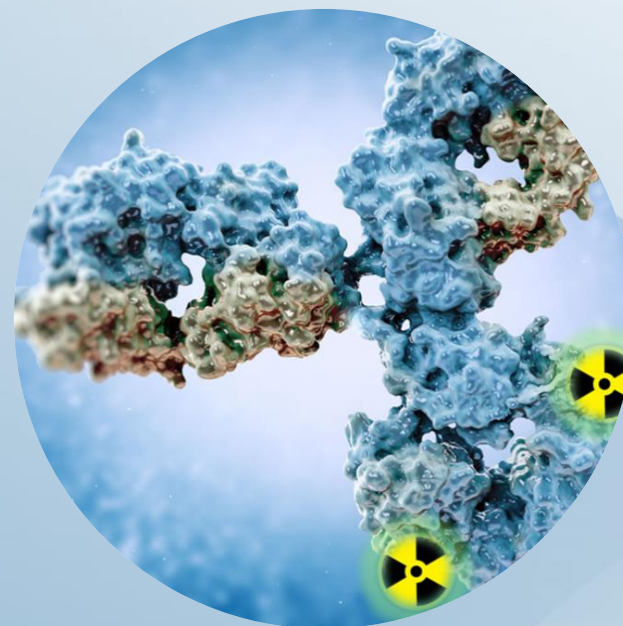




Precision Oncology.  
See it. Treat it.



# Telix Pharmaceuticals Limited

## ASX CEO Connect

20<sup>th</sup> April 2021

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There can be no assurance or guarantee that actual outcomes will not differ materially from these statements. The data and results pertaining to clinical subjects used in this presentation are illustrative of medical conditions and outcomes associated with potential applications of Telix’s product pipeline. Actual results from clinical trials may vary from those shown. None of the products or potential products described in this presentation have received a marketing authorisation in any jurisdiction.

# Telix: At a glance...



## Extensive late stage product portfolio – diagnostics and therapeutics

- ✓ **Oncology** with focus on prostate, renal, glioblastoma, hematologic cancers
- ✓ **Immunology** applications and high value rare diseases

## Major milestones achieved during 2020...despite COVID-19

- ✓ **Illuccix® (prostate cancer imaging):**
  - Regulatory filings in US, EU, Canada, Australia
  - Commercial distribution agreements in US (Cardinal Health and Pharmalogic) and major EU & APAC territories
- ✓ **Licensed production facility** acquired in Seneffe, Belgium from Eckert & Ziegler AG
- ✓ **China Grand Pharma transaction:** Up to \$400M+ value, delivers long-term clinical & commercial partner for Greater China region
- ✓ **TheraPharm acquisition:** Broadens development pipeline to hematologic oncology, bone marrow transplantation, rare diseases
- ✓ **Multiple strategic collaborations:** Varian Medical Systems, RefleXion, Mauna Kea Technologies

## Significant inflection points in 2021

- ✓ **Illuccix®:** Regulatory approval and commercial launch in US, EU, Canada, Australia. First commercial product revenue
- ✓ **Second product:** Completion of ZIRCON Phase III trial of TLX250-CDx (renal cancer imaging)
- ✓ **Therapeutics:** Launch ProstACT Phase III trial of TLX591 (prostate cancer therapy) in Australia, EU, US
- ✓ **Extend global reach:** Asia, Latin America – currently clinically active in 30+ countries

# Financial Snapshot



**\$3.97**

(16 Apr 2021)

**Mkt. Cap: ~A\$1.12Bn**

<b>Disease Focus</b>	Oncology
<b>Clinical Stage</b>	Phase I - III
<b>Shares on Issue</b>	~281m
<b>Options on Issue</b>	~22m
<b>Cash on Hand</b>	~AUD \$80m
<b>ASX Ticker</b>	TLX
<b>Index</b>	ASX 300

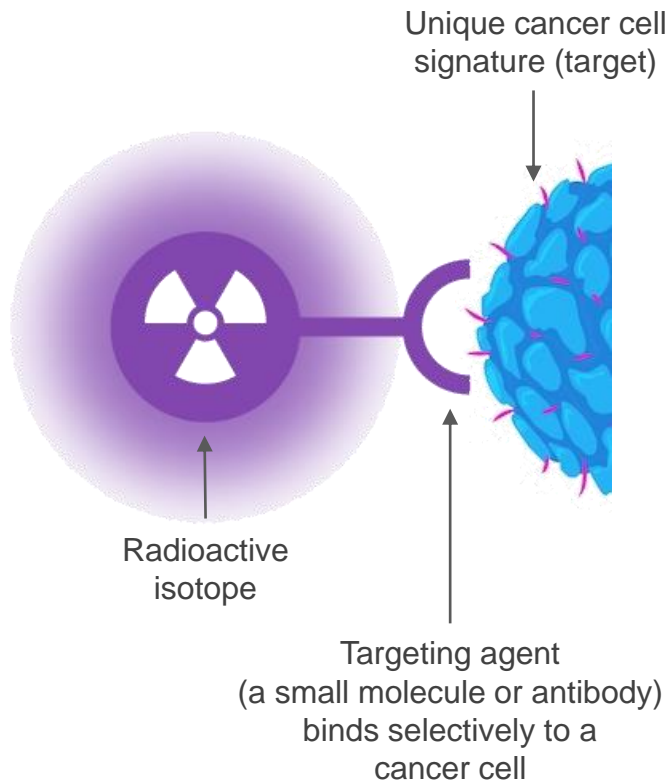


- November 2017 – IPO on the Australian Securities Exchange (ASX). Raised AUD \$50m
- August 2019 – placement/SPP for AUD \$45m (@\$1.30)
- Predominantly an institutional shareholder base : Fidelity, Portland, China Grand Pharma (strategic investor)
- Cash at hand : AUD ~\$80m (Dec '20)
- Early revenue generation from prostate cancer imaging product – approved product revenue expected Q4 2021
- Runway to mid-2022 (excluding product-related revenue)

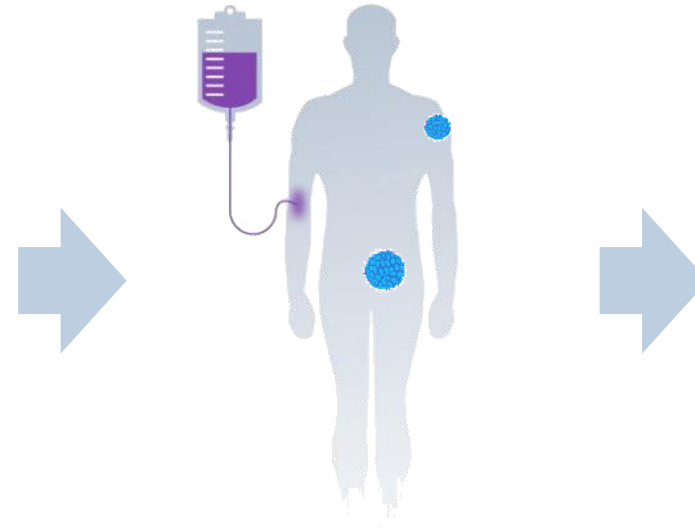
# Our technology : Molecularly-Targeted Radiation (MTR) See It. Treat it.



## Targeted radiation delivery



## Systemically administered



## Imaging

$^{68}\text{Ga}$ ,  $^{89}\text{Zr}$   
(diagnostic isotopes)

Enables **PET images** of cancer

## PET scanner



## TLX591-CDx<sup>1</sup> (Prostate cancer)

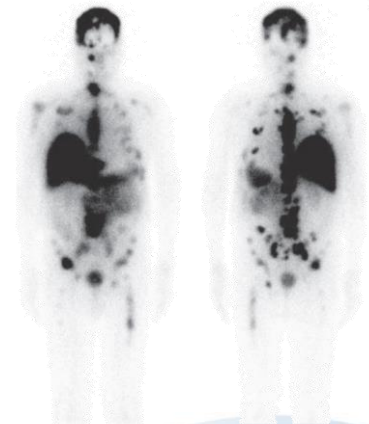


## Therapy

$^{177}\text{Lu}$ ,  $^{131}\text{I}$ ,  $^{225}\text{Ac}$   
(therapeutic isotopes)

Enables precise **radiation delivery** to the cancer

## TLX591 (Prostate cancer)



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

# Deep Pipeline in Oncology, Rare Diseases



	Targeting Molecule	Cancer Cell Target	Radioactive Isotope	Phase I	Phase II	Phase III	Commercial
Prostate	Small molecule	PSMA	<sup>68</sup> Ga	TLX591-CDx ( <sup>68</sup> Ga-PSMA-11, Illuccix®)			Imaging
	Antibody	PSMA	<sup>177</sup> Lu	TLX591 ( <sup>177</sup> Lu-rosopatamab)		PROSTACT	Therapy
	Antibody	PSMA	<sup>225</sup> Ac	TLX592 ( <sup>225</sup> Ac-RADmAb®)		CUPID	Therapy (2 <sup>nd</sup> Gen)
	Small molecule	PSMA	<sup>99m</sup> Tc	TLX599-CDx ( <sup>99m</sup> Tc-iPSMA)		NQBLE	Imaging / Surgery
	Small molecule	PSMA	<sup>68</sup> Ga	TLX591-Sx ( <sup>68</sup> Ga-PSMA-IRDye)			Imaging / Surgery
Kidney	Antibody	CA9	<sup>89</sup> Zr	TLX250-CDx ( <sup>89</sup> Zr-girentuximab)			ZIRCON Imaging
	Antibody	CA9	<sup>177</sup> Lu	TLX250 ( <sup>177</sup> Lu-girentuximab)		STARLITE <sup>+</sup>	Therapy
Brain	Small molecule	LAT1	<sup>18</sup> F	TLX101-CDx ( <sup>18</sup> F-FET)			Imaging
	Small molecule	LAT1	<sup>131</sup> I	TLX101 ( <sup>131</sup> I-IPA)		IPAX-1	Therapy
BMC/RD <sup>1</sup>	Antibody	CD66	<sup>99m</sup> Tc	TLX66-CDx ( <sup>99m</sup> Tc-besilesomab, Scintimun® <sup>2</sup> )			Imaging
	Antibody	CD66	<sup>90</sup> Y	TLX66 ( <sup>90</sup> Y-besilesomab)		TRALA	Therapy

1. Bone marrow conditioning / rare diseases.  
 2. Scintimun® is a registered trademark of Curium Pharma.

Shaded arrows indicate expected development stage in the next 12 months.

# Outstanding team, global presence



## Co-founders:

Dr. Christian Behrenbruch (MD and CEO, Melbourne)  
Dr. Andreas Kluge (Director, Dresden)



## Chairman

Mr. Kevin McCann, AO

Chairman of China Matters, a Pro-Chancellor of the University of Sydney, a Trustee of the Sydney Opera House, Director of E&P Financial Services Group. Former Chairman of Macquarie, Origin Energy, Healthscope, ING Management Limited, Allens partner



## Non-Executive Director

Ms. Jann Skinner

Former PwC partner, Director of QBE Insurance (Chair audit committee), Create Foundation Limited and HSBC Bank Australia Limited.



## Non-Executive Director

Dr. Mark Nelson

Chairman/Co-Founder of the Caledonia Investments Group. Chairman of Art Exhibitions Australia, Director of Kaldor Public Art Projects, The Mindgardens Neuroscience Network, and a Governor of the Florey Neurosciences Institute.

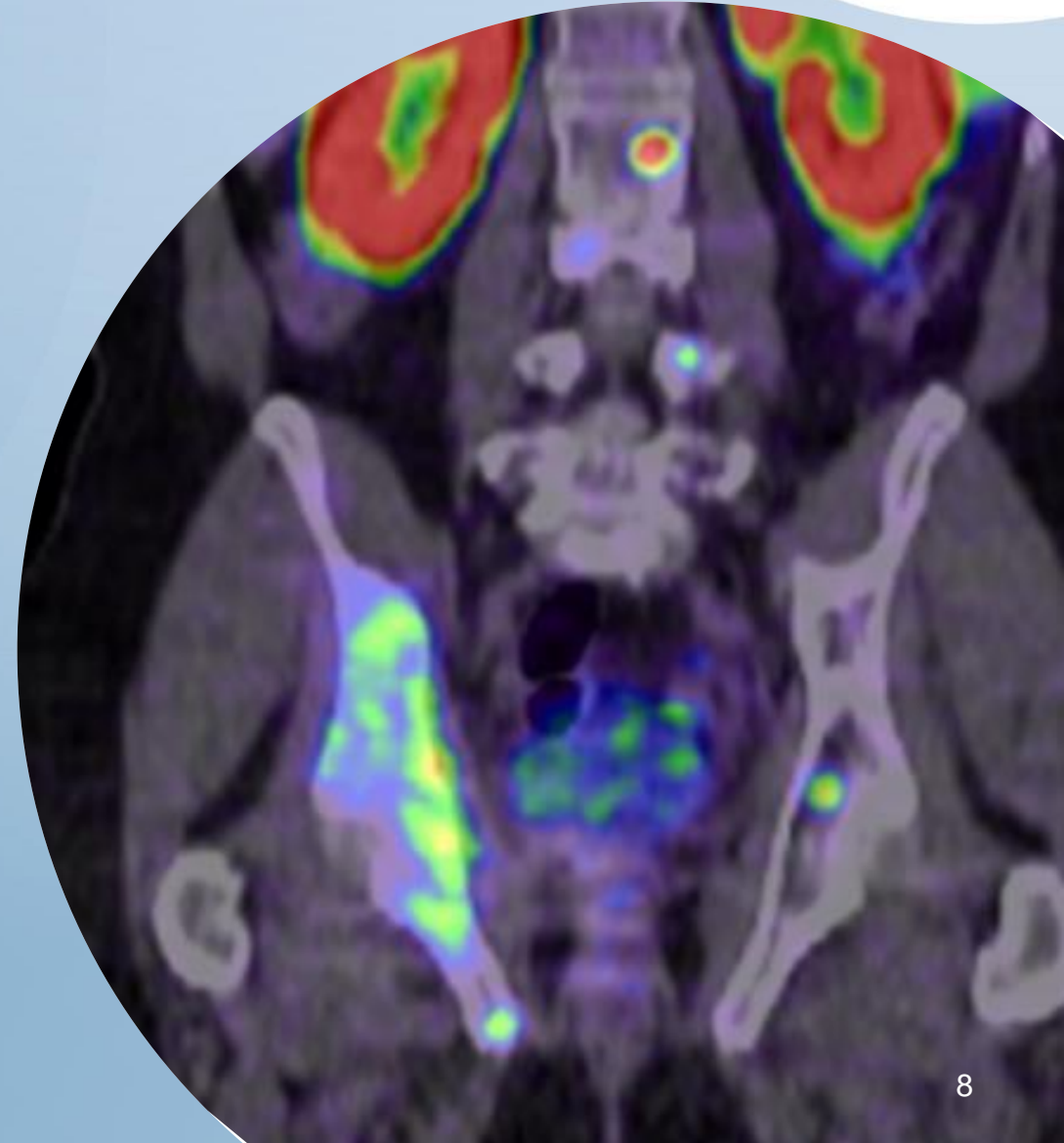


## Non-Executive Director

Mr. Oliver Buck

Oliver has served as founder and management of multiple companies in manufacturing, technology, pharmaceuticals and IT. He is the co-founder of ITM Isotopen Technologien München AG, a leading isotope manufacturing and distribution company

# Prostate Cancer Program





# Flagship product : TLX591-CDx (Illuccix<sup>®</sup>) prostate cancer imaging



## New Drug Application submitted to the US FDA in September 2020<sup>1</sup>

- NDA accepted for filing in December 2020, currently in review
- FDA mid-cycle review meeting occurred on the 2<sup>nd</sup> March 2020
- Late-cycle review meeting scheduled for mid-June
- No major issues identified following initial FDA assessment and no plan by FDA to conduct an advisory committee meeting
- Seeking an indication for the imaging of prostate cancer, from the early pre-treatment setting through to the later stages of advanced disease
- US commercial partners, including Cardinal Health and Pharmalogic provide access to ~95% of US hospital beds
- FDA approval expected second half of 2021<sup>2</sup>



1. United States Food and Drug Administration.

2. Subject to satisfying the necessary approval requirements.

## Marketing Authorisation Application submitted in April 2020

- Danish Medicines Agency serves as the reference Competent Authority for Telix's submission
- 14 EU member countries included in Telix's submission, including the 'EU5' (+UK)
- Broad indication for the imaging of recurrent prostate cancer
- Temporary authorisations in some EU member states are expected ahead of full MAA approval
  - ✓ Czech Republic authorised national (STP<sup>1</sup>) use of TLX591-CDx for a broad prostate cancer imaging indication (February 2021)
  - ✓ Other countries in progress
- Estimated EU MAA approval (country-by-country) commencing Q3 2021<sup>2</sup>



1. Specific Therapeutic Programme. <https://www.sukl.eu/pharmaceutical-industry/related-information>.

2. Subject to satisfying the necessary regulatory approvals.

# Regulatory Submissions for TLX591-CDx (Illuccix<sup>®</sup>) in Other Markets



Telix is working towards a global product launch<sup>1</sup>



- Granted Priority Review status by Australian TGA in December 2020<sup>2</sup>
- TGA submission accepted April 2021, with 150-day dossier review and approval



- New Drug Submission (NDS) filed with Health Canada in December 2020
- NDS accepted for review, anticipate Canadian approval with broad indication Q4 2021



- Swissmedic filing in progress
- Important jurisdiction for countries following EU/Swiss regulatory approvals



- Japanese 'bridging' study for TLX591-CDx has commenced at Kanazawa University
- Data facilitates planning discussions with PMDA for approval in Japan<sup>3</sup>

1. Subject to satisfying the necessary regulatory approvals in each jurisdiction.

2. Therapeutic Goods Administration.

3. Pharmaceutical and Medical Device Agency.

# For prostate cancer imaging with TLX591-CDx (Illuccix<sup>®</sup>) the total addressable market (TAM) is ~USD \$850m



Annual incidence of prostate cancer in Telix's US & EU markets <sup>(1)</sup>

478,000 <sup>(2)</sup>

Patients with prostate cancer eligible for PET imaging with TLX591-CDx (Illuccix<sup>®</sup>), 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

363,000

Total addressable market (TAM) value

USD \$850m <sup>(3)</sup>

1. Telix's markets = US + EU countries included in MAA submission to Danish Medicines Authority on 30<sup>th</sup> April 2020.  
2. GLOBOCAN 2020 reported incidence of prostate cancer in Telix's markets.  
3. US TAM value = USD \$575M, EU TAM value = USD \$275M.

# ProstACT Phase III trial of TLX591 for Treatment of mCRPC<sup>2</sup>



## PROSTACT

### Eligible patients

- mCRPC
- Expressing PSMA (defined by TLX591-CDx)
- Progressed despite prior therapy with NAAD<sup>3</sup>

TLX591 + standard of care therapy

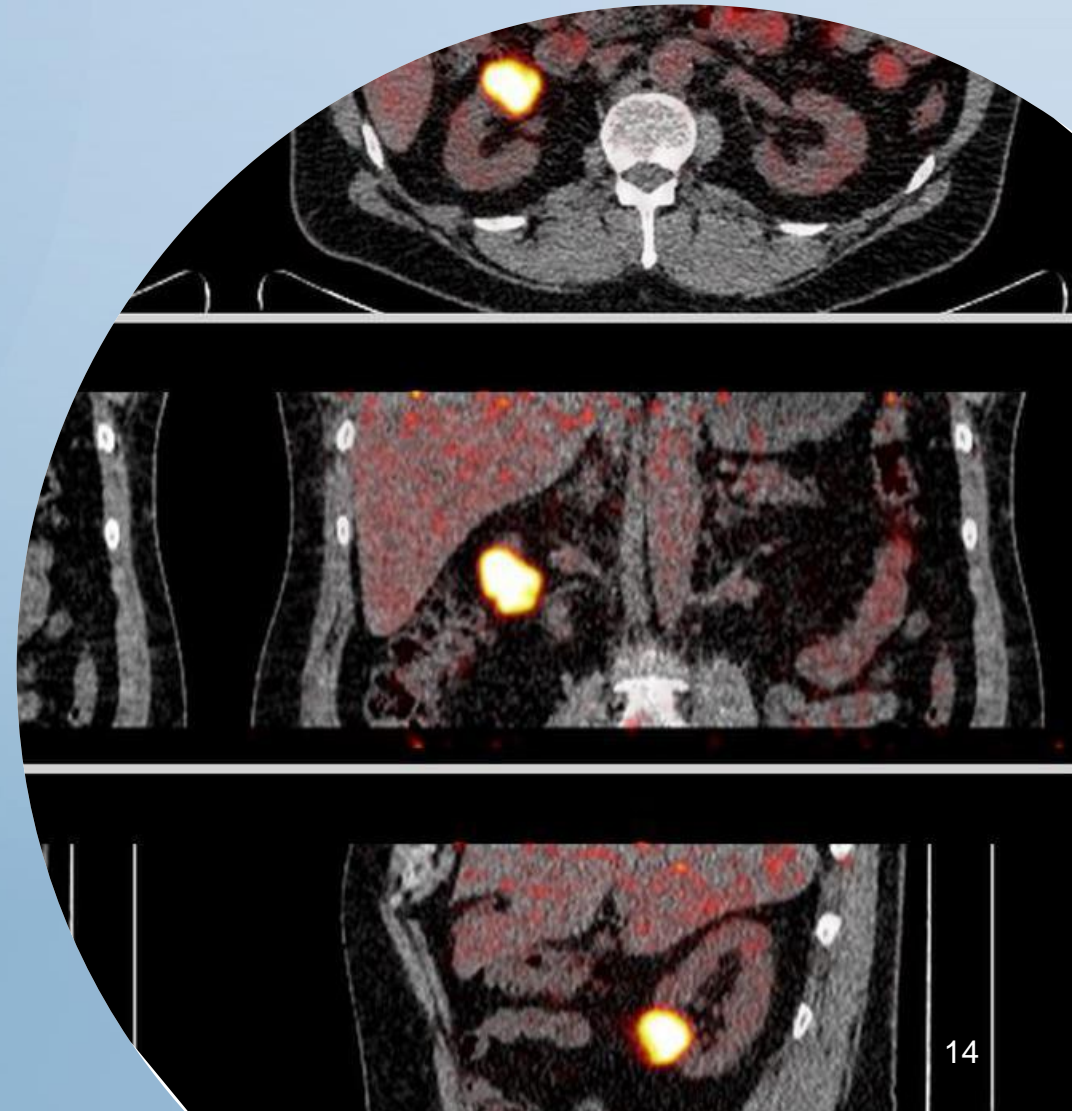
Standard of care therapy alone



- Pre-IND meeting with US FDA in November 2020 enabled ProstACT trial to be finalised<sup>4</sup>
  - ✓ International, multi-centre, Phase III RCT in ~390 patients with PSMA-expressing metastatic prostate cancer (mCRPC), experiencing disease progression following prior treatment with an anti-androgen drug (NAAD<sup>3</sup>)
  - ✓ **Primary endpoint:** radiographic progression-free survival
  - ✓ **Secondary endpoints include:** overall Survival, quality of life, safety<sup>5</sup>
  - ✓ 2:1 randomisation and enrichment of study population, patient selection with TLX591-CDx
- Anticipate initiation of ProstACT in Australia in Q2 2021 and progressively add EU and US sites during H2 2021, subject to satisfying the requisite approvals

1. Metastatic castration resistant prostate cancer.  
2. Novel androgen axis drug

# Renal Cancer Program



# ZIRCON Phase III Trial of TLX250-CDx for Imaging of ccRCC<sup>1</sup>



## ZIRCON

### Eligible patients

- Single indeterminate renal mass  $\leq 7$ cm diameter on CT or MRI suspicious for ccRCC<sup>(1)</sup>
- Scheduled for surgical removal as part of diagnostic plan

TLX250-CDx  
PET/CT scan

Surgical removal &  
histology as  
standard of truth



- International, multi-centre, Ph 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
- FDA approved Telix's IND in January 2020 to enable ZIRCON to be conducted in US (COVID-19 delays)
- FDA subsequently granted Breakthrough Therapy (BT) designation for TLX250-CDx in July
  - ✓ Facilitates closer interaction with FDA and expedited approval process
- 36 sites now participating, anticipate completion of patient recruitment mid-2021
  - ✓ US, Canada, Europe, Turkey, Australia
- Commence FDA approval process by year-end (2021)

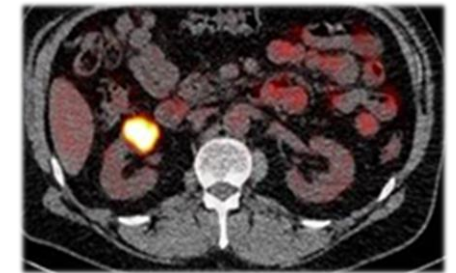
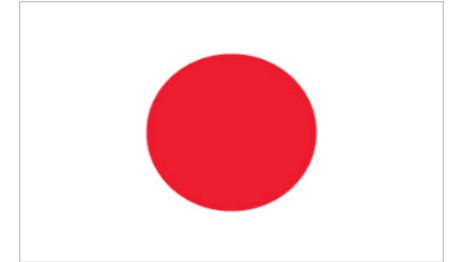
1. Clear cell renal cell carcinoma.

# ZIRDAC-JP Phase I/II Bridging Trial of TLX250-CDx in Japan



## ZIRDAC Zirconium Dosing and Comparison in Japan

- Japanese, multi-centre, Phase I/II trial in ~40 patients with an indeterminate renal mass suspicious for ccRCC
- Primary endpoints
  - ✓ Phase I – Safety and tolerability
  - ✓ Phase II – 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
- Design aligned with global Phase III ZIRCON trial
- Carefully designed in consultation with Japanese PMDA<sup>1</sup> to potentially bridge to the ZIRCON trial
- Pk/Pd<sup>2</sup> Phase I in 6 patients completed – study met all objectives
- Phase II in planning, potential to include Chinese patients to expand Asian utility<sup>3</sup>



1. Pharmaceutical and Medical Devices Agency.  
2. Pharmacokinetics / pharmacodynamics.

3. Subject to satisfying the necessary regulatory approvals.

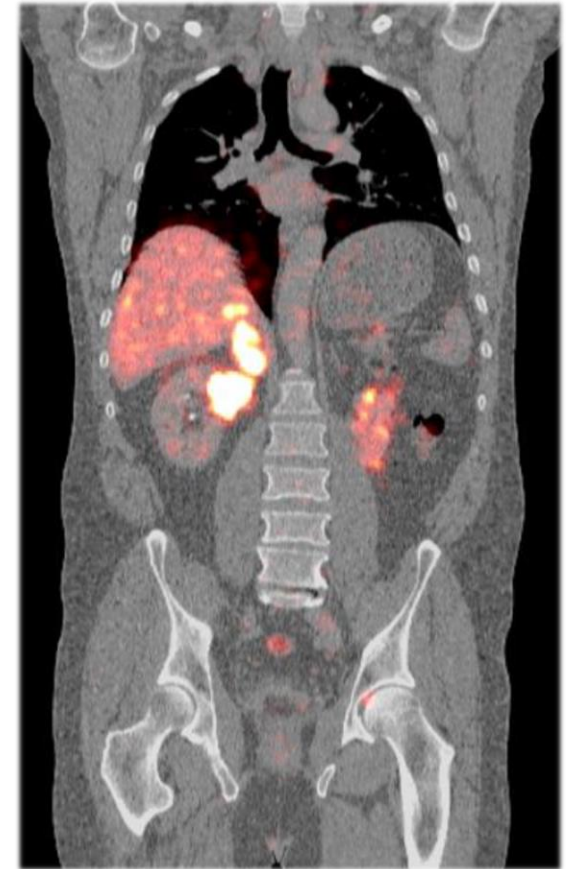


# STARLITE Phase II Trial of TLX250 for Treatment of ccRCC



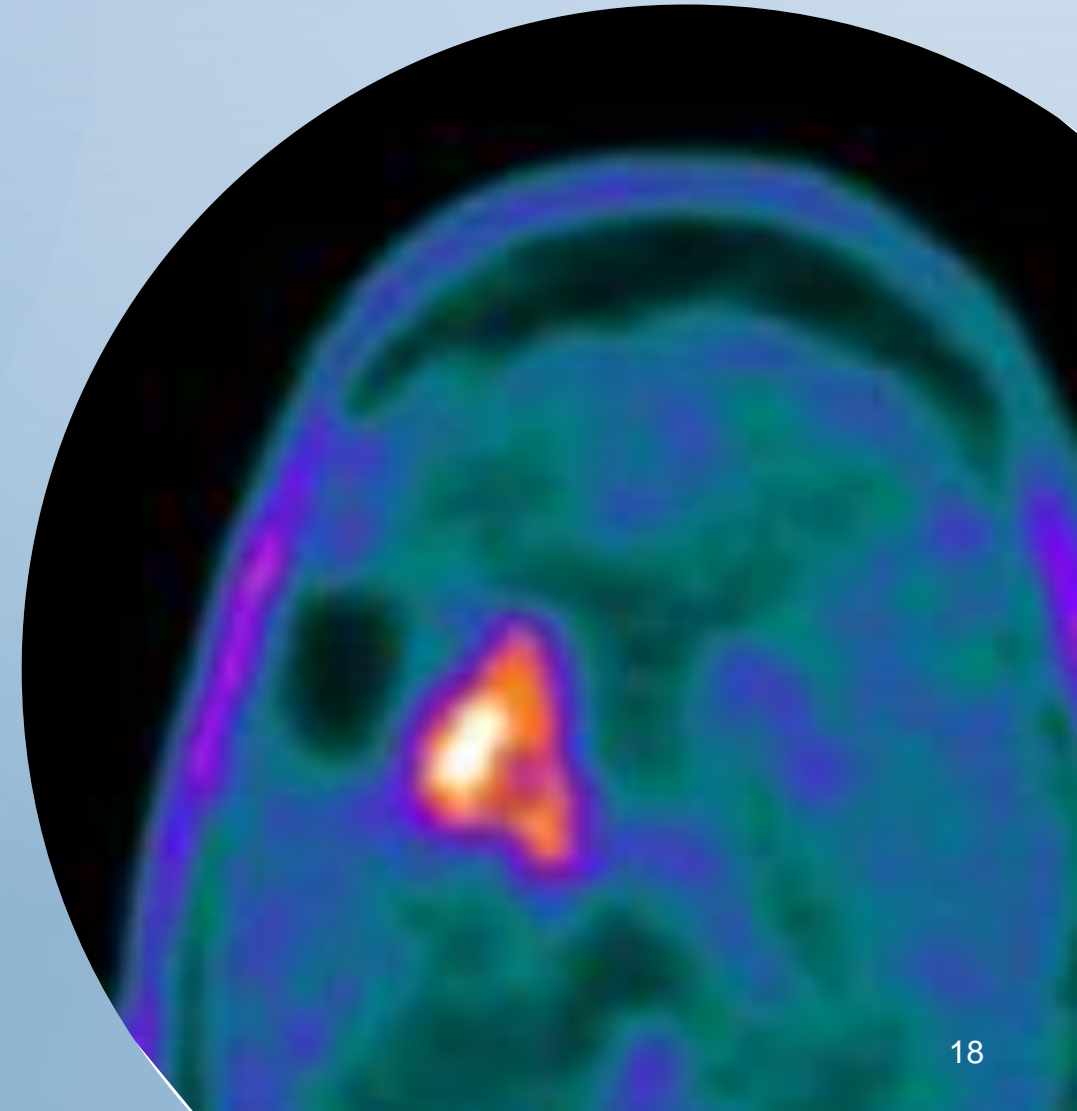
## STARLITE<sup>★</sup> TLX250 in combination with immunotherapy

- Phase II trial of TLX250 plus nivolumab in ~30 patients with ccRCC who have progressed following prior immunotherapy
- Primary endpoint
  - ✓ To determine the efficacy of combination therapy with <sup>177</sup>Lu-girentuximab (TLX250) as assessed by objective response rate
- STARLITE program intended to be conducted at two US institutions was significantly impacted by COVID-19 and diversion of clinical research personnel away from usual research activities
- FDA Investigational New Drug Application (IND) filing in progress
- Patient recruitment expected to commence May 2021<sup>1</sup>



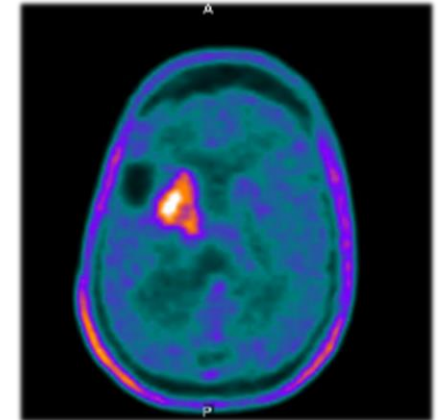
1. Subject to satisfying the necessary regulatory approvals.

# Glioblastoma Program

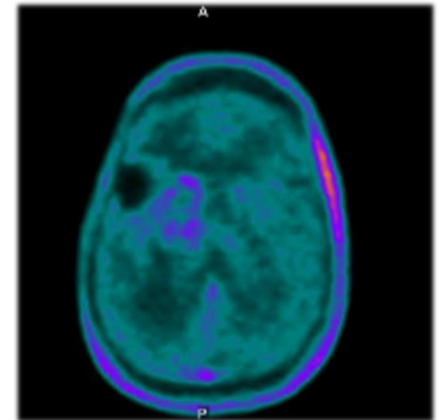


## IPAX-1 TLX101 in combination with EBRT<sup>2</sup>

- Multi-centre Phase I/II trial of TLX101 in combination with EBRT in up to 44 patients with recurrent GBM
  - ✓ **Primary endpoint:** Safety and tolerability
  - ✓ **Secondary endpoints include:** MTD<sup>3</sup>, efficacy, dosimetry
- Promising initial data from lowest dose cohorts presented in Dec 2020
  - ✓ Initial treatment cohort, treated in single and triple fractions
  - ✓ Treatment well tolerated, predominantly grade 1 – 2 adverse events
  - ✓ Clear evidence of anti-tumour effect from both imaging and clinical assessment
- Intend to accelerate dosing to determine optimal dose, to support consultation with regulatory authorities and pivotal trial design
  - ✓ Expand TLX101 program to US patients, IND in preparation



Baseline PET scan



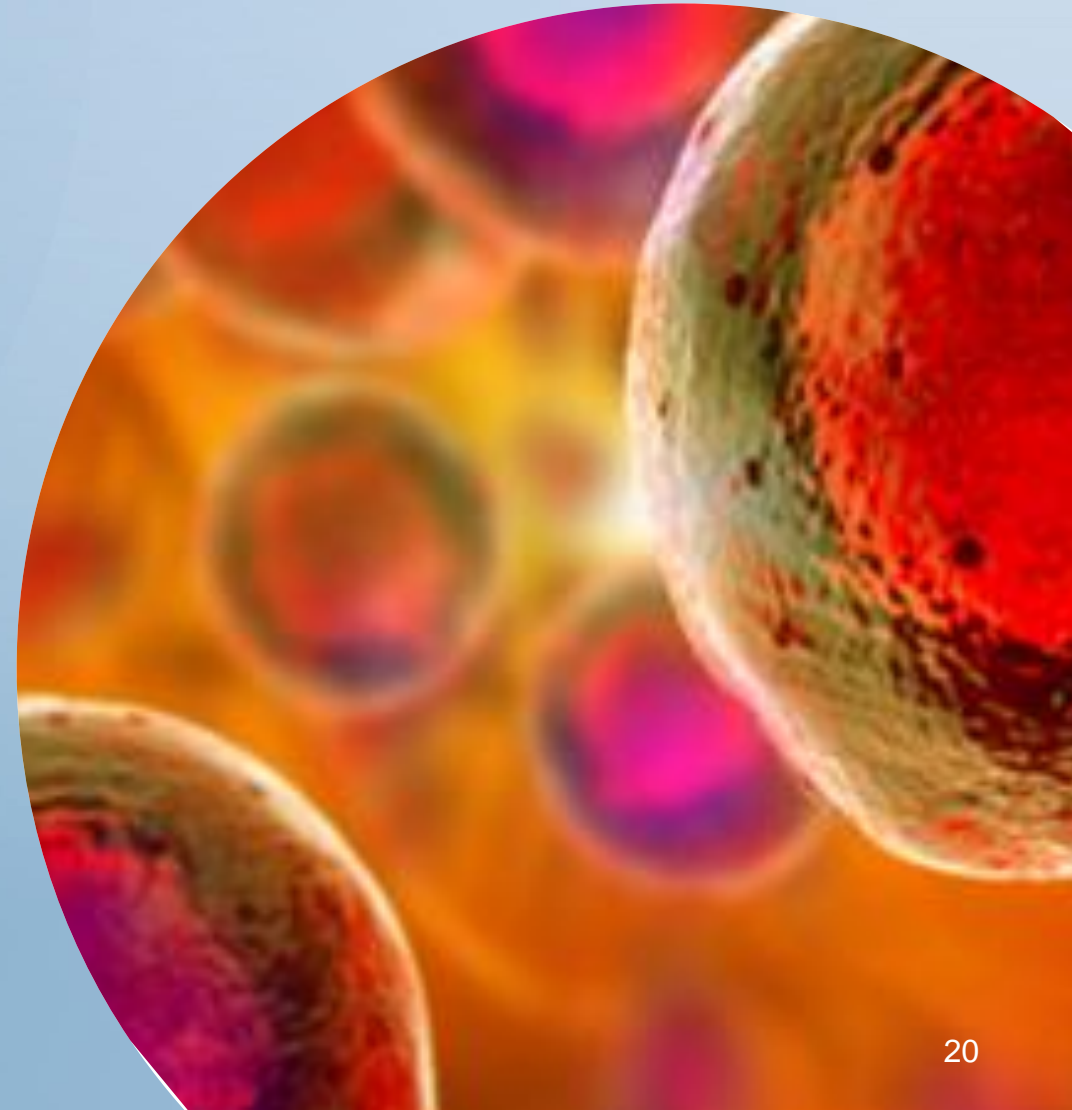
Day 45 PET scan post TLX101 therapy

1. Glioblastoma Multiforme.

2. External beam radiation therapy.

3. Maximum tolerated dose.

# Bone Marrow Conditioning / Rare Diseases Program



## Targeted Radiotherapy for Amyloid Light Chain Amyloidosis (TRALA)<sup>2</sup>

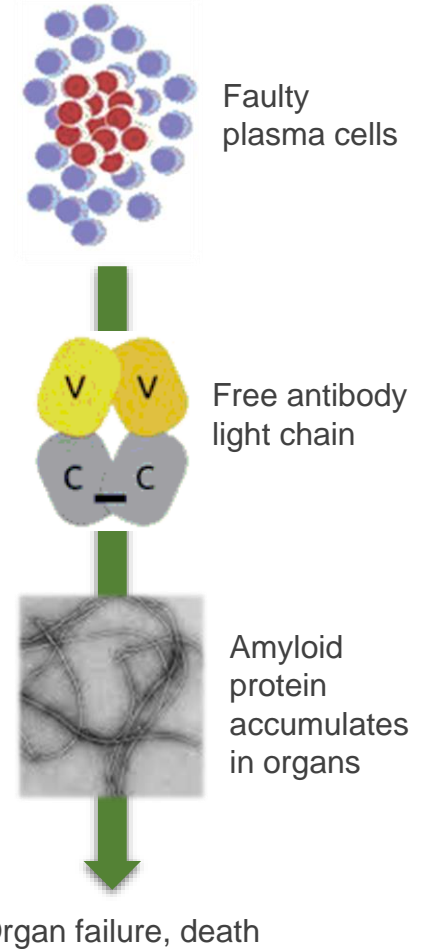
### • SALA

- ✓ Rare disease with a poor prognosis (median survival ~11 months if untreated)
- ✓ Plasma cells in the bone marrow produce abnormal protein called 'amyloid' which accumulates in the organs and causes them to fail
- ✓ Prevalence of ~30,000 (US) and 45,000 (EU) patients, ~US\$600M TAM<sup>3</sup> in US and 'EU5'

- Current standard of care comprises induction therapy (cyclophosphamide, bortezomib, dexamethasone) plus high dose melphalan BMC<sup>4</sup>, followed by HSCT<sup>5, 6</sup>

### • TRALA study

- ✓ **Primary endpoint:** Safety and toxicity of <sup>90</sup>Y-besilesomab as the sole BMC regime for autologous HSCT in patients with SALA
- ✓ Study complete, data readout in the next few weeks



1. Systemic amyloid light chain amyloidosis.

2. <https://www.clinicaltrialsregister.eu/ctr-search/trial/2015-002231-18/GB>

3. Total addressable market.

4. Bone marrow conditioning.

5. Hematopoietic stem cell transplant.

6. Venner C, et al. *Blood*. (2012) 119 (19): 4387–4390.

# Looking Ahead



# Catalysts : Three Major Value Events in 2021

## Commence ProstACT

**PROSTACT**

Commence Phase III therapy trial  
Australia initially (H1)  
EU and US (H2)

## Complete ZIRCON

 **ZIRCON**

Complete Phase III trial  
BLA<sup>(1)</sup> preparation  
Second commercial product

## Launch Illuccix<sup>®</sup>



Regulatory approval  
Commercial launch  
First commercial revenue

## Stakeholder Focus:

*Become patient centric in everything we do. Become a revenue generating company.*

1. Biologic license application.



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