Global Part 1 data on file. Telix Pharmaceuticals.

Patient case: TLX591-Tx plus abiraterone

64-year-old patient with metastatic disease in lymph nodes[1]

SPECT TLX591-Tx biodistribution: Single dose Distribution of TLX591-Tx over 15 days[2]



TLX591-Tx seen in the vascular space and liver

TLX591-Tx seen at metastatic sites (and liver)

Administration of one dose of TLX591-Tx

BASELINE PET MAR 25	4 hours	24 hours	96 hours	168 hours	360 hours*

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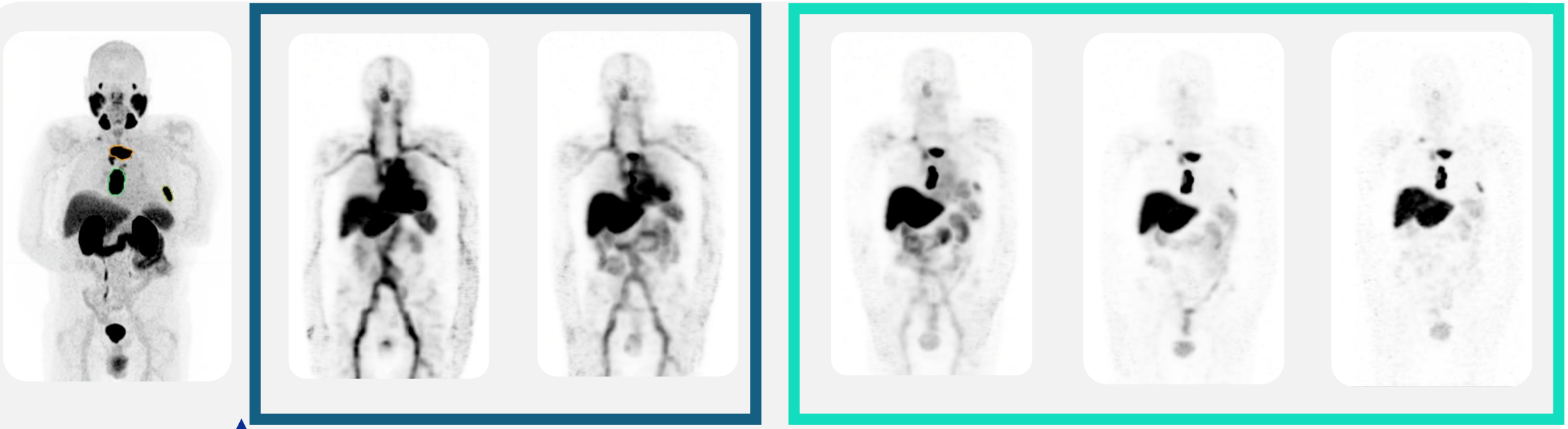
1. Subcarinal, right upper para-tracheal, abdominal, pelvic lymph nodes.
2. ProstACT Global Part 1 data on file. Telix Pharmaceuticals.

Patient representative scans – individual results may vary.
Images are non-quantitative

Patient case: TLX591-Tx sequenced with docetaxel

83-year-old patient with bony metastatic lesions[1]

SPECT TLX591-Tx biodistribution: Single dose Distribution of TLX591-Tx over 15 days[2]



TLX591-Tx seen in the vascular space and liver

TLX591-Tx seen at metastatic sites (and liver)

Administration of one dose of TLX591-Tx

BASELINE PET MAR 25	4 hours	24 hours	96 hours	168 hours	360 hours*

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1. Thoracic vertebrae, ribs.
2. ProstACT Global Part 1 data on file. Telix Pharmaceuticals.

Patient representative scans – individual results may vary.
Images are non-quantitative

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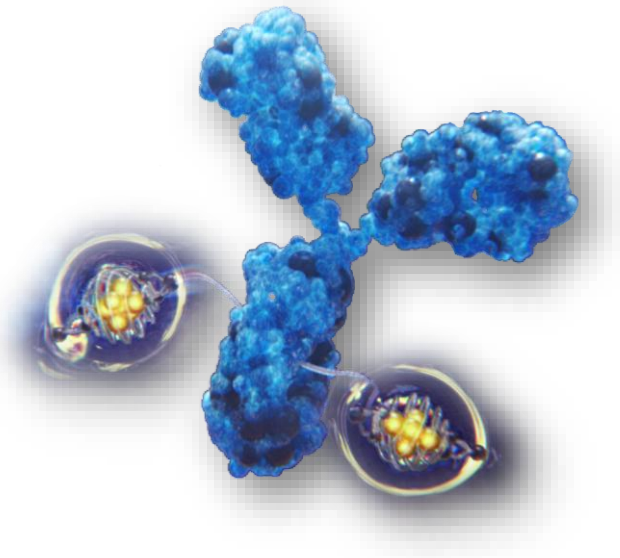
Summary

Summary: ProstACT Global Part 1

TLX591-Tx plus standard of care has acceptable safety and favorable dosimetry[1]

- **Acceptable and manageable safety and tolerability** demonstrated across combination cohorts, no new safety signals or adverse drug-drug interactions
- **Low radiation exposure to salivary glands and kidneys** support acceptable tolerability profile
- **Pharmacokinetics supports sustained activity at 15 days**, imaging shows prolonged tumor retention
- **Patient friendly two dose regimen** supports compliance to treatment and ease of integration with standard of care (SOC)



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1. ProstACT Global Part 1 data on file. Telix Pharmaceuticals.

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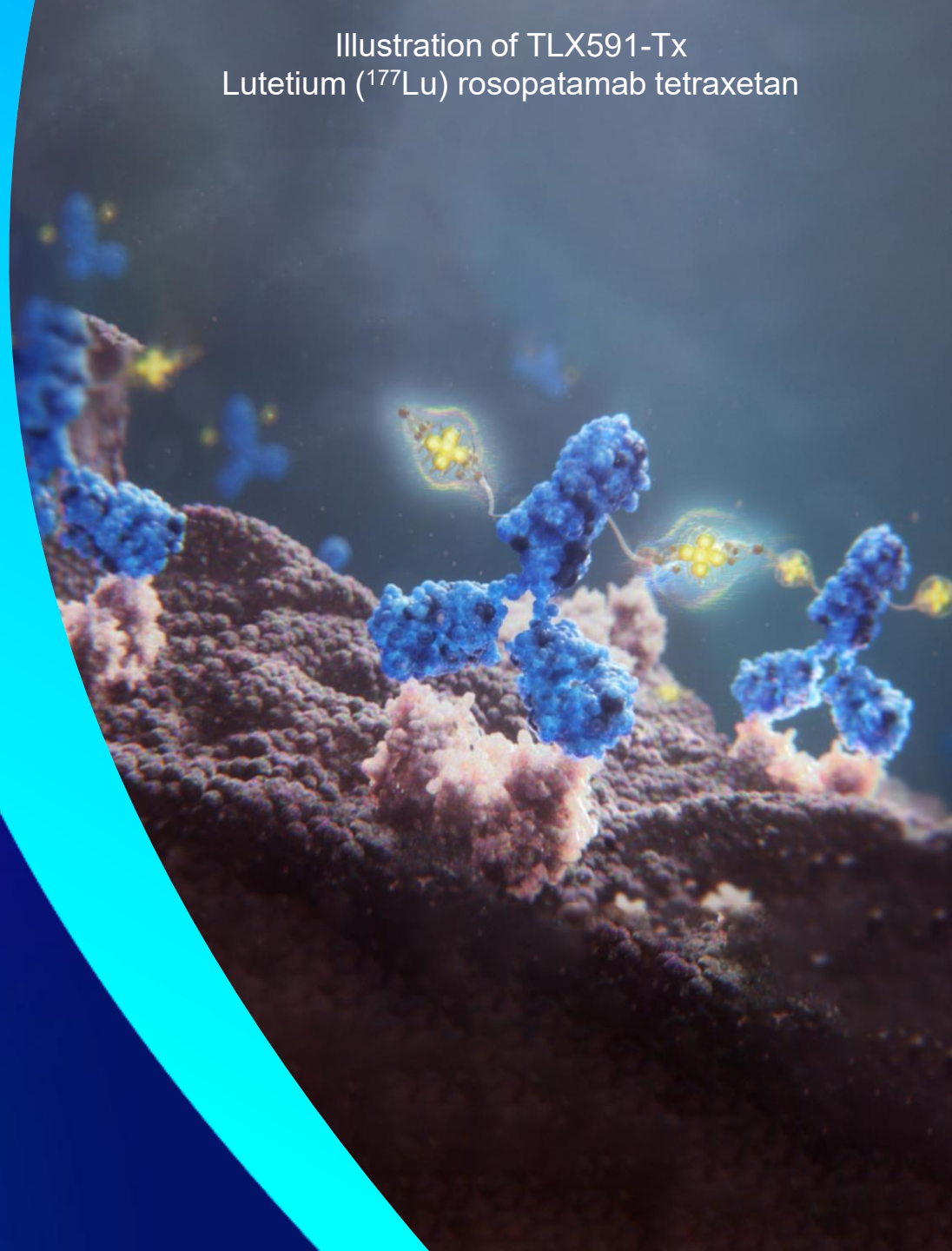

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