

Telix Pharmaceuticals

J.P. Morgan Healthcare Conference San Francisco, January 8 - 11, 2024 ASX: TLX TLX250-CDx (PET Imaging of CAIX)

> TLX250 (CAIX 177Lu Therapy)

> > Images from STARLITE-2 study. Credit: Memorial Sloan Kettering Cancer Center.

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Telix's lead imaging product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been approved by the Australian Therapeutic Goods Administration (TGA), the U.S. Food and Drug Administration (FDA), and Health Canada. With the exception of Illuccix® as noted above, no Telix product has received a marketing authorization in any jurisdiction.

Full United States prescribing information for Illuccix® can be found at http://illuccixhcp.com/s/illuccix-prescribing-information.pdf

All figures are in AU\$ unless otherwise stated. 2023 financial year figures provided on an unaudited basis.

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Telix: A leading "theranostic" radiopharma company

Deep pipeline focused on oncology and rare diseases



- diagnostic "theranostic" assets in clinical trials
- First-in-class **rADC¹ for** prostate cancer therapy in Phase 3 trial (TLX591)
- Highly differentiated therapeutic pipeline utilizing alpha and beta emitters

COMMERCIAL STAGE **IMAGING (DIAGNOSTIC)** PORTFOLIO



- Significant growth from **Illuccix**®, total revenue up 214% to A\$502.5M² in 2023
- BLA³ filing commenced for TLX250-CDx (Zircaix[™])⁴ for kidney cancer imaging
- Preparing to file NDA⁵ for TLX101-CDx (**Pixclara**[™])⁴ for imaging of glioma

INVESTING FOR FUTURE GROWTH



- Commercial revenue funds substantial R&D activity
- Addition of complementary technologies and capability through **acquisition**
- Vertically integrated and world-class supply, logistics and manufacturing

Radio antibody drug conjugate



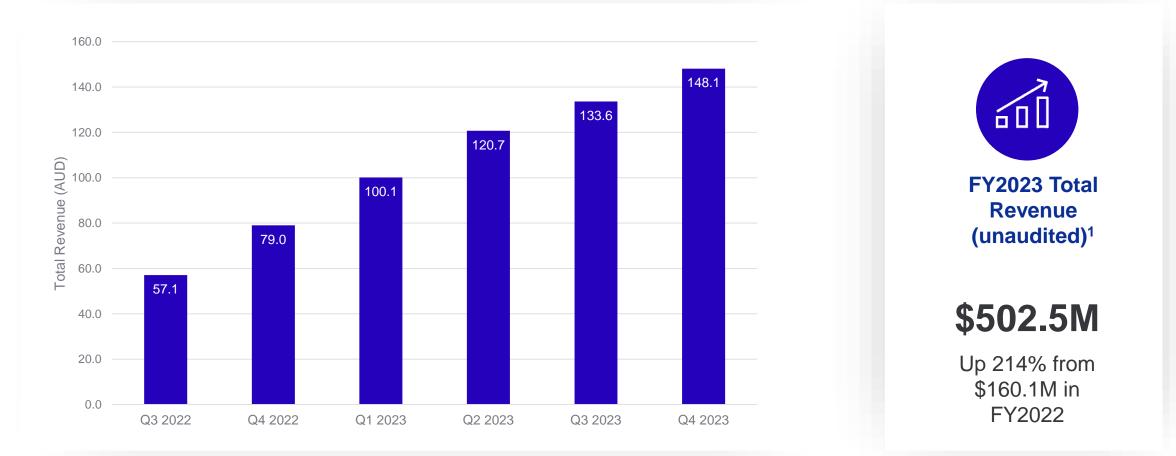
FY2023 revenues are unaudited, preliminary and based on management's estimate as of the date of this presentation and are subject to completion of the Company's financial closing procedures. Biologics License Application, Telix ASX disclosure 19 December 2023.

Brand name subject to final regulatory approval.

New Drug Application

Q4 2023: Total revenue update

U.S. sales driving consistent, strong growth





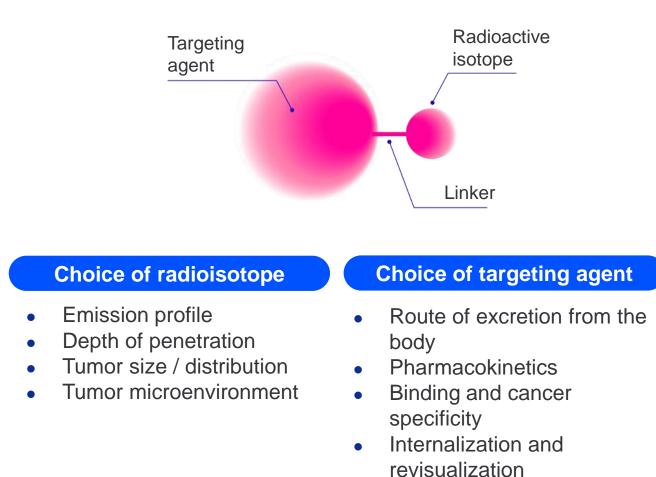
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Deep radiopharma expertise

Broad development toolkit enables development of first-in-class / best-in-class assets

Innovation and development expertise drives pipeline candidate selection:

- Deep understanding of radiation biology
- First-in-class or best-in-class products
- **Isotope agnostic** (both alpha- and betaemitters under development)
- Validated clinical targets
- Vector tailored to tumor-type and situation





Core pipeline: Oncology and rare diseases

	TARGETING AGENT	ISOTOPE	Dx/ Tx	PHASE 1	PHASE 2	PHASE 3	COMMERCIAL	UPCOMING MILESTONES
Prostate PSMA ¹	Antibody	¹⁷⁷ Lu	Тх	TLX591 (¹⁷⁷ Lu rosopa	atamab tetraxetan)			ProstACT GLOBAL interim readout: Q1 2025
	Antibody	α (alpha)	Тх	TLX592 (alpha-RADm	Ab®)			Phase 1 CUPID trial results: H1 2024
	Small molecule	⁶⁸ Ga	Dx	TLX591-CDx (⁶⁸ Ga-PS	SMA-11, Illuccix®)			EU approval decision: H1 2024 Phase 3 China bridging study complete: H2 2024
Kidney CAIX ²	Antibody	¹⁷⁷ Lu	Тх	TLX250 (¹⁷⁷ Lu-girentu	ximab)			Phase 2 trial data readouts: H2 2024
	Antibody	⁸⁹ Zr	Dx	TLX250-CDx (⁸⁹ Zr-gird	entuximab, Zircaix ^{™*})			FDA approval decision: H2 2024
Brain LAT-1 ³	Small molecule	131	Тх	TLX101 (¹³¹ I-IPA)				Phase 1 IPAX-2 trial data readout: H1 2025
	Small molecule	¹⁸ F	Dx	TLX101-CDx (¹⁸ F-flore	etyrosine)			FDA approval decision: H2 2024
STS⁴ PDGFRα⁵	Antibody	Undisclosed	Тх	TLX300 (-olaratumab)				Phase 1 trial commencement: H1 2024
	Antibody	⁸⁹ Zr	Dx	TLX300-CDx (⁸⁹ Zr-olara	atumab)			
BMC ⁶ CD66 ⁷	Antibody	⁹⁰ Y	Тх	TLX66 (⁹⁰ Y-besilesom	ab)			Phase 2 trial commencement: H1 2024
	Antibody	^{99m} Tc	Dx		silesomab, Scintimun ^{®8})			
🔇 Tel	1. Prostate-	ated brand name su -specific membrane anhydrase IX.			L-type amino acid transporter 1. Soft tissue sarcoma. Platelet derived growth factor red	ceptor alpha.	 Bone marrow conditioning. Cluster of differentiation 66 Marketed under license by 	ð.

A strong foundation for growth

R&D program to drive value creation

Progress late-stage pipeline

- Phase 3 ProstACT GLOBAL trial for prostate cancer therapy (TLX591)
- Phase 2 STARLITE trials and Phase 1b STARSTRUCK trial of TLX250
- Phase 2 trials exploring CAIX pan-cancer utility

Advance next-generation radiopharmaceuticals

- Additional trial of alpha therapy candidate for prostate cancer (TLX592)¹
- Phase 1 trial of TLX300-CDx in soft-tissue sarcoma expected to commence in 2024¹

Commercialize diagnostics

- Planned launch of Zircaix[™] and Pixclara^{™1}
- Geographic expansion of Illuccix®
- Illuccix® life cycle management

Vertically integrate supply chain

• Continue to expand U.S. manufacturing footprint

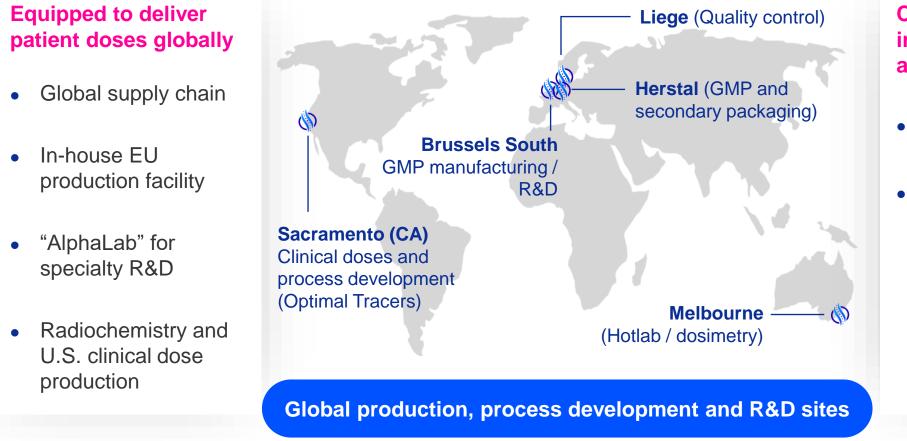
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• Enhance in-house process development and production capacity

Building a vertically integrated business

World-class innovation and manufacturing infrastructure

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Continuing to invest in-house development and production capacity

- Isotope production at EU facility
 - End-to-end process development and manufacturing technologies

Prostate cancer therapy program



Illustration of TLX591 binding to PSMA

TLX591: Phase 3 prostate cancer therapy First-in-class radio-antibody drug conjugate (rADC) targeting PSMA

Product

TLX591 (¹⁷⁷Lu rosopatamab tetraxetan)

Targeting molecule

Monoclonal antibody (mAb)

 $\stackrel{\circ}{\sim}$ Indication

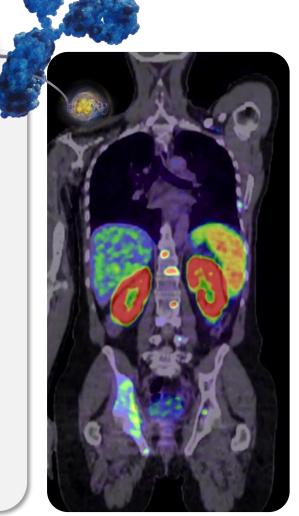
Prostate cancer (mCRPC¹)

Scientific rationale

- Antibodies are functionally specific for tumorexpressed PSMA
- High internalization and long retention with high selectivity for tumor-expressed PSMA
- "Patient-friendly" 2 dose regimen with low occurrence of off-target side effects
- Liver-cleared and excreted

Development pathway

- Recently initiated ProstACT GLOBAL Phase 3 trial, expect to report an interim analysis after 96 events (120 patients)
- Final readout of the ProstACT SELECT Phase 1 trial expected mid-2024



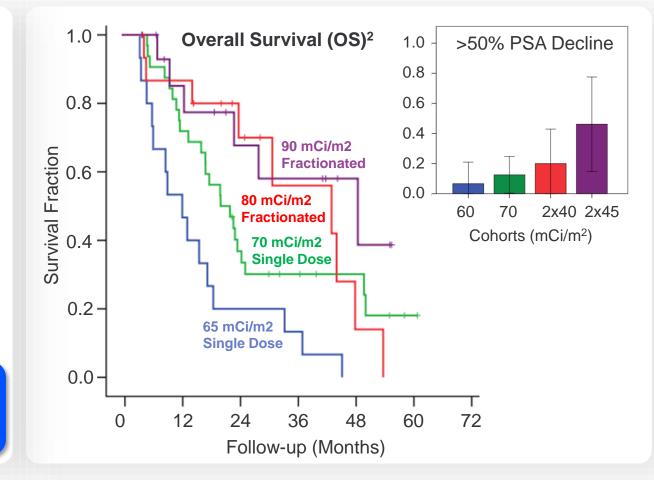


TLX591 data generated to date

Demonstrated evidence of anti-tumor effect and overall survival benefits^{1,2}

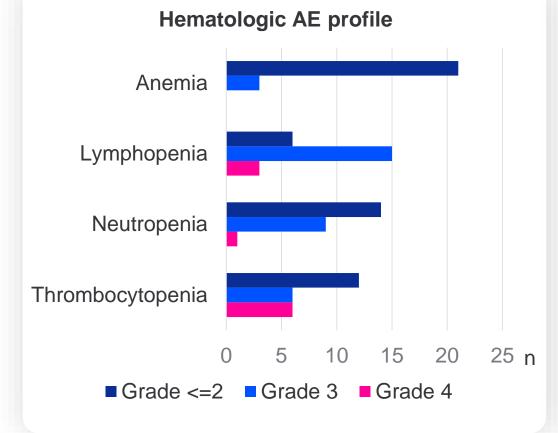
- Previously evaluated in 242 prostate cancer patients in eight Ph1/2 studies
- Evidence of anti-tumor effect and a clear doseresponse profile for key measures of activity
 - Prostate-specific antigen (PSA) response
 - Overall survival (OS) published 42.3 months median survival in end-stage (heavily pre-treated) patients¹
- Well tolerated with predictable and transient reductions in hematological parameters, with subsequent recovery

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



TLX591 safety data reported from SELECT study¹

Safety and tolerability profile confirmed



Key observations

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

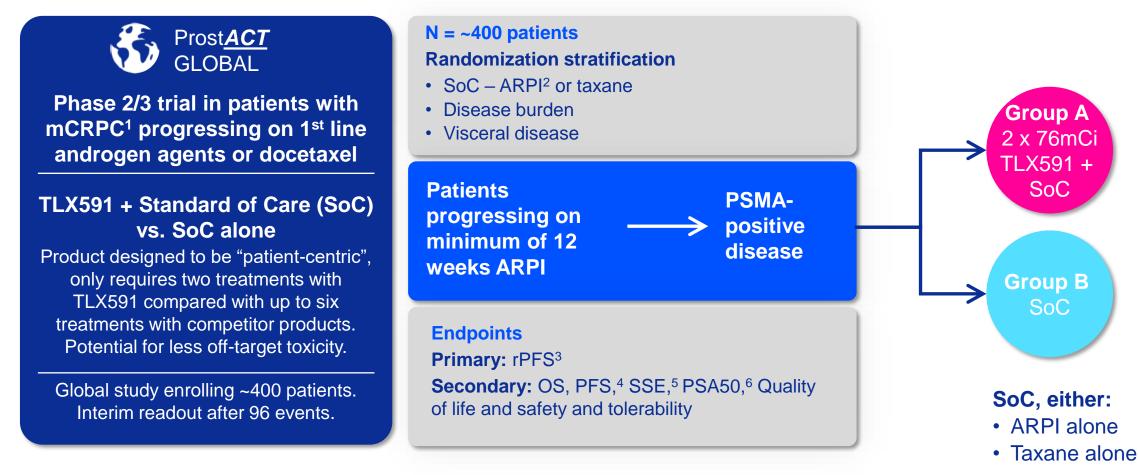
Non-hematologic events

- 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%)

1. ASX release 23 October 2023. Total evaluable patient population, N=28.

ProstACT GLOBAL trial design

First patient recruited, designed to integrate with real-world standard of care



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- Metastatic castrate-resistant prostate cancer.
- 2. Androgen receptor pathway inhibitor.
- Radiographic progression-free survival
- Progression-free survival.

- 5. Symptomatic skeletal event.
- 6. Prostate-specific antigen decline of >50%.

TLX591: benefits rival small molecule-based approach

	Efficacy	\rightarrow	Promising overall survival seen in early phase studies ¹ Dosing schedule enables combination with concurrent therapies	
$\widehat{\oslash}$	Patient comfort	\rightarrow	No dry eye, no xerostomia (salivary gland ablation), no ganglia irradiation Implications for alpha therapy	
	Patient-centric dosing	\rightarrow	Short treatment duration/significantly fewer hospital visits – 2 weeks total vs. up to 36 weeks, supports close supervision by medical oncology	
	Reduced radioactivity	\rightarrow	152mCi cumulative radiation exposure with TLX591 ² vs 1200mCi with current approved treatment ³ = reduced costs and radiation protection implications	

1. Tagawa et al, Cancer. 2019.

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- 2. Administered every two weeks for up to two weeks for up to two treatments, solution for injection contains 76mCi (2.8GBq) at time of use.
- 3. Pluvicto® prescribing information. Administered every six weeks for up to six treatments, solution for injection contains 200mCi (7.4GBq) at time of use.

TLX592: "Next gen" alpha therapy for prostate cancer

RADmAb® PK engineered antibody with novel properties to facilitate rapid clearance



Targeting molecule

Engineered antibody (RADmAb)

 ζ° Indication

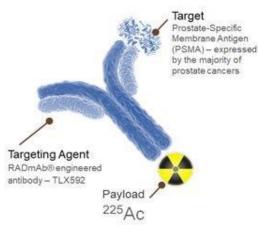
Prostate cancer (mCRPC)

Scientific rationale

- RADmAb® is a proprietary antibody engineered for use with ²²⁵Ac for targeted alpha therapy
- Faster elimination from circulation than standard antibodies, yet slower than small molecules
- Designed to reduce bone marrow residence time to mitigate hematologic toxicity and retain PSMAmediated tumor localization and cytotoxic activity
- Liver-cleared, no exocrine uptake¹

Development pathway

 Phase 1 CUPID biodistribution study dosing final cohort, ahead of initiating Phase 1/2 efficacy study



TLX592: CUPID study dosing final cohort

Taking TLX592 into patients with a "theranostic" approach

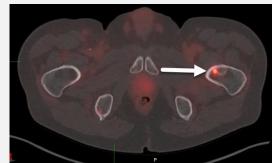
- TLX592 is being developed as a targeted alpha therapy, complementary to TLX591
- May be suitable for patients with very early-stage metastatic disease with low disease burden AND also may be suitable for patients with very late-stage disease and no longer responding to PSMA-therapy
- First clinical program to utilize Telix's proprietary RADmAb® platform technology

CUPID trial

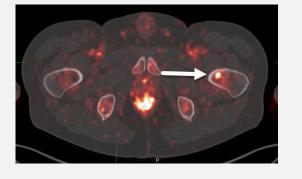
- Phase 1 safety, PK, biodistribution and dosimetry trial
- Uses ⁶⁴Cu (copper-64) which is detectable with PET¹ imaging, as a proxy for ²²⁵Ac (not detectable by PET), to confirm biological properties of TLX592 and predict therapeutic behavior (dosimetry)
- 3 + 3 dose escalation study with 4 cohorts of TLX592 final cohort recruiting
- Expected to advance to ²²⁵Ac therapeutic Phase 1/2 study in 2024

Early signs of encouraging tumor discrimination

Illuccix® (68Ga-PSMA-11)



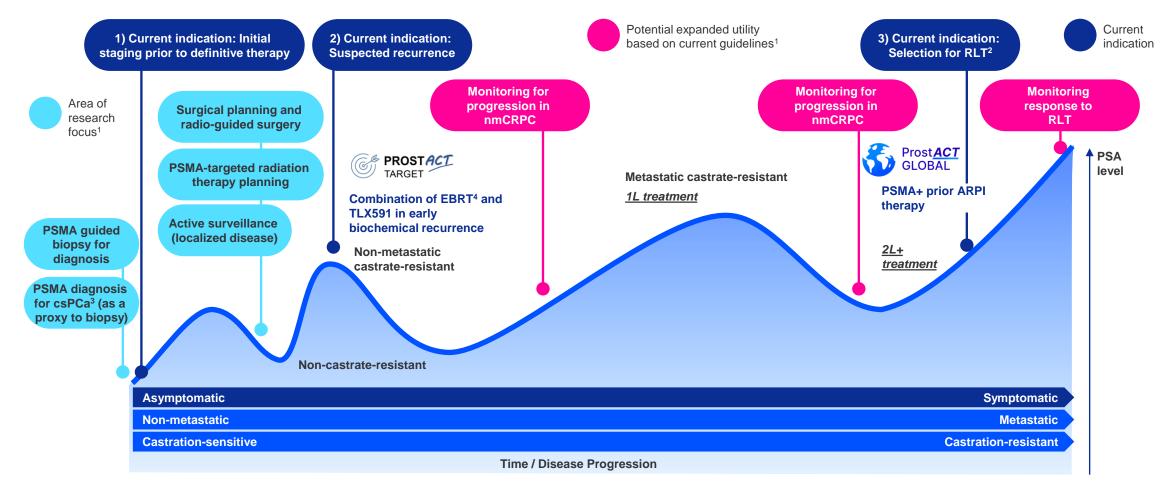
⁶⁴Cu-TLX592



Note: Sample patient response only, individual results may vary.

Supporting patients and physicians throughout the journey

Solutions across the prostate cancer patient care continuum



- 1. Areas of research focus and expanded utility are not approved indications for Illuccix in any jurisdiction.
- 2. Radioligand therapy.
- 3. Clinically significant prostate cancer.
- 4. External beam radiation therapy.

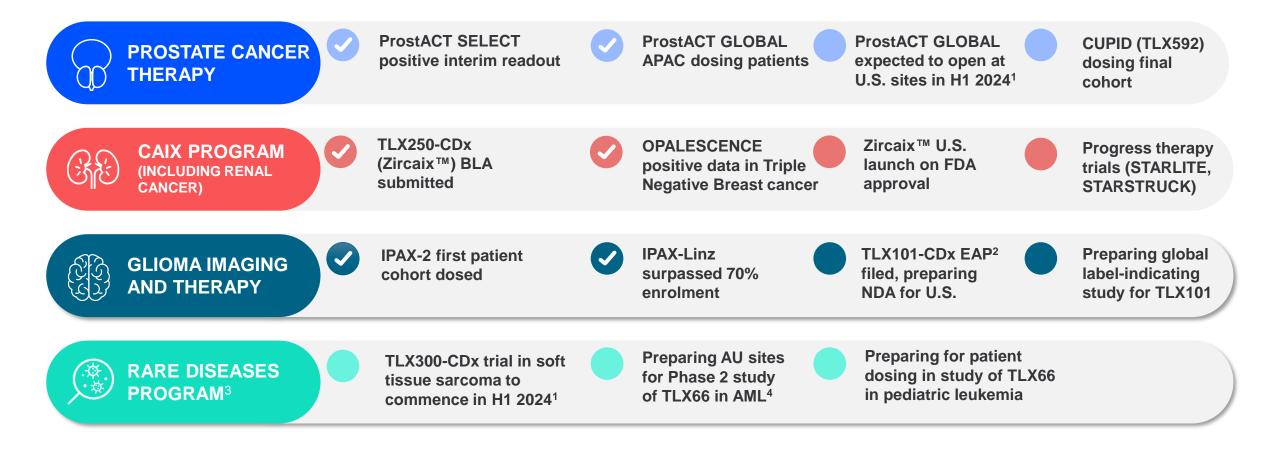
Other therapeutic programs



Illustration of TLX250 binding to CAIX

Core pipeline: clinical highlights

Recent updates and progress





Subject to regulatory approval.

- Expanded Access Program.
- . Rare Disease program includes programs for bone marrow conditioning and soft tissue sarcoma.
- 4. Acute myeloid leukemia.

TLX250: Phase 2 renal cancer therapy

Potential to further develop as a "pan-cancer" solid tumour therapeutic targeting CAIX

Product

TLX250 (¹⁷⁷Lu-DOTAgirentuximab)

Targeting molecule

Monoclonal antibody (mAb)



Kidney: Studies underway to assess treatment in kidney cancer

Other CAIX-expressing tumors: potential to develop as a pancancer therapy

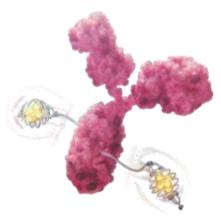
Scientific rationale

- CAIX expressed in up to 95% of ccRCC¹ and many hypoxic / resistant solid tumors, with low expression in normal tissue
- Hypoxia correlates with progression and resistance to therapy²

Development pathway

- Phase 2 STARLITE studies for kidney cancer therapy and Phase 2 STARBURST study investigating expression in patients with solid tumors dosing patients
- Under investigation for combination with protein kinase inhibitor candidate for solid tumors

Targeting Agent: girentuximab IgG1 monoclonal antibody

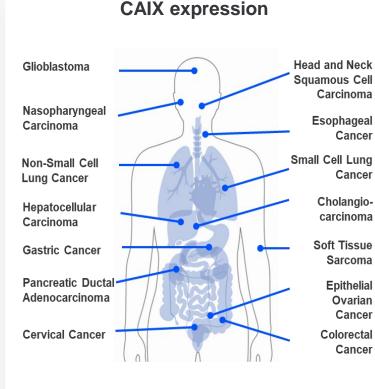


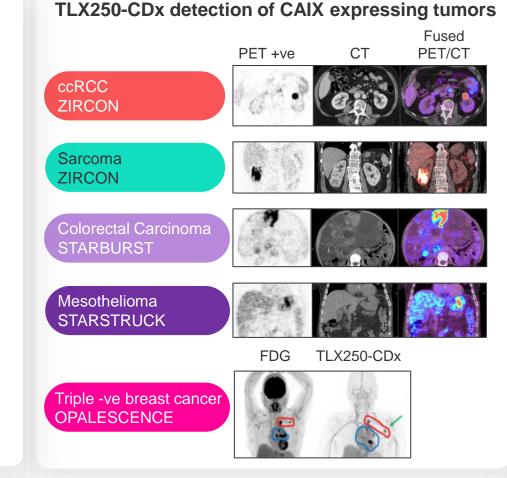
Payload: 177Lu



CAIX expression is associated with poor clinical outcomes

Studies in progress reinforce potential of CAIX as a therapeutic target





"Theranostic" trials of TLX250-CDx and TLX250

襚 STAR**BURST**

 Phase 2 imaging study scouting "theranostic" utility

STARLITE-1

STARLITE-2

 Phase 2 combination I-O¹ therapy studies (IITs²)

STAR**STRUCK**

Phase 1b combination therapy study TLX250 + Merck KGaA DNA Damage Response Inhibitor (DDRi, peposertib)

TLX101: Phase 2 brain cancer therapy

Large amino acid transporter 1 (LAT-1) program

TLX101 (¹³¹I-IPA)

Targeting molecule

Small molecule

 \bigcirc Indication

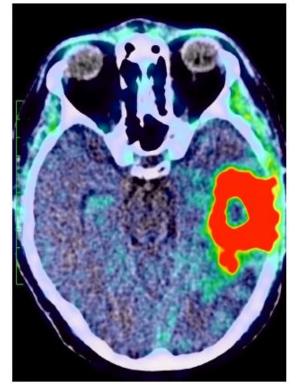
Brain: Undergoing evaluation in both front-line and recurrent glioblastoma (GBM)

Scientific rationale

- A novel approach that is readily able to pass through the blood-brain barrier
- IPAX-1 trial demonstrated median OS of 13 months from the initiation of treatment in the recurrent setting, or 23 months from initial diagnosis¹

Development pathway

- Orphan drug designation granted in U.S. and EU²
- Phase 1 IPAX-2 study in front-line setting, dosing patients
- Phase 2 IPAX-Linz (IIT) continuing investigation in second line (refractory) setting, 70% recruited



Note: Sample patient response only, individual results may vary.

https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu-3-06-363.

TLX300: Soft tissue sarcoma therapy

Leveraged clinically established targeting antibody olaratumab

AA Product

TLX300 (olaratumab)

Targeting molecule

Antibody

C Indication

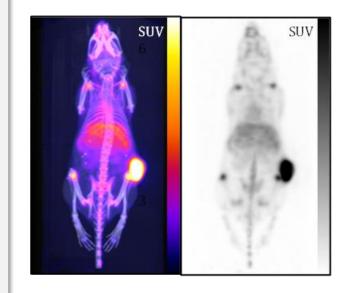
Soft tissue sarcoma (STS)

Scientific rationale

- STS is a radiation susceptible cancer that may be inherently amenable to systemic radionuclide therapy¹
- Ability to target PDGFRα² makes TLX300 a promising candidate for use as a radionuclide targeting agent in a range of cancers
- Excellent tumor targeting and retention of TLX300-CDx demonstrated in a mouse biodistribution study³

Development pathway

- mAb safety demonstrated in pre-clinical repeatdose toxicology studies
- Preparing to commence Phase 1 trials (nuclide not disclosed)



PET image of a mouse 120 hours after dosing with TLX300-CDx demonstrating high tumor uptake and retention.

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1. Haas et al. *Radiation Research.* 2021.

Platelet-derived growth factor alpha.

8. Ivashkevich, A. Presentation to ANZSA Annual Scientific Meeting 2023, Melbourne, Nov 11, 2023.

Radiolabelled olaratumab (TLX300) advancing to clinical trials

Strong scientific, clinical and commercial rationale for development

Olaratumab (Lartruvo®) was commercialized by Lilly as a "naked" antibody¹

- In-licensed from Lilly in April 2022 with exclusive rights to develop as a radiopharmaceutical²
- It has an established clinical safety profile, favorable toxicology dataset and advanced manufacturing
- Lartruvo® was granted an accelerated approval for the treatment of soft tissue sarcoma (STS) based on Phase 2 data, but was subsequently withdrawn voluntarily from market

High unmet medical need for treatment of STS

- Poor prognosis (12-18 months in advanced metastatic cases) and few treatment options
- While STS is generally responsive to radiation, external beam radiation can be difficult to administer in patients with advanced disease
- A rare disease, meets eligibility criteria for orphan designation³
- Annual incidence rates:⁴ U.S., 13,040 and Europe, 23,600 patients





On October 19, 2016 the FDA granted accelerated approval for Olaratumab (LARTRUVO, Eli Lilly and Company). Telix ASX disclosure April 11 2022.

Haas et al. *Radiation Research.* 2021.

www.cancer.org.

PDGFRα (platelet-derived growth factor receptor alpha)

TLX66 program

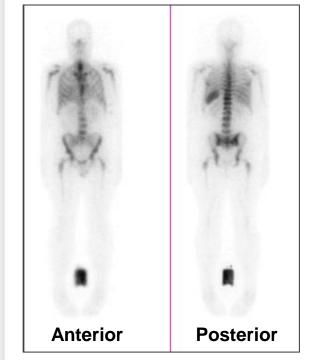
Phase 2 therapeutic clinical trial to commence in H1 2024

Product
 TLX66 (⁹⁰Y-DTPA-besilesomab)
 Targeting molecule
 Monoclonal antibody
 Coldication
 Bone Marrow Conditioning e.g. in acute myeloid leukemia

Scientific rationale

- The target of TLX66 cluster of differentiation 66, or CD66 is a well validated leukocyte / neutrophil target
- 98 patients treated in several Phase 1 and 2 investigator-initiated trials of TLX66 in different hematological diseases (AML, MM, SALA) requiring autologous or allogeneic stem cell transplantation
- US FDA and EMA Orphan Drug Designation granted for TLX66 for bone marrow conditioning

Whole-body imaging 24h post infusion of ¹¹¹In-labelled TLX66



Excellent Biodistribution: Minimal uptake in nonhematopoietic organs such as liver, kidneys and gut



TLX66: Clinical data in 98 patients

Excellent safety profile and encouraging efficacy signals

TLX66 has been tested in 98 patients (including children) with a range of hematological malignancies:

- *Phase 1*: Dose-escalation study in hematological malignancies (n=55 pts)
- Phase 1: Study in childhood relapsed/refractory leukemia (n=9 pts)
- Phase 1/2: Targeted Radiotherapy for AL-Amyloidosis (n=10 pts)
- Phase 2: A randomised phase 2 in multiple myeloma (n=24 pts)

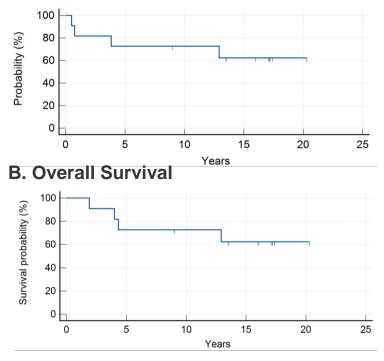
Safety

- No significant toxicities, no detectable non-hematological toxicity such as mucositis/colitis avoiding hospitalization
- In the pediatric population, the therapy was well-tolerated with no serious toxicities

Efficacy

 Encouraging increases in relapse free survival (RFS) and OS detected relative to historical data Encouraging long-term RFS and OS in high-risk AML patients (RFS and OS >10 years in most patients)¹

A. Relapse Free Survival



Kidney and brain cancer imaging for "theranostics"



Illustration of TLX101-CDx binding to LAT-`1

TLX250-CDx (Zircaix™) for imaging of kidney cancer

Antibody-based PET imaging targeting CAIX

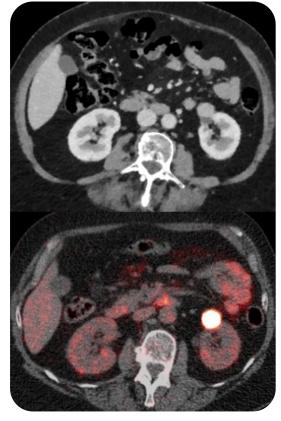
Antibody: Girentuximab

- Binds with high specificity to CAIX and is internalized
- Extensive safety experience with girentuximab in prior imaging and therapeutic studies
- Hepato-biliary excretion allows optimal renal visualization
- Hepatically cleared

High unmet need: Market opportunity >US\$500M¹

- ccRCC is the most common and aggressive form of kidney cancer
- Potential to change standard of care in the diagnosis and management of renal masses and ccRCC
- Sensitivity of ≥84% and specificity of ≥84% in all three readers in ZIRCON Phase 3 trial²

U.S. BLA for TLX250-CDx (Zircaix[™]) filing commenced³



Positive TLX250-CDx PET scan in ccRCC Source: Ph3 ZIRCON study



Dollar (\$) value is management estimate based on U.S. reported incidence; assumes 1-2 scans per patient as a baseline.

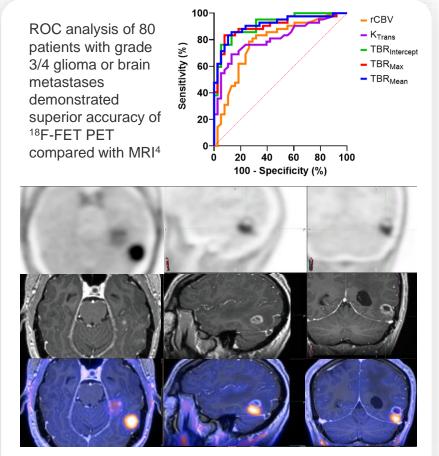
- 2. Telix ASX disclosure 7 November 2022
- . Telix ASX disclosure 19 December 2023.

TLX101-CDx (Pixclara™) for imaging of glioma

Unmet need for delineating progressive disease from treatment-induced changes

Preparing to file U.S. NDA for TLX101-CDx (¹⁸F- floretyrosine):

- Initial indication: Characterizing recurrent glioma or treatmentinduced change
- A potential tool for management of progression/ treatment monitoring
- ~US\$90M initial U.S. market opportunity¹
- Orphan drug designation, potential to meet major unmet need
- Widely used in Europe and recommended in the EANM/EANO/RANO/SNMMI guidelines for PET imaging of gliomas²
- First PET-based response assessment criteria for diffuse gliomas issued by RANO in January 2024³



Note: Patient representative sample - individual results may vary.



Dollar (\$) value is management estimate based on U.S. reported incidence; assumes 1-2 scans per patient as a baseline.

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.

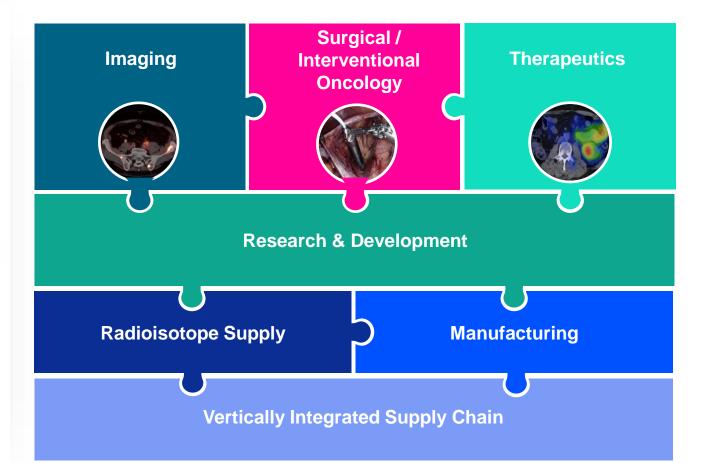
- Albert et al. Lancet Oncol. 2024.
- Veronesi et al. J Nucl Med. 2023.

Telix is pioneering the next generation of radiopharmaceuticals

Therapeutic pipeline underpinned by deep understanding of drug development

Summary

- Pioneers in radiopharmaceutical drug development, team with a collective 320+ years experience
- Expertise in cancer + radiation biology driving pipeline selection, exemplified by our first-in-class rADC for prostate cancer therapy (Phase 3) and proprietary RADmAb® antibody platform
- Differentiated by our end-to-end offering for the field of urology and specialist commercial team
- Underpinned by a **vertically integrated** manufacturing and robust global supply chain





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