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Precision Oncology See it. Treat it.

Onvestor Presentation

November 2021

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Telix's lead product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been approved by the Australian Therapeutic Goods Administration (TGA), and accepted for filing by the U.S. Food and Drug Administration (FDA). Telix is also progressing marketing authorisation applications for Illuccix in the European Union and Canada. With the exception of Illuccix in Australia and Scintimun®, none of Telix's products have received a marketing authorisation in any jurisdiction.

An established global leader in radiopharmaceuticals





Extensive portfolio of diagnostic and therapeutic assets with compelling clinical data

12,150 patient doses in past 12 months¹

1 st marketing authorisation approval for TLX591-CDx (Illuccix[®]) received²

17 active clinical trials (7 indications)³

Leading supply chain and distribution network

80 countries in the Telix distribution network

1 countries with a manufacturing footprint



1. Clinical trial doses and magisterial / compassionate use of TLX591-CDx. 12 months from Q4 2020

2. Therapeutic Goods Administration (TGA) Australia – ASX 2/11/21 3. Includes partnered investigator-led studies.

Telix Pharmaceuticals Limited (ASX: TLX)

Our strategy: See It. Treat it. Personalised, precision medicine





Telix Pharmaceuticals Limited (ASX: TLX)

Radiation has never been more important in cancer care Underpinned by the shift from radiation "in a box" to radiation "in a shot"



- Synergy between imaging and therapy Broad cancer utility
- Potential to enhance existing drug classes (androgens, taxanes etc)
- A vitally important "primer" for immuno-oncology
 - A future cornerstone modality for gene/cell therapy conditioning



Telix is driving the integration of nuclear medicine and medical oncology with more targeted and personalised therapy and patient-friendly dosing regimens

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Telix is pioneering a new cancer modality





Kidney Cancer

| Ph | Name | Asset | Dx/Tx |
|------|------------------|------------|-------|
| | | TLX250-CDx | Dx |
| 1/11 | ZIRDAC | TLX250-CDx | Dx |
| | STARLITE-1 (IIT) | TLX250 | Тx |
| 11 | STARLITE-2 (IIT) | TLX250 | Тx |

Prostate Cancer

| Ph | Name | Asset | Dx/Tx |
|------|-------------------------------------|------------|-------|
| | University of Linz (IIT) | TLX591-CDx | Dx |
| II | Emory University (IIT) | TLX591-CDx | Dx |
| II | Enzalutamide-Enhanced Imaging (IIT) | TLX591-CDx | Dx |
| II | Mem. Sloan Kettering (IIT) | TLX591-CDx | Dx |
| N/A* | | TLX599-CDx | Dx |
| | PROSTACT | TLX591 | Тx |
| Ι | CUPID | TLX592 | Тх |

*Registry study

Core pipeline: 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-1 | 1, Illuccix®) | | Imaging |
| | Antibody | PSMA | ¹⁷⁷ Lu | TLX591 (¹⁷⁷ Lu–rosopatamak |) | | 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 |
| 615 | Small molecule | PSMA | ⁶⁸ Ga | TLX591-Sx (68Ga-PSMA-IRI | Dye) | | Imaging/ Surgery |
| Kidney | Antibody | CA9 ⁽²⁾ | ⁸⁹ Zr | TLX250-CDx (⁸⁹ Zr–girentuxi | mab) | | Imaging |
| Kid | Antibody | CA9 | ¹⁷⁷ Lu | TLX250 (177Lu–girentuximat | | | Therapy |
| Brain | Small molecule | LAT-1 ⁽³⁾ | ¹⁸ F | TLX101-CDx (¹⁸ F-FET) | | • | Imaging |
| | Small molecule | LAT-1 | 131 | TLX101(¹³¹ I-IPA) | | | Therapy |
| BMC/RD ⁽⁴⁾ | Antibody | CD66 ⁽⁵⁾ | ^{99m} Tc | TLX66-CDx (^{99m} Tc-besilesor | nab, Scintimun®) | | Imaging |
| | Antibody | CD66 | ⁹⁰ Y | TLX66 (⁹⁰ Y-besilesomab) | | | Therapy |
| Shadeo | Shaded arrows indicate completion expectations in the next 12 months. *Registry study | | | | | | |

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.

Telix Pharmaceuticals Limited (ASX: TLX)

Strategic Priorities



Use Illuccix as a commercial launchpad

Create a high-value diagnostic portfolio

Deliver on commercial value of therapeutics

Expand the pipeline

Establish Telix's leadership in the urologic oncology domain

Kidney cancer imaging agent addresses major unmet need, builds on Illuccix engagement Advance late-stage assets in the core pipeline that benefit from diagnostic market entrance Novel targets, clinical applications and manufacturing technologies

Near-term objectives Unlocking the value in our pipeline





2022

Illuccix commercial rollout Establish a leading presence in the urologic oncology domain

Regulatory filing for kidney cancer imaging product to follow-on Illuccix

Advance late-stage therapeutic portfolio to address significant unmet medical needs

Patient-centered Billuccix® Imaging Ready to launch

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Illuccix[®] approval and rollout milestones US FDA PDUFA¹ goal date 23 December 2021





1. United States Food and Drug Administration (FDA) Prescription Drug User Fee Act, Goal Date

2. Healthcare Common Procedure Coding System

Telix Pharmaceuticals Limited (ASX: TLX)

Illuccix (TLX591-CDx) PSMA-PET¹ imaging A differentiated offering in the PSMA-PET market



Access to ~90% of eligible PET sites

On-demand pharmacy-based production with a high yield product

Customer and patient scheduling flexibility



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

1. Prostate-specific membrane antigen (PSMA) Positron emission tomography (PET)

PSMA-PET imaging emerging as standard of care in prostate cancer Inclusion in guidelines are driving clinical adoption and reimbursement



- Updated National Comprehensive Cancer Network Guidelines® include Ga-68 PSMA-11 PET/CT to be considered as an alternative to standard imaging of bone and soft tissue¹
 - Conventional imaging no longer a necessary prerequisite to PSMA-PET
 - Expanded indication: detection of unfavourable intermediate, high and very high risk as well as recurrent prostate cancer

Society of Nuclear Medicine and Molecular Imaging (<u>SNMMI</u>) updated Appropriate Use Criteria (<u>AUC</u>) recognises higher accuracy in the initial staging evaluation²

Two of the four main Radiology Benefit Managers (RBMs) - AIM Specialty Health³ and NIA Magellan⁴ – are now recommending PSMA-PET representing a significant portion of commercial payor (health insurance) reimbursement policies

NCCN® Prostate Cancer Guidelines Update, Version 1.2022 – 10/09/21 SNMMI AUC for PSMA-PET Imaging: <u>https://www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber=38657</u> AIM Clinical Appropriateness Guidelines, Advanced Imaging. AUC: Oncologic Imaging (Effective 7/11/21). National Imaging Associates Magellan Clinical Guidelines For Medical Necessity Review, Advanced Imaging Guideline (Effective 01/01/22)









Market opportunity expanded Due to growing incidence rates and guideline inclusions





The NOBLE Registry (TLX599-CDx): Nobody left behind Improving access to PSMA imaging



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- Collaboration to investigate utility of ^{99m}Tc-iPSMA SPECT¹ imaging in prostate cancer
- Global consortium of clinical sites and investigators with experience using ^{99m}Tc-iPSMA
- Geographic focus on developing markets or remote regions where access to PET imaging is limited²
- Isotope (99Tc) supply chain well established and inexpensive
- Rapid expansion planned including APAC

Telix Pharmaceuticals Limited (ASX: TLX)

 Single photon emission computed tomography 2. Worldwide SPECT cameras outnumber PET by 4:1 (MEDraysintell 2020)

Dr. Batool Albaloosh Chair Ambassador | UAE **Dr. Akintunde** Orunmuvi Nigeria Dr. Ivan E. Diaz Meneses Dr. Yehia Omar Ambassador | Mexico Ambassador | Equp Dr. Mike Sathekge South Africa MRC GAUTENG PROVINC مركز مصر للأشعة MISR RADIOLOGY





Peter Tually Australia

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ZIRCON STARLITE

Kidney cancer program A clinical leadership opportunity in diagnostics and therapy



Building a high-value diagnostics portfolio "Breakthrough Therapy" designation, clinical leadership opportunity

TLX250-CDx is an investigational product being developed for the imaging of clear cell renal cell carcinoma (ccRCC) with PET/CT

- Current options for patients are limited, potential for clinical leadership with a non-invasive imaging modality for ccRCC
- Being studied as an imaging agent assessing ability to determine if "indeterminate renal masses" are malignant through improved, whole of body imaging



May aid decision making and avoids unnecessary surgical intervention

Biologics License Application (BLA) consultation process to commence by end-year 2021

Opportunity to follow prostate cancer imaging, with a second high-value product for the genitourinary (GU) oncology field

An example of PET/CT imaging showing the uptake of ⁸⁹Zr-girentuximab in a primary renal mass. The insert shows the identification of a metastatic lesion of the proximal radius, confirmed as ccRCC upon biopsy¹.

1. Hekman et al, European Urology (2018).

ZIRCON Phase III trial of TLX250-CDx for imaging of ccRCC **Study overview**

TLX250-CDx

PET/CT scan



Surgical removal

& histology as

standard of truth

ZIRCON **Eligible Patients** Single indeterminate renal mass ≤7cm diameter on CT or MRI suspicious for ccRCC Scheduled for surgical removal as part of management plan 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 \checkmark 75% recruited, progressing well towards completion ✓ 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 Telix Pharmaceuticals Limited (ASX: TLX)

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



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



Telix Pharmaceuticals Limited (ASX: TLX)

Total addressable market value in US

at US\$3-400M

and Europe estimated

Potential for market

limited patient options

leadership, given

Addresses a major unmet medical need

CA9¹ is an exciting target



New understanding leads to potential for applications beyond kidney cancer

A transmembrane protein and a tumor-associated carbonic anhydrase isoenzyme Over-expressed in mutated ccRCC

- and many hypoxic solid tumors, with low expression in most normal tissue
- High expression includes cervix, esophagus, lung, breast, colon, brain, and vulval cancers
- Imaging is being used to "indication scout" for future therapy applications

| Potentia | Status | |
|----------|-------------------------------|-------------|
| | Bladder or Urothelial Cancer | Commenced |
| Fi | Triple Negative Breast Cancer | Commenced |
| (HE) | Lung Cancer | In planning |
| | Ovarian Cancer | In planning |
| | Colorectal Cancer | In planning |
| | Head and Neck Cancer | In planning |
| E) | Pancreatic Cancer | In planning |



Phase II trial of TLX250 plus nivolumab in with ccRCC who have progressed following prior immunotherapy

- Evaluates TLX250-delivered radiation as an immune system "primer"
 - ✓ Targets carbonic anhydrase IX (CA9)¹ a protein highly expressed in patients that are likely to demonstrate a more limited response to cancer immunotherapy

Primary endpoint

✓ To determine the safety and efficacy of combination therapy with 177Lugirentuximab (TLX250) as assessed by the number of tumours responding to the Telix therapy versus the current standard of care alone

FDA Investigational New Drug Application (IND) accepted for STARLITE 2 study, being undertaken at Memorial Sloan Kettering Cancer Centre

Additional Phase II study – STARLITE 1 - (first-line combination study) to be initiated at a second US site (submission in progress)

1. Giatromanolaki et al. British Journal of Cancer. 2020.



CA9 expression is correlated with the presence of tumour-infiltrating lymphocytes, which may confer resistance to immunotherapy.²

>PROSTACT

Prostate cancer therapy Our vision for prostate cancer

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ProstACT program overview Multiple opportunities to deliver insights into TLX591



Radiogenomics study

- ~50 patients
- First line mCRPC
- Rapid recruitment



Treat the scan Correlation between imaging and therapy to optimise patient selection

Combination with EBRT in oligometastatic early recurrence (Phase II)

- ~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 • 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 (Ph III) – Multiple data read-outs throughout the ProstACT program duration

ProstACT GLOBAL Ph III trial of TLX591 for the treatment of mCRPC² Study overview



PROST ACT



- 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 (NAAD¹)
- Primary endpoint: radiographic progression-free survival
- Secondary endpoints include: overall survival, quality of life, safety
- 2:1 randomisation and enrichment of study population, patient selection with TLX591-CDx
- ProstACT has been initiated in Australia and will add EU, US and potentially Chinese sites over the next six months, subject to satisfying the requisite regulator approvals

TLX591 differentiation Antibody vs small molecule



| | Efficacy• | Significantly improved overall survival in a comparable end-stage patient population 40+ months vs. 15.3 months ^{1,2} | | |
|---|-----------------|--|--|--|
| | Patient comfort | Reduced potential for undesirable side-effects; dry eye, xerostomia (salivary gland ablation), back pain (ganglia irradiation) | | |
| | Patient-centric | Short treatment duration/significantly fewer hospital visits – two weeks total vs. 36 weeks, supports close supervision by medical oncology | | |
| | Cost effective | Reduced ¹⁷⁷ Lu isotope requirement via more targeted dosing/less waste COGS ~1/5 of competition, expected to also be available in "cold kit" format ³ | | |
| Tagawa et al, Cancer 2019. Cross-trial comparison, randomised controlled trial (RCT) required for verification. Modelled from publicly available information. | | | | |

TLX591 patient experience Off-target irradiation – quality of life matters





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

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- Xerostomia
- Back pain from ganglia irradiation

Data courtesy of Prof. Neil Bander, WCMC.



Our long-term vision for prostate cancer Improving access, imaging and treatment options for patients

Further development of the PSMA target underpins our lifecycle management strategy for prostate cancer and vision to improve patient outcomes

PSMA pipeline includes imaging, therapy and surgical tools

- NOBLE Registry (PSMA-SPECT tracer): TLX599-CDx (^{99m}Tc-iPSMA) – PSMA imaging access for patients in developing and remote areas, where PET is not readily available
- Next-generation alpha therapy: TLX592 (225Ac-RADmAb®) – high potency, complementary to TLX591
- Image guided surgery: TLX591-Sx (⁶⁸Ga-PSMA-IRDye) dual-labelled PET-optical tracer for image guided surgery, enables real-time cancer detection¹

1. Imaging and Robotics in Surgery Alliance with Mauna Kea Technologies.

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



PROSTACT

CUPID

Symptomatic

Castration-resistant

Radiogenomics and

tumour targeting of

androgen agents

Second line +

Pivotal Phase III study in patients with

mCRPC progressing on 1st line novel

Clinical trial

TLX591

PSMA-617 failures



Rare diseases program High potential, high impact

IPAX-I Phase I/II trial of TLX101 for the treatment of GBM¹ TLX101 in combination with EBRT²

- Multi-centre Phase I/II trial of TLX101 in combination with EBRT in patients with recurrent GBM
 - ✓ Primary endpoint: Safety and tolerability
 - ✓ Secondary endpoints include: MTD³, efficacy, dosimetry

First-peer review data presented at Congress of Neurological Surgeons (CNS) Annual Meeting in October 2021

- ✓ All patients evaluated received similar total activity dose of ~2GBq (2000 MBq) of TLX101, either in a single administration or a triple-fractionated regime.
- ✓ Treatment well tolerated, typically grade 1 2 adverse events
- ✓ Evidence of anti-tumour effect from both imaging and clinical assessment
- ✓ Overall survival (OS) on this interim analysis shows median 15.97 months to date, with three patients exhibiting stable disease at day 135 and two with stable disease at day 180
- ✓ 6/ 10 patients still alive and will be followed until 1 year after dosing for the final OS calculation (May 2022).

Baseline PET scan



Day 45 PET scan post TLX101 therapy

3. Maximum tolerated dose. Telix Pharmaceuticals Limited (ASX: TLX)

Glioblastoma Multiforme. External beam radiation therapy.





Follow on study IPAX-2 in planning

Evaluating the potential of TLX101 in newly-diagnosed patients

- Initial dose finding study TLX101 plus standard of care (SOC) in patients with newly diagnosed glioblastoma, after surgery
- Evaluates the potential for "DNA damage" from targeted radiation using TLX101 to enhance SOC chemotherapy for newly diagnosed glioma

Study objectives expected to include:

- ✓ Maximum tolerated dose
- ✓ Safety and tolerability in combination with the Stupp regimen (SOC)
- ✓ 12 months overall survival
- \checkmark Progression free survival at a range of treatment intervals
- Single-arm, multi-centre trial, expected to enrol 12-15 patients
- Patients to be treated and monitored for up to 64 weeks

Study protocol in final stages of design, IND / ethics approval submissions expected in late 2021 / early 2022



New hope in a rare disease Progressing development of TLX66 in bone marrow conditioning

- SALA¹ is a 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 to 45,000 (US + EU combined) patients, ~US\$600M TAM³ in US and 'EU5'
- Current standard of care comprises induction therapy (cyclophosphamide, bortezomib, dexamethasone) plus high dose melphalan BMC⁴, followed by HSCT^{5, 6}
- A novel monoclonal antibody, daratumumab has potential as an initial therapy for patients but is not curative or suitable for all patient populations.
- TRALA study: Phase I trial of ⁹⁰Y-besilesomab (TLX66) in SALA
- Primary endpoint: Safety and toxicity of ⁹⁰Y-besilesomab as the sole BMC regimen for autologous HSCT in patients with SALA
- Study complete, preliminary data (9 pts) demonstrated 100% engraftment and high PR/CR rate (5/2) survival data. Regulator consultation in progress for next phase of development

Systemic amyloid light chain amyloidosis.
 <u>https://www.clinicaltrialsregister.eu/ctr-search/trial/2015-002231-18/GB</u>
 Total addressable market.

Bone marrow conditioning.
 Hematopoietic stem cell transplant.
 Venner C, et al. *Blood.* (2012) 119 (19): 4387–4390.





Organ failure, death

Future value creation Focus on innovation and growth markets

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Near-term growth opportunities Expansion into new geographic markets



Launch Illuccix with distribution partner (in progress) NOBLE Registry expansion National Evidence-based Healthcare Collaborating Agency. Health Technology Assessment. Telix Pharmaceuticals Limited (ASX: TLX)

- China Grand Pharma partnership
- NMPA consultations have commenced (Mainland China)
- Regulatory filings for Illuccix Q1 2022 (Taiwan, Hong Kong)

- Largest Asia Pacific market
 opportunity
- Key bridging clinical trials have been successfully completed (TLX591-CDx & TLX250-CDx)
- DuChemBio partnership
 - NECA HTA¹ completed
- Illuccix kit sales have commenced, pursuing reimbursement



Buildout of the Brussels (Seneffe) manufacturing facility Vertical integration in Europe

- Seneffe will serve as the primary EU manufacturing site for Telix's products
 - ✓ Will also be used manufacture 131I-based products for export (i.e. TLX101) using Belgian-sourced isotopes (Belgium is a major global supplier)
 - \checkmark One of the deepest isotope production licences in Europe
 - ✓ Provides certainty / control over supply chain

Seneffe will be an integral part of Telix's EU R&D capability

Allows us to capture the IP that is intrinsic in manufacturing scale-up of this class of drugs

- ✓ Buildout has commenced
- ✓ First cyclotron removed October 2021, second scheduled for November 2021
- ✓ Removed in one piece, with the aim to recycle as much material as possible

Build of two new cyclotrons to commence in early 2022



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Future research and innovation focus





Near-Term Catalysts



Calendar Q4 2021

- Illuccix EU "clock stop" for final review (end-Nov)
- Illuccix US FDA decision (PDUFA goal date 23 Dec 2021)
- Distributors finalised for EU product launch
- First ProstACT patients
- STARLITE 1/2 trials active (FDA IND approval) and recruiting

Calendar Q1 2022

- Illuccix EU marketing authorisation decision
- HCPCS reimbursement submission for Illuccix in the US (Jan)
- ZIRCON trial enrolment completed
- IPAX-2 study launched (glioblastoma)
- US, AU Illuccix product launch

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