



Precision Oncology
See it. Treat it.



Telix Pharmaceuticals Limited

Half-Year Shareholder Update (1H21)

19 August 2021

ersonal use only

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¹. Scintimun® is a registered trademark of Curium Pharma

Telix: A global leader in radiopharmaceuticals



Extensive, clinically-validated portfolio of diagnostic and therapeutic assets

11,000 patient doses in past 12 months¹

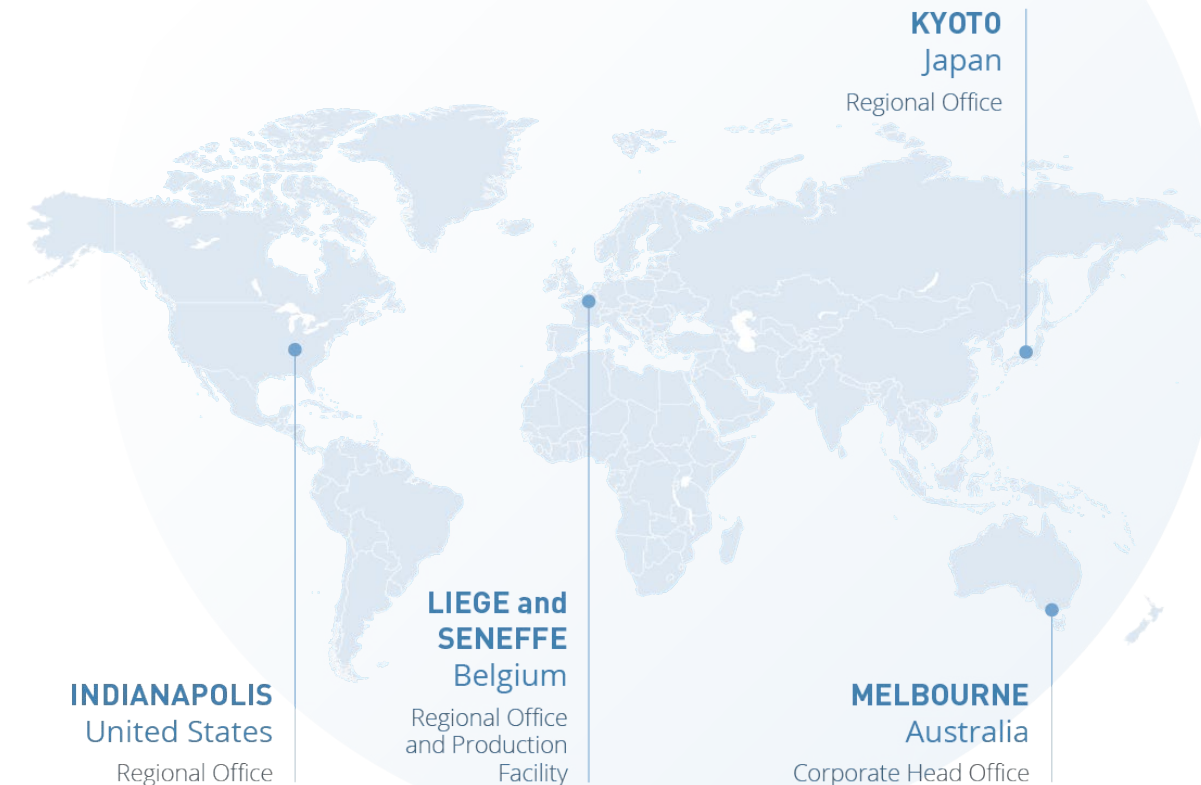
17 countries with a marketing authorisation for TLX591-CDx (illuccix®) in progress

17 active clinical trials (7 indications)²

Leading supply chain and distribution network

80 countries in the Telix distribution network

11 countries with a manufacturing footprint

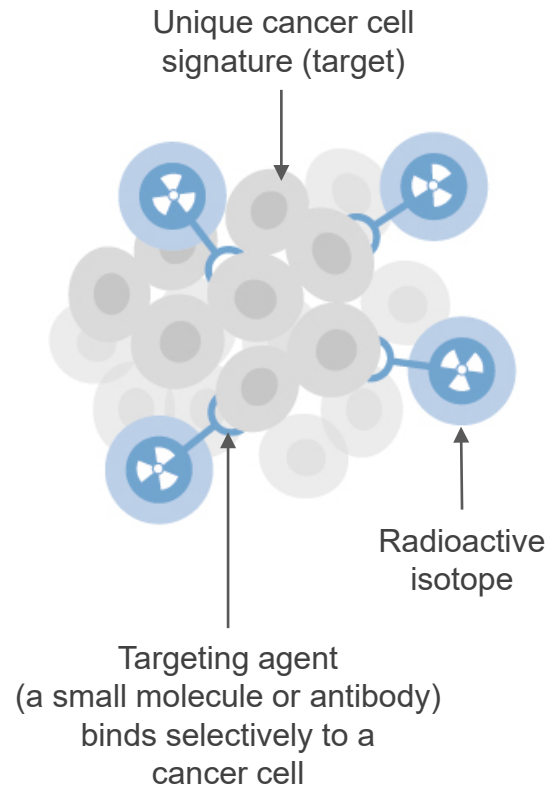


1. Clinical trial doses and magisterial / compassionate use of TLX591-CDx.

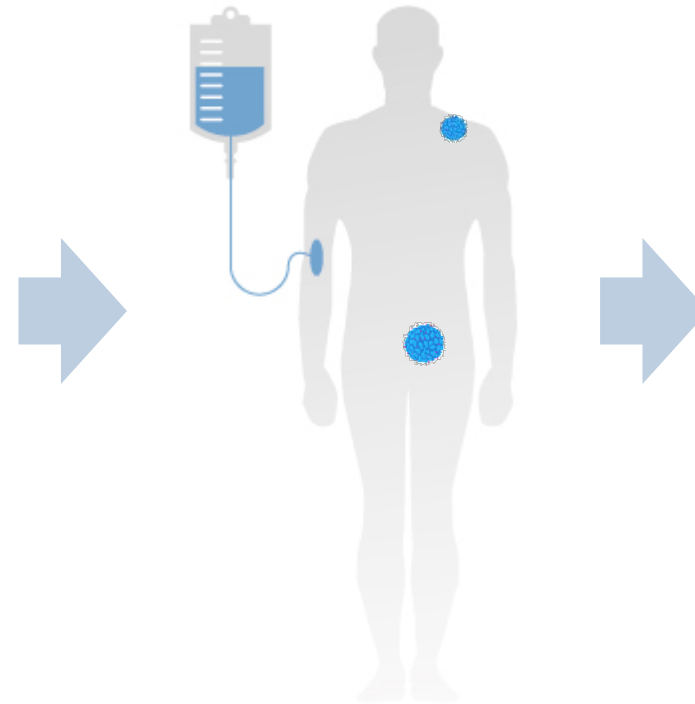
2. Includes partnered investigator-led studies.

Our strategy: *See It. Treat it.*

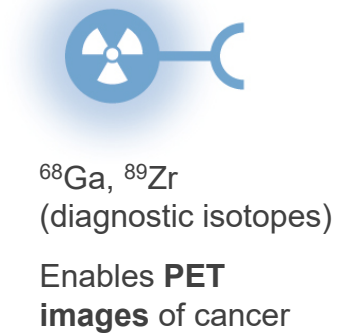
Targeted radiation delivery



Systemically administered



Imaging



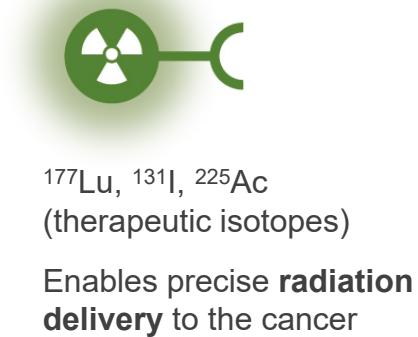
PET scanner



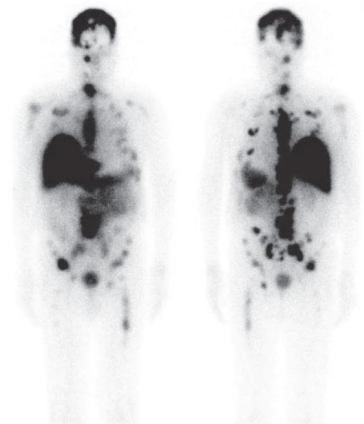
TLX591-CDx¹ (Prostate cancer)



Therapy



TLX591 (Prostate cancer)



1. Courtesy of Ammar Chaudhry MD, City of Hope, Duarte CA, USA.

Deep pipeline in oncology, rare diseases

	Targeting Molecule	Target	Radioactive Isotope	Phase I	Phase II	Phase III	Commercial
Prostate	Small molecule	PSMA ⁽¹⁾	⁶⁸ Ga	TLX591-CDx (⁶⁸ Ga-PSMA-11, Illuccix®)			Imaging
	Antibody	PSMA	¹⁷⁷ Lu	TLX591 (¹⁷⁷ Lu-rosopatamab)			Therapy
	Antibody	PSMA	²²⁵ Ac	TLX592 (²²⁵ Ac-RADmAb®)			Therapy (2 nd Gen)
	Small molecule	PSMA	^{99m} Tc	TLX599-CDx (^{99m} Tc-iPSMA)			Imaging/Surgery
	Small molecule	PSMA	⁶⁸ Ga	TLX591-Sx (⁶⁸ Ga-PSMA-IRDye)			Imaging/ Surgery
Kidney	Antibody	CA9 ⁽²⁾	⁸⁹ Zr	TLX250-CDx (⁸⁹ Zr-girentuximab)			Imaging
	Antibody	CA9	¹⁷⁷ Lu	TLX250 (¹⁷⁷ Lu-girentuximab)			Therapy
Brain	Small molecule	LAT-1 ⁽³⁾	¹⁸ F	TLX101-CDx (¹⁸ F-FET)			Imaging
	Small molecule	LAT-1	¹³¹ I	TLX101(¹³¹ I-IPA)			Therapy
BMC/RD ⁽⁴⁾	Antibody	CD66 ⁽⁵⁾	^{99m} Tc	TLX66-CDx (^{99m} Tc-besilesomab, Scintimun®)			Imaging
	Antibody	CD66	⁹⁰ Y	TLX66 (⁹⁰ Y-besilesomab)			Therapy

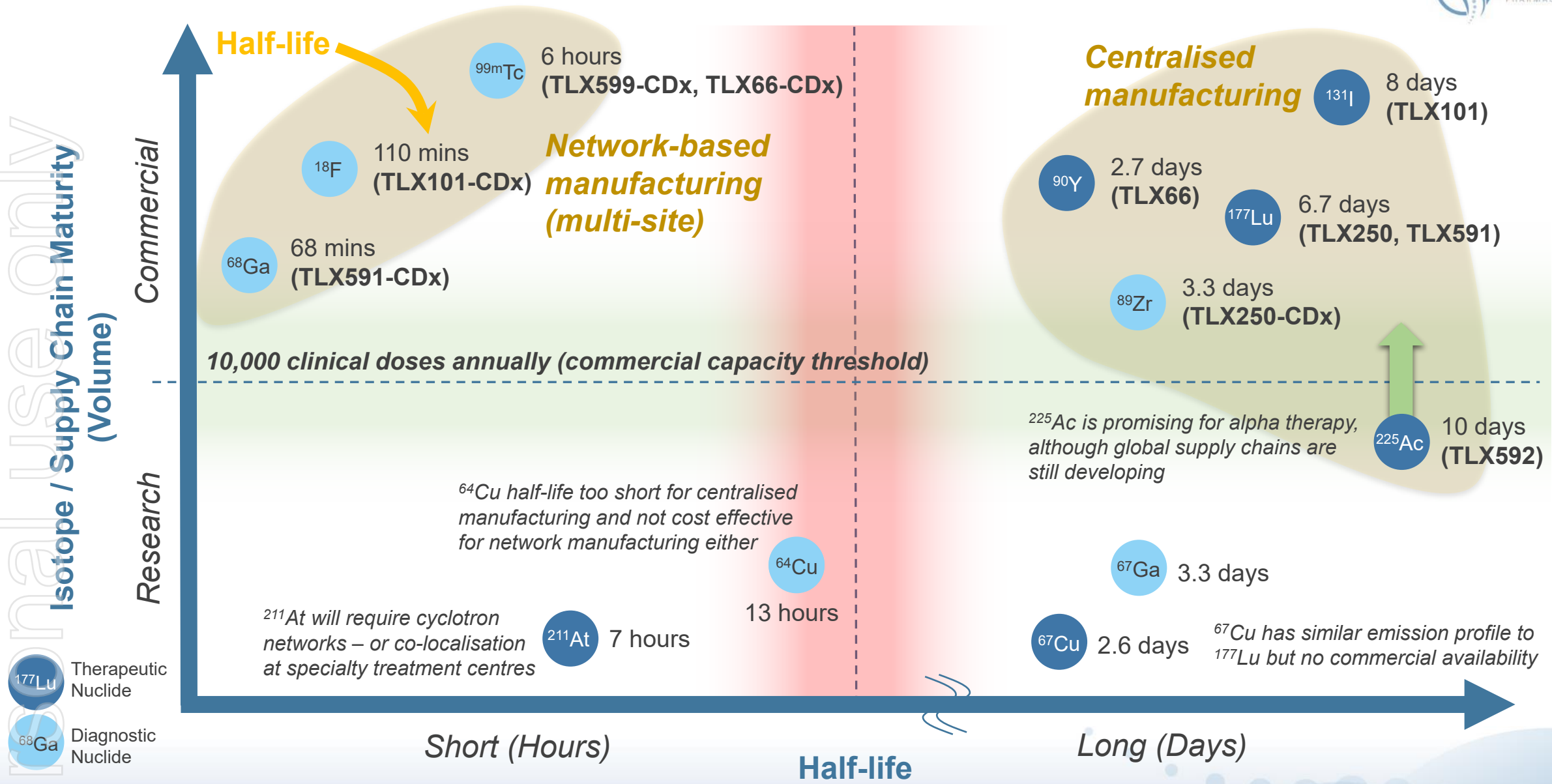
Shaded arrows indicate completion expectations in the next 12 months.

1. Prostate-specific membrane antigen.
2. Carbonic anhydrase IX.
3. Large amino acid transporter 1.

4. Bone marrow conditioning and rare disease.
5. Cluster of differentiation 66.

Isotope and manufacturing supply chain matters

Internal use only



ersonal use only

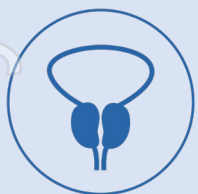
1H21 Highlights



Operational highlights



Momentum and focus leading into key inflection points



Launch illuccix[®]

**US FDA decision on
23 September 2021**

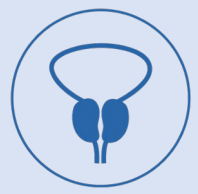
- ✓ Launch ready
- ✓ TGA and EU approvals to follow by year-end



Complete ZIRCON

**Phase III imaging trial in renal cancer,
Breakthrough Designation,
and year-end completion**

- ✓ Enrolment expected to complete by year-end, recruitment accelerating
- ✓ FDA BLA² consultation process to commence by year-end



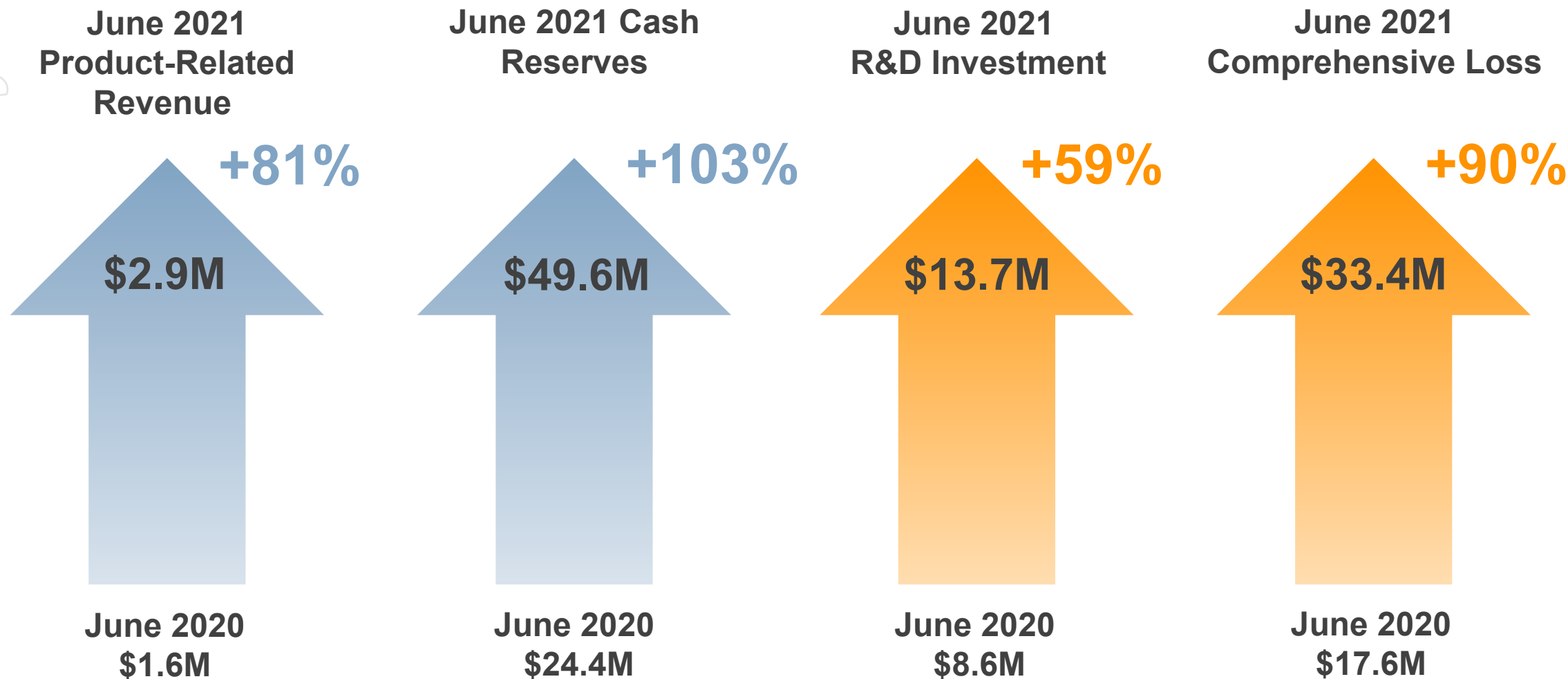
Commence ProstACT

**Phase III therapy trial initiated in
metastatic castrate resistant
prostate cancer (mCRPC)**

- ✓ Initial launch in Australia (CTN³/ethics)
- ✓ US/EU site selection underway
- ✓ Expanded ProstACT program launched to support future indication expansion

1. Biologics Licence Application
2. Clinical Trial Notification

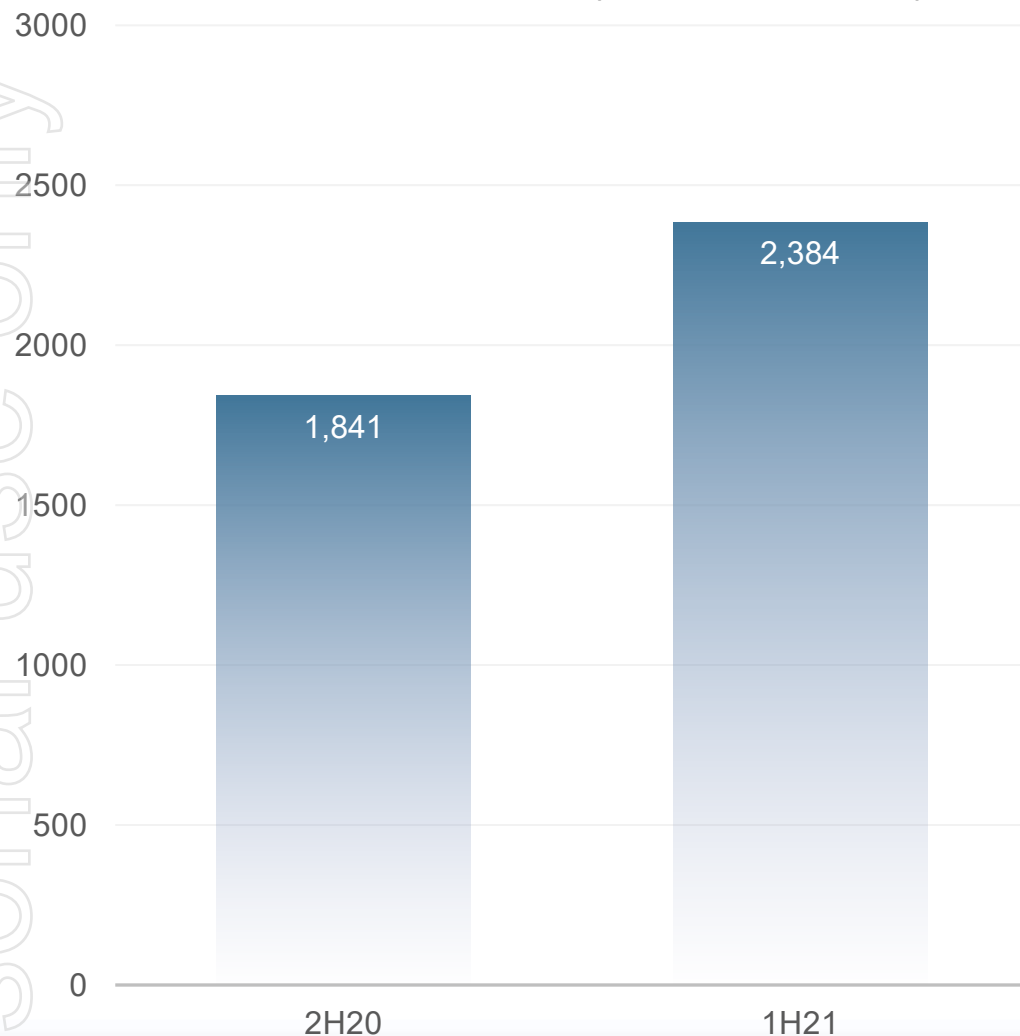
Investing for commercial launch and pipeline expansion



Pre-approval revenue as kit sales recover from COVID-19 impact



TLX591-CDx Kit Sales (Jul 20 – Jun 21)



Delivering at commercial scale:

- Growing user base with 2,384 kits sold (investigational, clinical trial, magisterial and compassionate use access only) up 30% from 2H20
- Equivalent to approximately 6,200 individual patient doses (multi-dose kit)

Early revenue generation validates the product:

- Telix received \$1.8M in cash receipts from customers in 1H21
- Average kit pricing remained stable on a territory-by-territory basis



Ilucix[®] Imaging
Ready to launch



Illuccix® approval timelines (estimated)



US FDA approval decision (PDUFA¹ action date) of 23 September 2021



¹ Prescription Drug User Fee Act

Planned US illuccix[®] roll-out : The gallium wave

www.galliumwave.com

- **Superior** network coverage at launch
- **On-demand** pharmacy-based production with a high yield product
- **Customer** and patient scheduling flexibility – we give control back to the customer



Illuccix[®] (Kit for the preparation of ⁶⁸Ga-PSMA-11) is an investigational product and has not attained a marketing authorisation in any jurisdiction, including the United States. Product launch in the United States is subject to FDA approval of a New Drug Application (NDA)

Planned US illuccix[®] roll-out: Ready to launch



Ready for commercial-scale delivery

Multi-disciplinary commercial team

- Telix + partners will have the largest commercial team (including sales, market access, MSL) to service the US prostate imaging market
- Direct sales force hired and cross-trained in both oncology and nuclear medicine aspects



Superior site coverage

- ~90% of eligible PET sites will have access to illuccix[®] upon approval
- Multiple sales targets : referring physicians, B2B collaboration, PET imaging sites and active profiling to potential early adopters
- Market access strategy in place



Manufacturing capacity to meet expected demand

- Generator capacity in place
- Pharmacy network manufacturing, close to our customer, gives sites complete control over patient management and scheduling for maximum flexibility



US\$900M total addressable market for illuccix®



Annual incidence of prostate cancer in Telix US & EU markets¹

478,000²

Patients with prostate cancer eligible for PET imaging with TLX591-CDx (illuccix®), across 4 potential indications

1. Biochemical recurrence following prostatectomy or radiation therapy
2. Patient selection for PSMA targeted radio-ligand therapy (RLT)
3. Primary staging in newly diagnosed high-risk prostate cancer
4. Monitoring of response to systemic therapy

386,000

Total addressable market (TAM) value

USD \$900M³

1. Telix markets = US + EU countries included in MAA submission to Danish Medicines Authority on 30th April 2020.
2. GLOBOCAN 2020 reported incidence of prostate cancer in Telix's markets.
3. US TAM value = USD \$575M, EU TAM value = USD \$325M.

Global launch backed by strong commercial partnerships

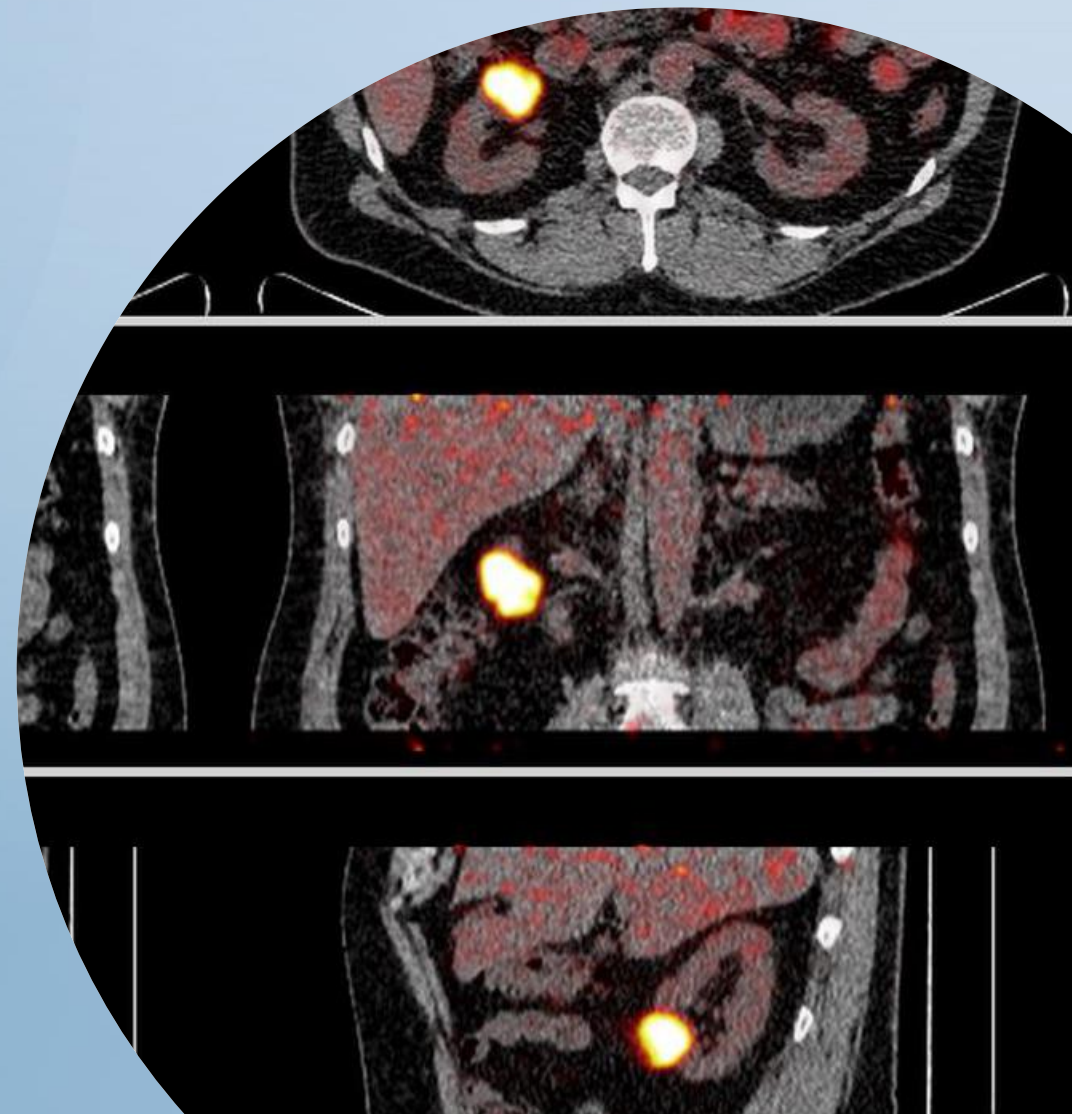


遠大醫藥健康控股有限公司
China Grand Pharmaceutical and Healthcare Holdings Limited



Renal Cancer Imaging

*Building a high value
genitourinary (GU)
oncology portfolio*



Building a high-value portfolio in GU oncology

“Breakthrough Therapy” designation, clinical leadership opportunity

- TLX250-CDx is an investigational product being developed for imaging of clear cell renal cell carcinoma (ccRCC) with PET
- Potential to deliver on unmet need for improved staging of ccRCC
 - Identifies “indeterminate renal masses” through improved, whole of body imaging and optimising opportunity for minimally invasive treatment options
- Mission is to build on illuccix® GU oncology customer base with a second high-value product
- BLA consultation process to commence by end-year
- Limited commercial competition, high unmet medical need



Whole body scan of a 57-year-old male patient revealing 3 lesions. Only those at renal and adrenal level (lower 2 arrows) were also detected on CT. Merx et al, EJNMMI, 2021.

ZIRCON Phase III trial of TLX250-CDx for imaging of ccRCC



Eligible Patients

- Single indeterminate renal mass ≤ 8 cm diameter on CT or MRI suspicious for ccRCC
- Scheduled for surgical remove as part of diagnostic plan

TLX250-CDx
PET/CT scan

Surgical removal &
histology as standard
of truth



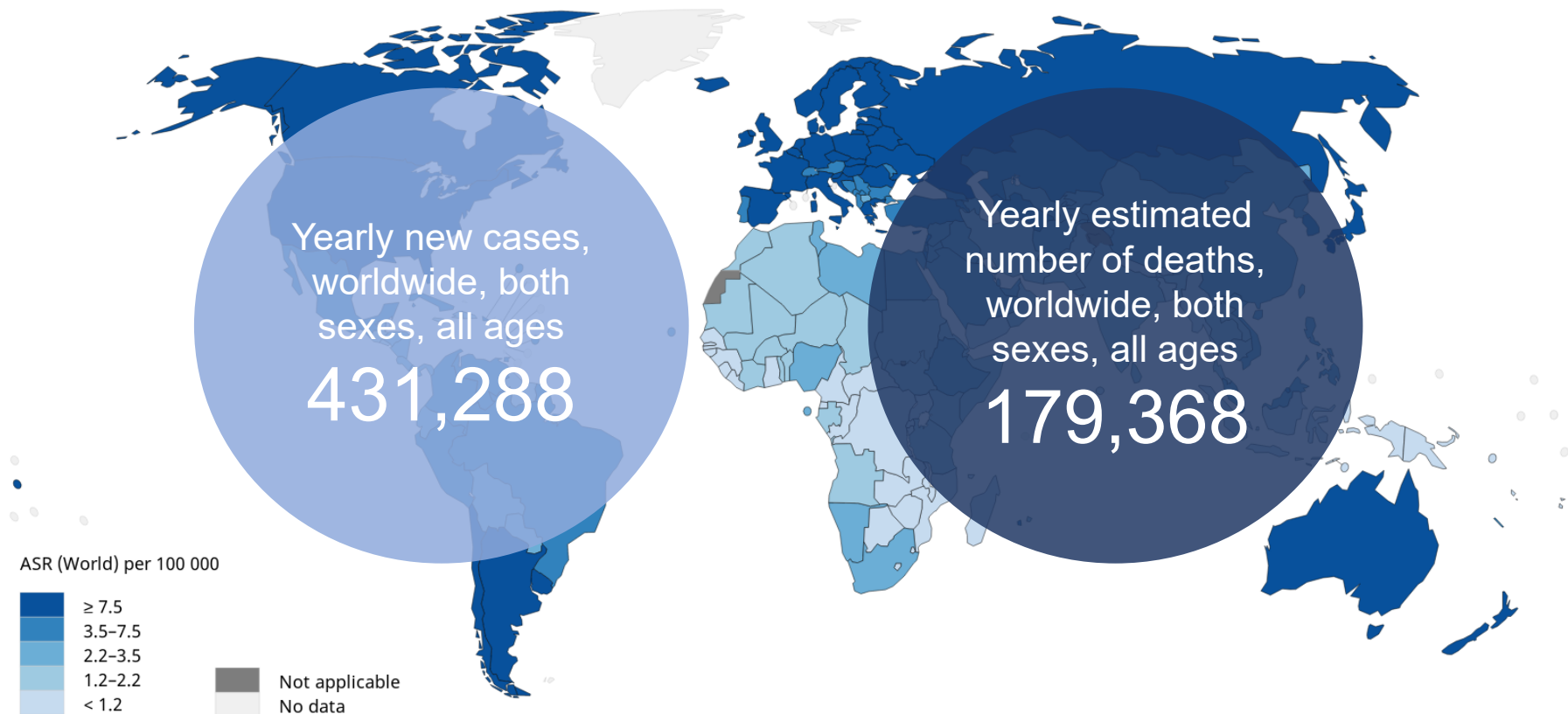
- International, multi-centre, Phase III trial in ~252 patients with an indeterminate renal mass suspicious of ccRCC
 - ✓ **Primary endpoint:** Sensitivity and specificity of PET/CT imaging with TLX250-CDx to non-invasively detect ccRCC in patients with indeterminate renal masses, using histology as standard of truth
- 34 sites participating
 - ✓ Recruitment accelerating (COVID impact) with completion of enrolment expected by end-year
 - ✓ United States, Canada, Europe, Turkey, Australia
- ZIRDAC-JP Phase I/II bridging trial of TLX250-CDx in Japan
 - ✓ Phase I objectives met, Phase II in planning, potential to include Chinese patients to expand Asian utility

TLX250-CDx: Delivering an unmet need in renal cancer imaging



- Total addressable market value in US and Europe estimated at US\$3-400M
- Low competition, opportunity for market leadership in renal cancer
- Addresses a major unmet medical need

Estimated age-standardized incidence rates (World) in 2020, kidney, both sexes, all ages



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Data source: GLOBOCAN 2020
Graph production: IARC
(<http://gco.iarc.fr/today>)
World Health Organization

PROST *ACT*

Prostate Cancer Therapy
Our vision for prostate cancer



ProstACT program overview



Expanded program will add value and clinical insight to TLX591 platform

Radiogenomics study (Phase I)

- Australia & NZ
- 30-50 patients
- First line mCRPC



Treat the scan

Correlation between imaging and therapy to optimise patient selection

Combination with EBRT in oligometastatic early recurrence (Phase II)

- Australia
- 50 patients
- Co-funded by GenesisCare



Early data in front line care

Efficacy data in patients in their first recurrence

Pivotal Phase III study in patients with mCRPC progressing on 1st line novel androgen agents

- International
- 390 patients
- Second line mCRPC



TLX591 + Standard of Care (SoC) vs. SoC alone

- **SELECT** – radiogenomics study enhances patient selection and supports indication expansion based on a “theranostic” approach
- **TARGET** – in partnership with GenesisCare, evaluates TLX591 in a front-line setting
- **GLOBAL** – Multiple data read-outs throughout the ProstACT program duration
- Growing pharma engagement and collaboration (i.e. Merck)

Antibody vs small molecule



Efficacy

Significantly improved overall survival; cross-trial comparison of 40+ months vs. 15.3 months in a comparable end-stage patient population^{1,2}



Patient comfort

Reduced potential for undesirable side-effects; dry eye, xerostomia (salivary gland ablation), back pain (ganglia irradiation)



Patient-centric regimen

Short treatment duration/significantly fewer hospital visits – two weeks total vs. 36 weeks, supports close supervision by medical oncology



Cost effective

Reduced ¹⁷⁷Lu isotope requirement via more targeted dosing/less waste
COGS ~1/5 of competition, expected to also be available in “cold kit” format

1. Tagawa et al, Cancer 2019.

2. Cross-trial comparison, randomised controlled trial (RCT) required for verification.

TLX591 patient experience

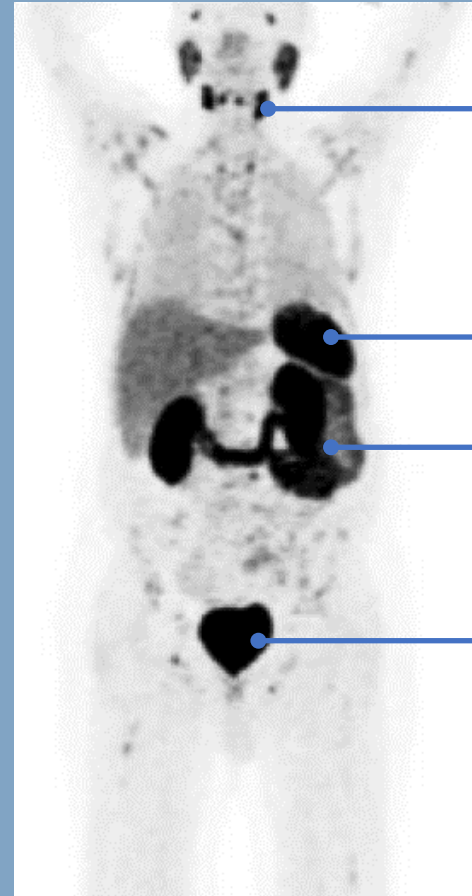
Off-target irradiation – quality of life matters

TLX591

Antibodies are functionally specific for tumour-expressed PSMA and do not “hit” most endogenous PSMA expression

Liver (preferred clearance organ)

Fecal excretion



Lacrimal, Parotid, Submandibular (salivary) glands

Spleen, Liver

Kidneys, Small bowel

Bladder (urinary excretion)

Small molecule

Small molecule radioligands taken up by endogenous PSMA

Additional off-target effects with small molecule radioligands (not experienced with TLX591)

- Dry eye
- Xerostomia
- Back pain from ganglia irradiation

Data courtesy of Prof. Neil Bander, WCMC.

Telix's dual approach for prostate cancer therapy



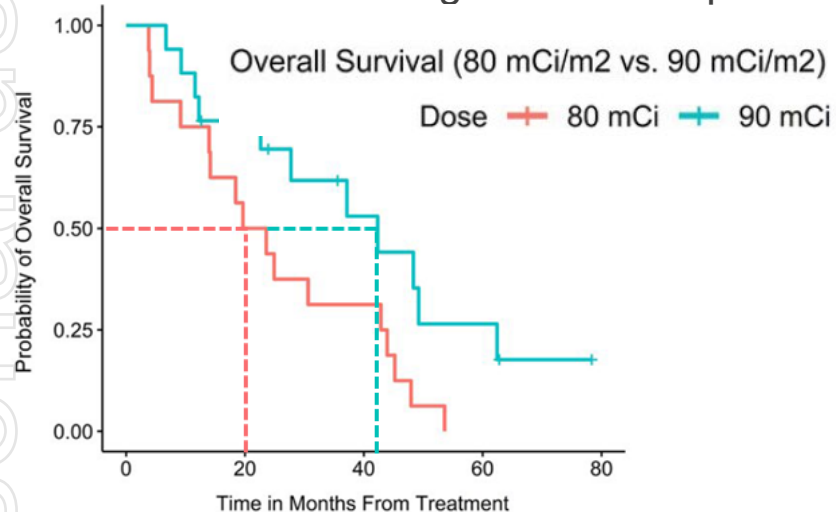
PROSTACT TLX591 (^{177}Lu -rosopatamab)

Traditional humanised antibody immunoconjugate

Well-validated for beta emitters

- Beta emitter (^{177}Lu) suited to bulky metastatic disease
- Telix is building on a significant body of clinical data
 - ✓ ~200 PC patients in five Phase I and II studies

✓ Demonstrates significant therapeutic impact ¹



1. Tagawa et al. Cancer 2019.

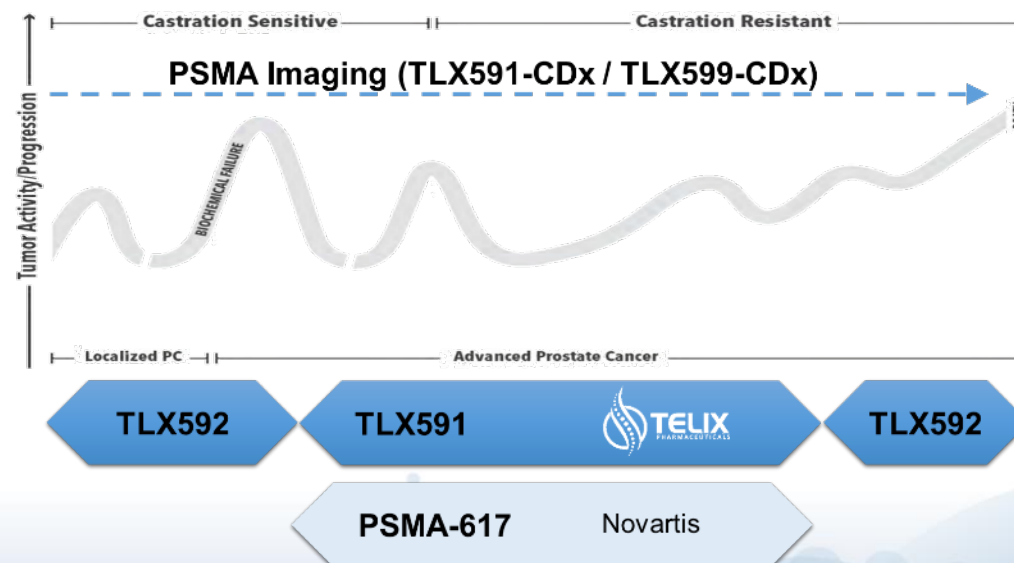
2. Biochemical recurrence.

CUPID TLX592 (^{225}Ac -TLX592)

Re-engineered antibody immunoconjugate (RADmAb[®])

Designed for delivering targeted alpha emitters

- Alpha emitter (^{225}Ac) intended for
 - ✓ Early-stage metastatic disease (e.g. BCR²)
 - ✓ Late-stage disease following ^{177}Lu -PSMA therapy
- First patient dosed August 2021



Prostate cancer: The patient journey

PSA level

Localised disease

Radiation therapy +/- ADT
Radical prostatectomy
Active surveillance

Advancing clinical stages

Docetaxel, abiraterone (metastatic, non-castrate), apalutamide, enzalutamide (non-metastatic, castrate resistant)

Metastatic castrate resistant

First line:

Docetaxel; Sipuleucel-T; Abiraterone
Enzalutamide; Pembrolizumab

Rising PSA

ADT (non-castrate)

Second line +
Clinical trial

Second line:

Cabazitaxel; Abiraterone
Enzalutamide; Radium 223
Pembrolizumab; Olaparib;
Rucaparib

Asymptomatic

Symptomatic

Non-metastatic

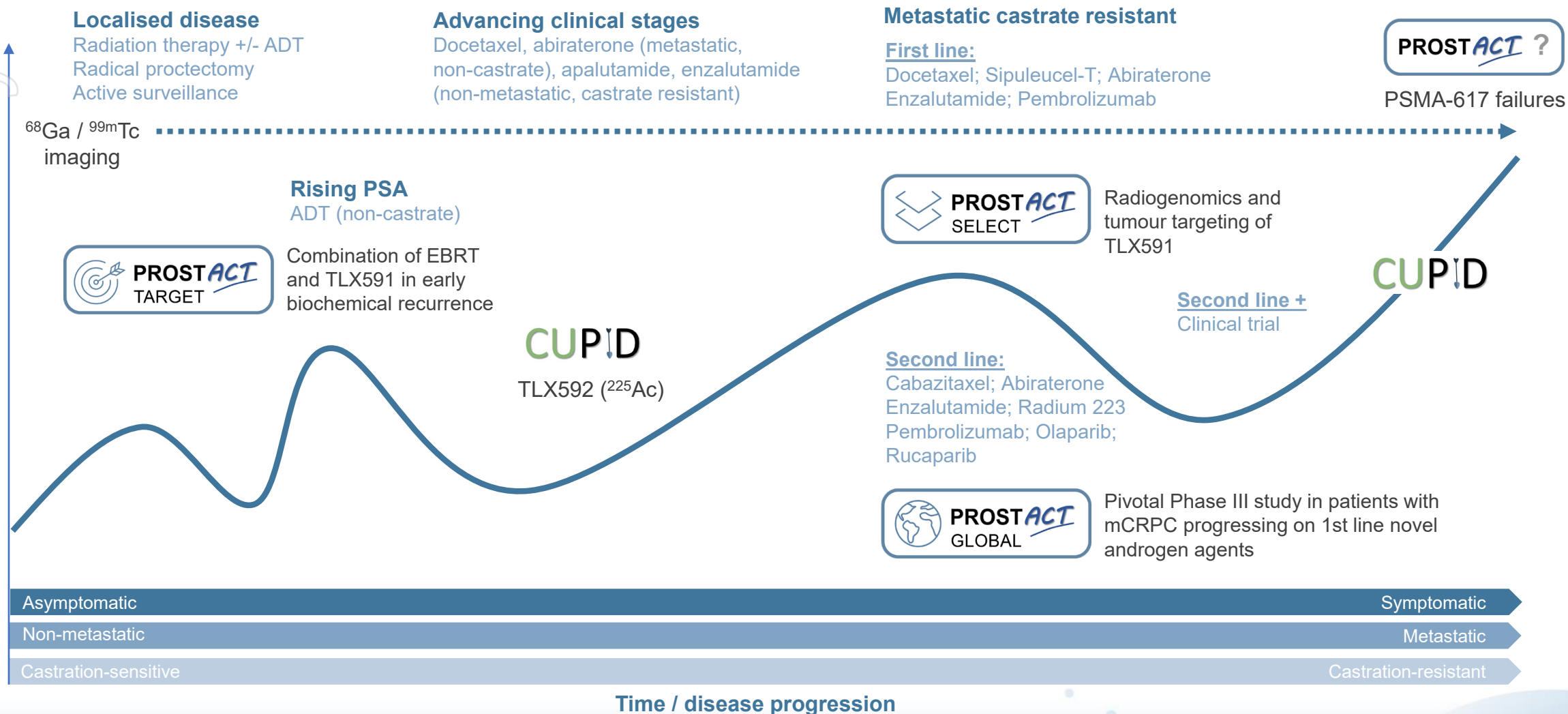
Metastatic

Castration-sensitive

Castration-resistant

Time / disease progression

Our clinical mission: Support the patient every step of the way



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Outlook



We are pioneering a new oncology modality



Glioblastoma

Ph	Name	Asset	Dx/Tx
I/II	IPAX-1	TLX101	Tx

Breast Cancer

Ph	Name	Asset	Dx/Tx
II	OPAESCENCE	TLX250-CDx	Dx
II	Emory University	TLX591-CDx	Dx

Lung Cancer

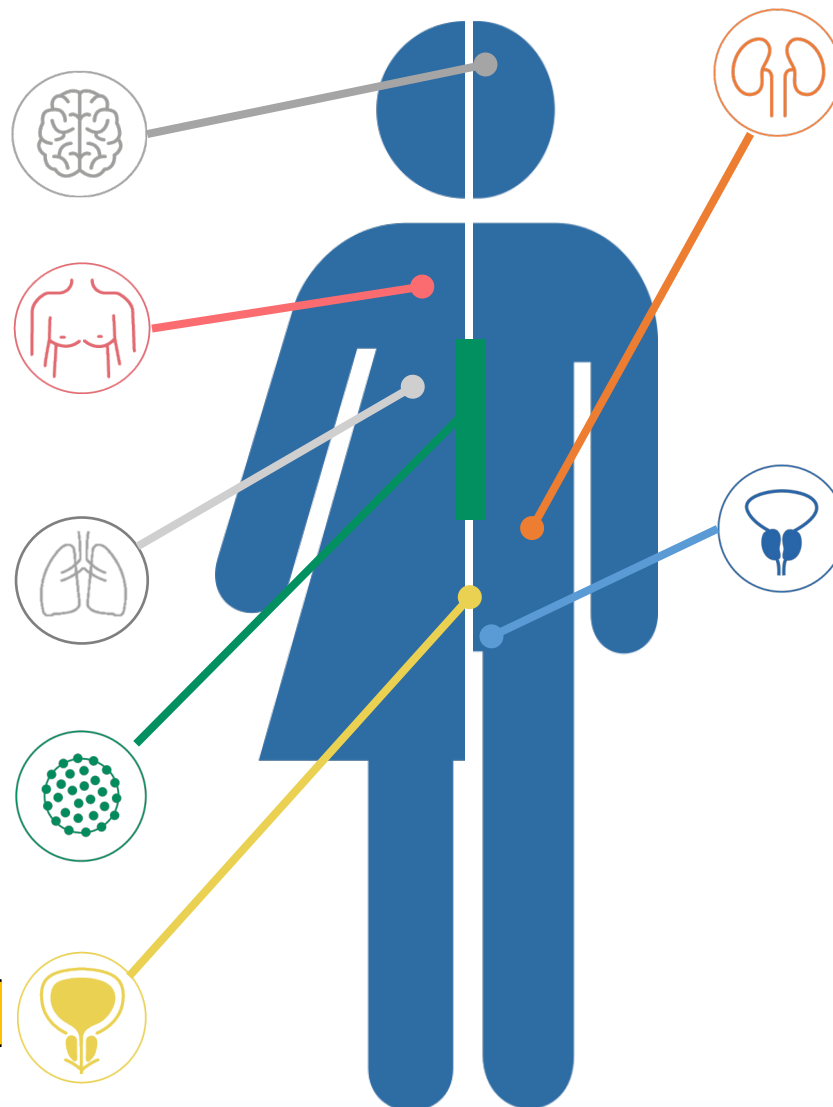
Ph	Name	Asset	Dx/Tx
I	Royal Adelaide (IIT)	APOMAB	Dx/Tx

Bone Marrow Conditioning

Ph	Name	Asset	Dx/Tx
I/IIa	TRALA	TLX66	Tx

Bladder Cancer

Ph	Name	Asset	Dx/Tx
I	ZiP-UP	TLX250-CDx	Dx



Renal Cancer

Ph	Name	Asset	Dx/Tx
III	ZIRCON	TLX250-CDx	Dx
I/II	ZIRDAC	TLX250-CDx	Dx
II	STARLITE-1	TLX250	Tx
II	STARLITE-2	TLX250	Tx

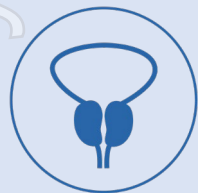
Prostate Cancer

Ph	Name	Asset	Dx/Tx
III	University of Linz (IIT)	TLX591-CDx	Dx
II	Emory University (IIT)	TLX591-CDx	Dx
II	ENHANCING Enzalutamide-Enhanced Imaging	TLX591-CDx	Dx
II	Mem. Sloan Kettering (IIT)	TLX591-CDx	Dx
N/A*	NABLE Nab-paclitaxel	TLX599-CDx	Dx
III	PROSTACT	TLX591	Tx
I	CUPID	TLX592	Tx

*Registry study

Summary

Momentum and focus leading into key inflection points



**Launch
illuccix®**

**US FDA decision
23 September 2021**

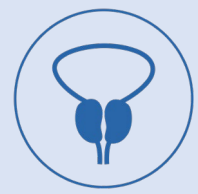
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