TELIX PHARMACEUTICALS

Precision Oncology
See it. Treat it.

Telix Pharmaceuticals Limited

Bell Potter Healthcare Conference

10th November 2021

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Telix: A global leader in radiopharmaceuticals

Extensive portfolio of diagnostic and therapeutic assets

11,000 patient doses in past 12 months[1]

1st marketing authorisation received[2]

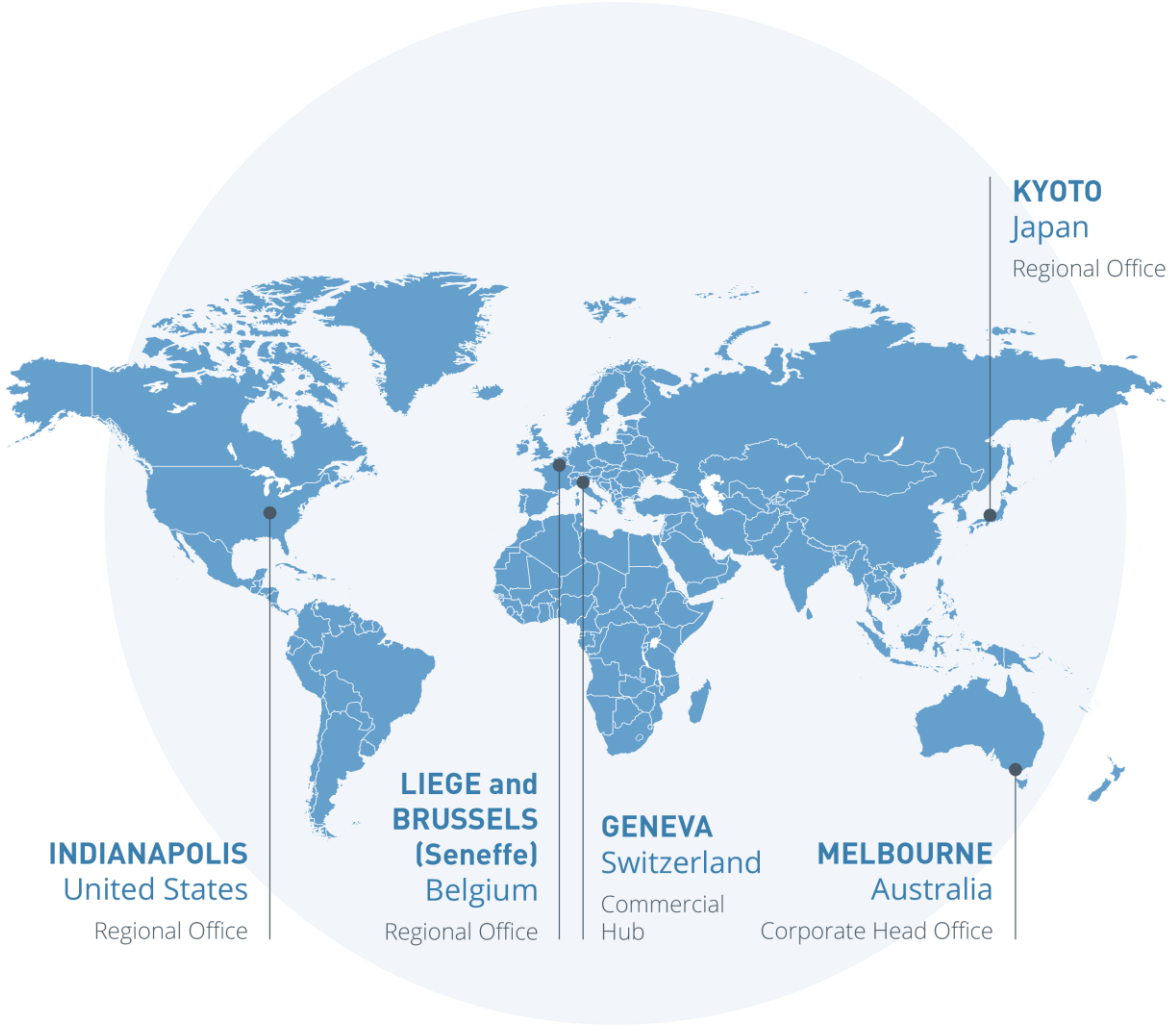
16 countries with a marketing authorisation for TLX591-CDx in progress

17 active clinical trials (7 indications)[3]

Leading supply chain and distribution network

80 countries in the Telix distribution network

11 countries with a manufacturing footprint

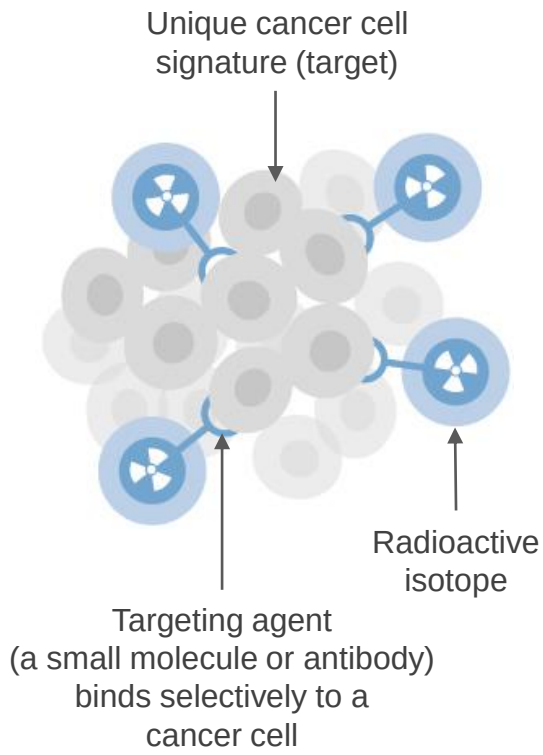


1. Clinical trial doses and magisterial / compassionate use of TLX591-CDx. 12 months from Q4 2020
2. Therapeutic Goods Administration (TGA) Australia for Illuccix® – ASX 2/11/21
3. Includes partnered investigator-led studies.

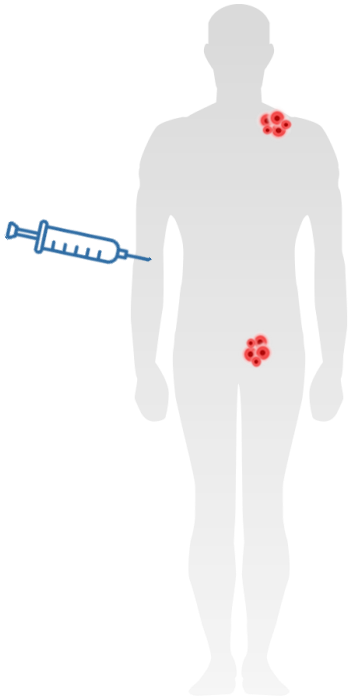
Our strategy: *See It. Treat it.*

Personalised, precision medicine

Targeted radiation delivery



Systemically administered



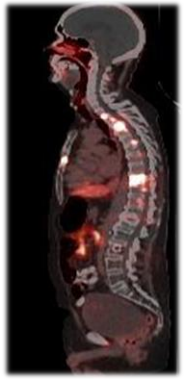
Imaging

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

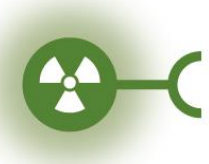
Enables **PET images** of cancer

PET scanner

TLX591-CDx[1]
(Prostate cancer)



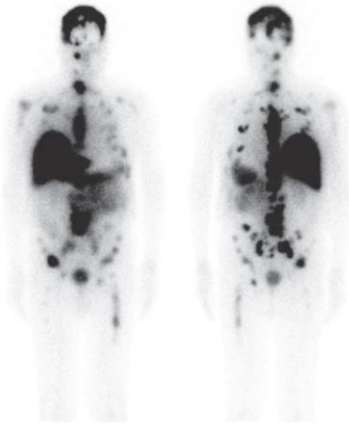
Therapy



^{177}Lu, ^{131}I, ^{225}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.

Strategic Priorities

Use Illuccix® as a commercial launchpad

Establish Telix's leadership in the urologic oncology domain

Create a high-value diagnostic portfolio

Kidney cancer imaging agent addresses major unmet need, builds on Illuccix® engagement

Deliver on commercial value of therapeutics

Advance late-stage assets in the core pipeline that benefit from diagnostic market entrance

Expand the pipeline

Build our "IP" reserves in novel targets, clinical applications and manufacturing technologies

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 (2nd 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.

POWERED BY ^{68}Ga

Accessible

Flexible

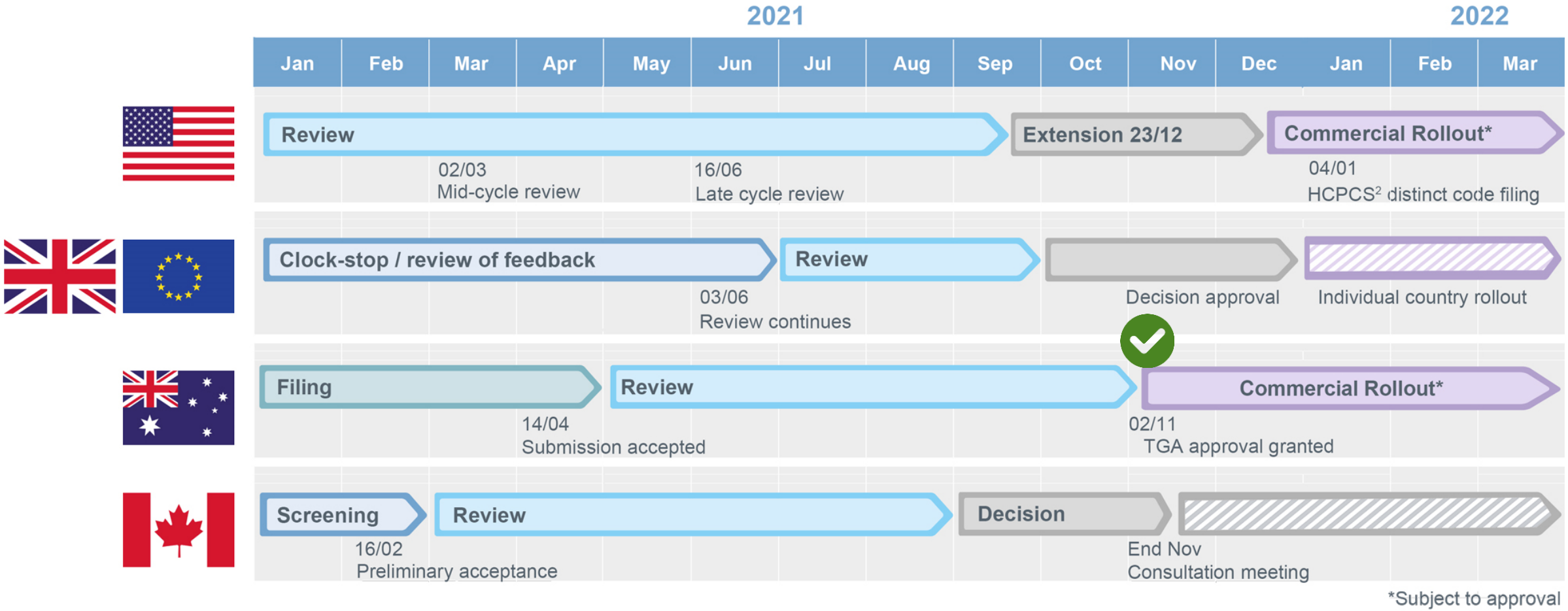
Patient-centered

Illuccix® Imaging

Ready to launch

Illuccix® approval and rollout milestones

US FDA PDUFA[1] 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

Planned US Illuccix® roll-out : The gallium wave

www.galliumwave.com

- **Access** to ~90% eligible PET sites
- **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 ^{68}Ga-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)

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 tissue[1]
  - ✓ 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 (SNMMI) updated Appropriate Use Criteria (AUC) recognizes higher accuracy in the initial staging evaluation[2]
- Two of the four main Radiology Benefit Managers (RBMs) - AIM Specialty Health[3] and NIA Magellan[4] – are now recommending PSMA-PET *representing a significant portion of commercial payor (health insurance) reimbursement policies*

NCCN National Comprehensive Cancer Network®

AIM SpecialtyHealth®

NIA Magellan℠

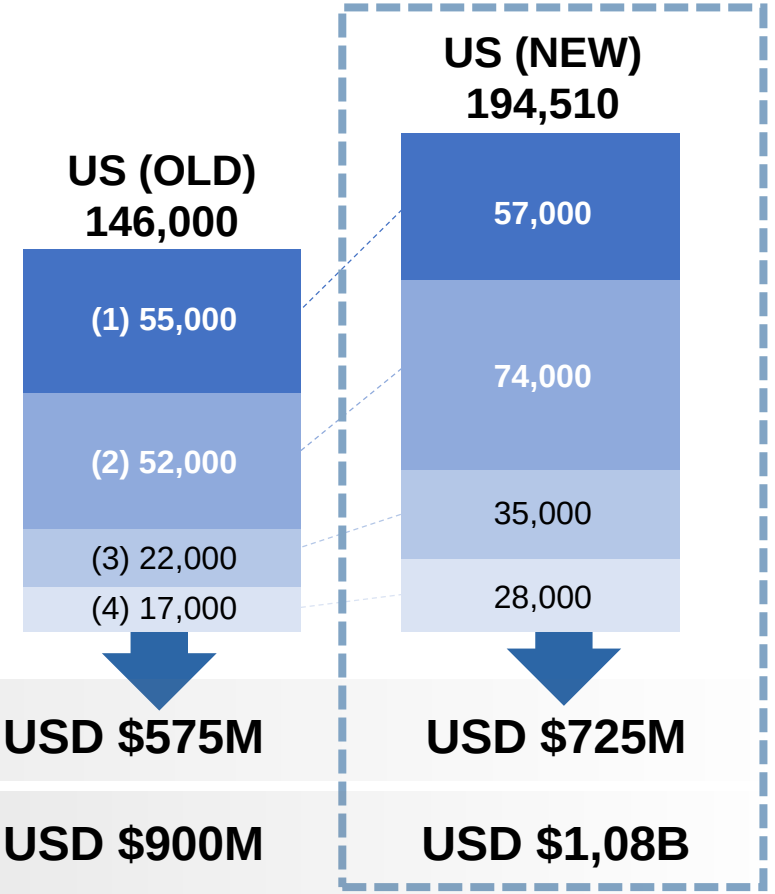
1. NCCN® Prostate Cancer Guidelines Update, Version 1.2022 – 10/09/21
2. SNMMI AUC for PSMA-PET Imaging: https://www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber=38657
3. AIM Clinical Appropriateness Guidelines, Advanced Imaging. AUC: Oncologic Imaging (Effective 7/11/21).
4. National Imaging Associates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

Market opportunity expanded

Due to growing incident rates and indication expansion

US patients with prostate cancer eligible for PSMA-PET imaging

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

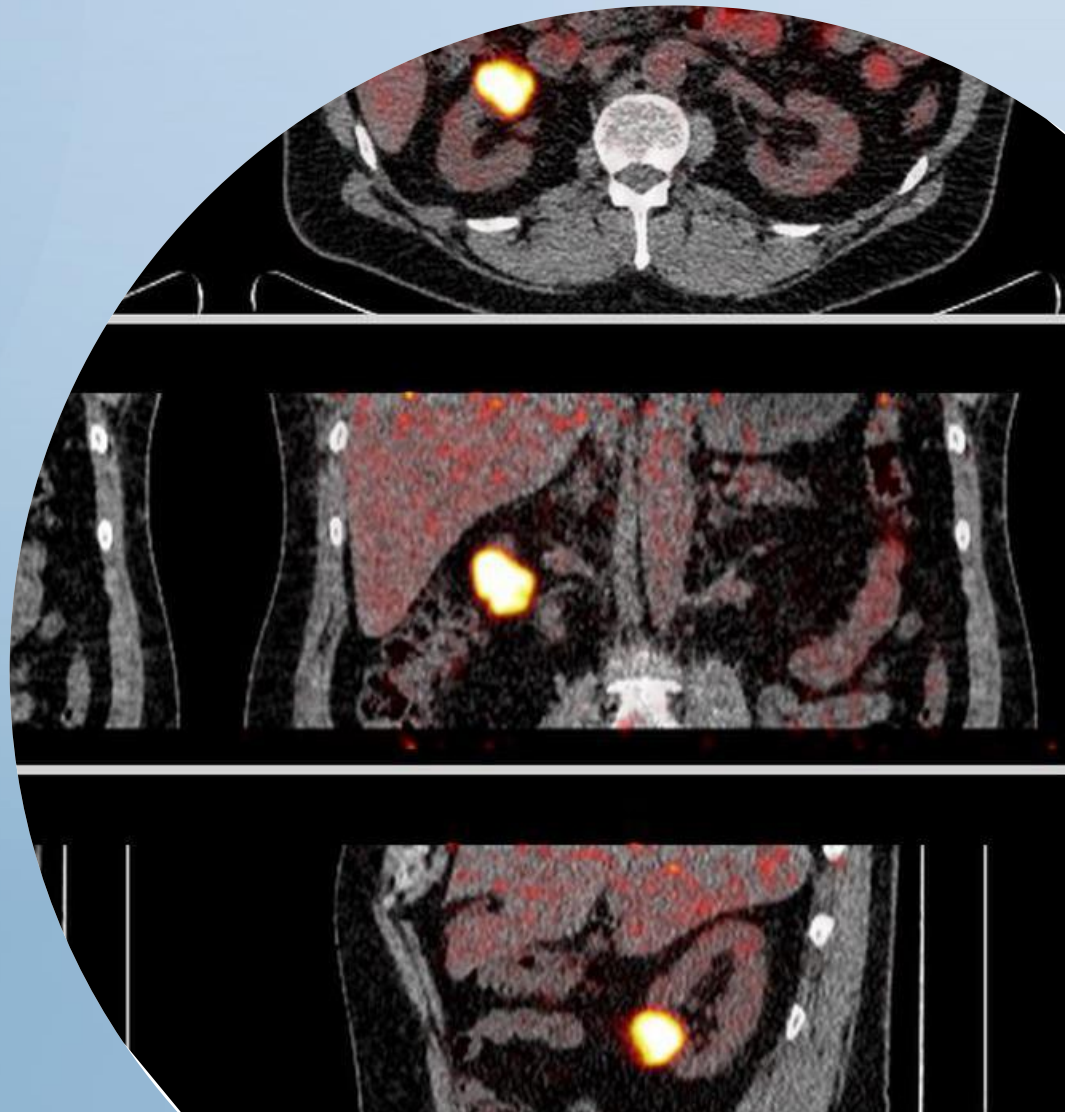


US total addressable market (TAM) value	USD $575M	USD $725M
TAM value including EU	USD $900M	USD $1,08B

1. Telix markets = US + EU countries included in MAA submission to Danish Medicines Authority on 30 April 2020.
2. American Cancer Society. Cancer Facts & Figures 2021. Atlanta, GA: American Cancer Society; 2021.
3. GLOBOCAN 2020 reported incidence of prostate cancer in Telix EU markets.
4. US TAM value = USD $750M, EU TAM value = USD $325M.

Renal Cancer Imaging

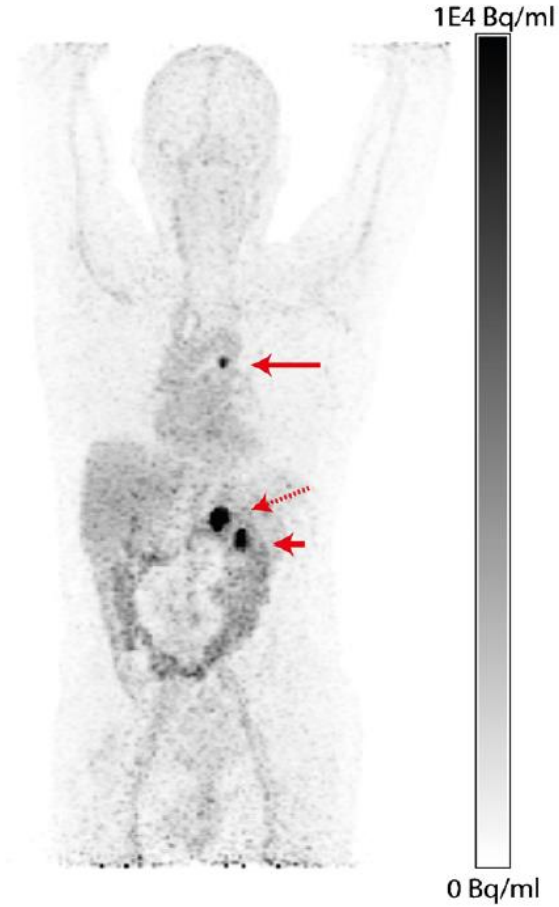
Building a high value genitourinary (GU) oncology portfolio



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



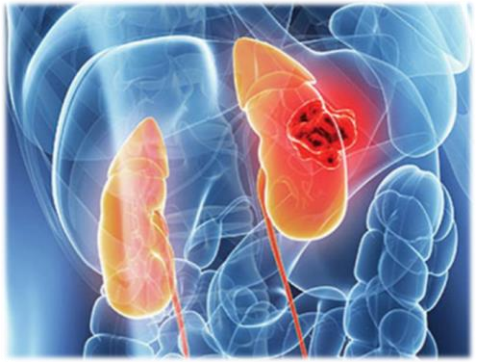
Whole body scan of a 57-year-old male patient revealing 3 lesions. Only those at renal and adrenal level (lower 2 arrows) were also detected on CT. Merkx et al, EJNMMI, 2021.

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

ZIRCON

Eligible Patients
- Single indeterminate renal mass ≤8cm 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

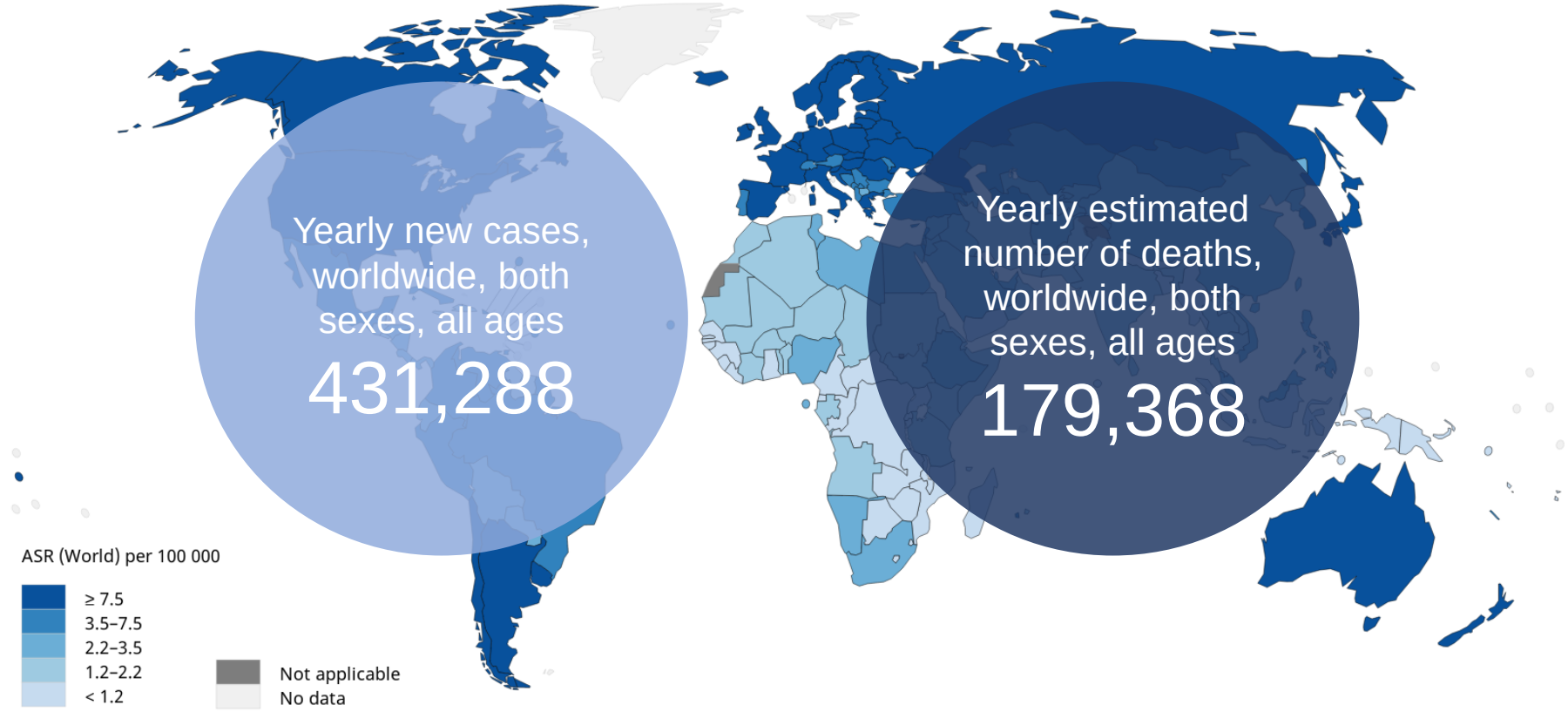


- International, multi-centre, Phase III trial in ~252 patients with an indeterminate renal mass suspicious of ccRCC
  - ✓ **Primary endpoint:** Sensitivity and specificity of PET/CT imaging with TLX250-CDx to non-invasively detect ccRCC in patients with indeterminate renal masses, using histology as standard of truth
- 34 sites participating
  - ✓ 70% 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

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

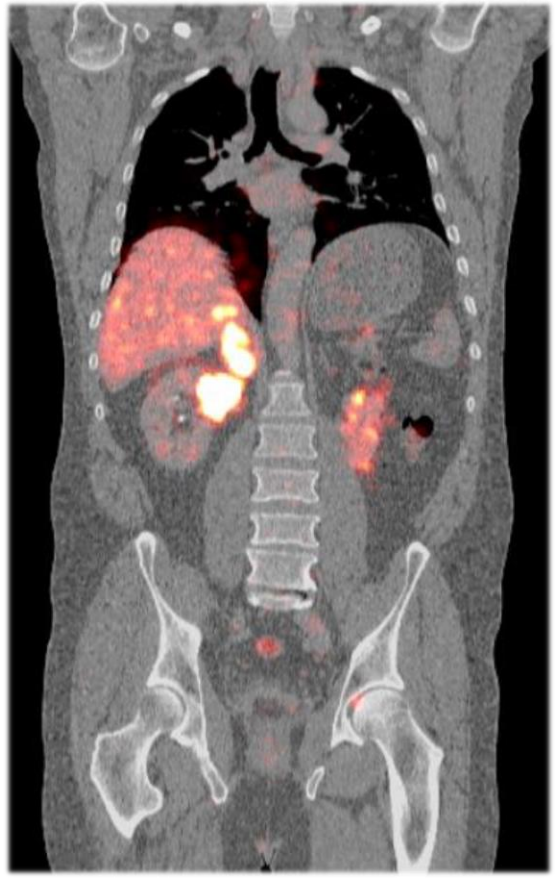


Data source: GLOBOCAN 2020
Graph production: IARC (http://gco.iarc.fr/today)
World Health Organization

STARLITE Phase II trial of TLX250 for Treatment of ccRCC

STARLITE TLX250 in combination with immunotherapy

- Phase II trial of TLX250 plus nivolumab in ~30 patients 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 efficacy of combination therapy with 177Lu-girentuximab (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 Starlite Phase II study to be initiated at a second US site



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

PROSTACT

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

PROSTACT SELECT

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

PROSTACT TARGET

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

PROSTACT GLOBAL

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)**

TLX591 differentiation

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 ^{177}Lu 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

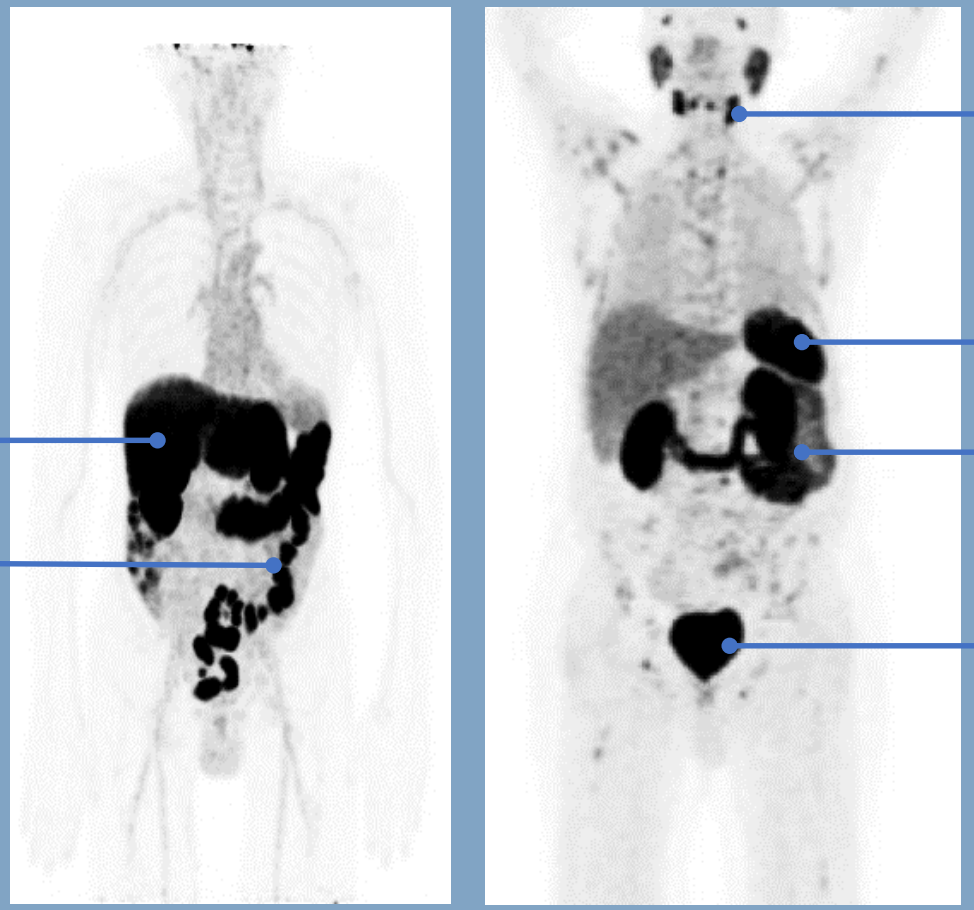
Off-target irradiation – quality of life matters

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

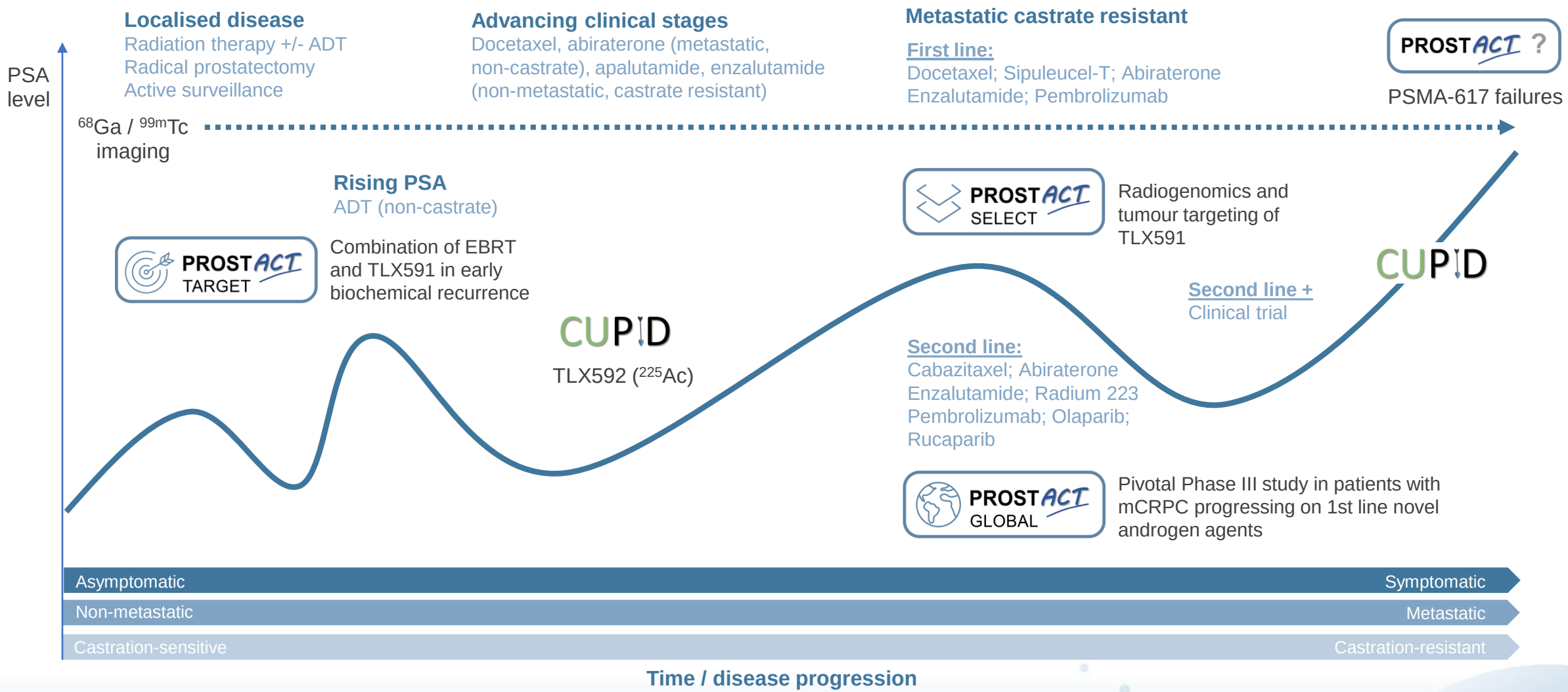
Small molecule radioligands taken up by endogenous PSMA

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

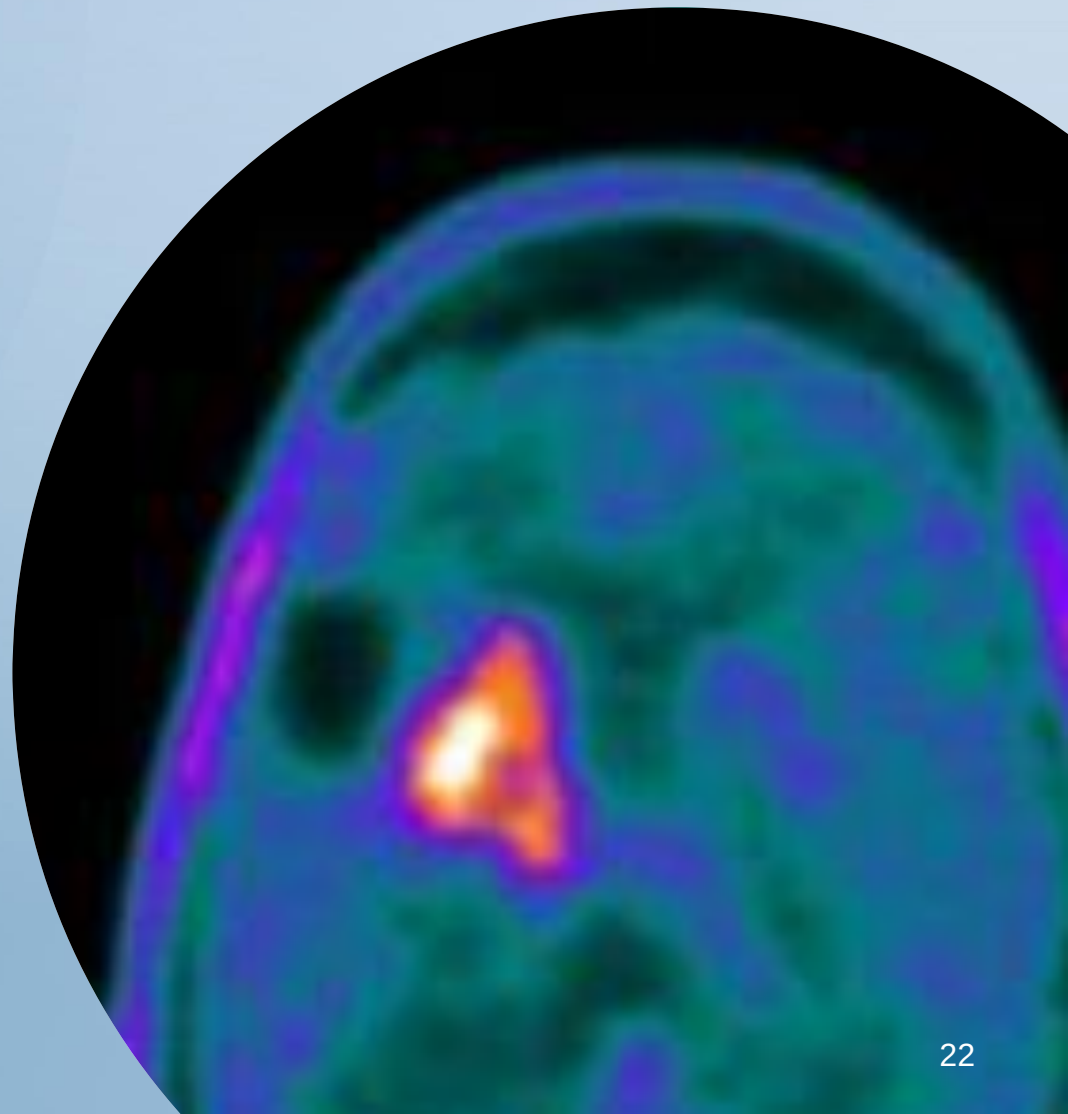
- Dry eye
- Xerostomia
- Back pain from ganglia irradiation

Data courtesy of Prof. Neil Bander, WCMC.

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



Rare Diseases Program

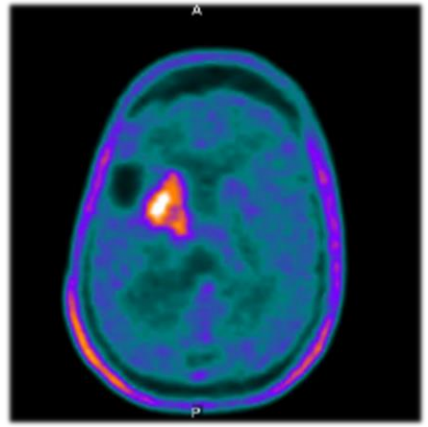


IPAX-I Phase I/II trial of TLX101 for the treatment of GBM[1]

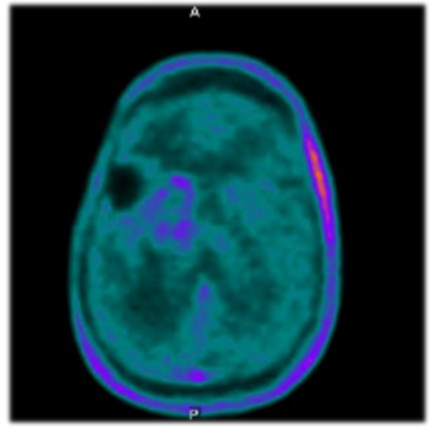
TLX101 in combination with EBRT[2]

IPAX-1

- 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:** MTD[3], efficacy, dosimetry
- ✓ All patients evaluated received similar total activity dose of ~2GBq (2000 MBq) of TLX101, either in a single administration or a triple-fractionated regimen.
- 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



Baseline PET scan



Day 45 PET scan post TLX101 therapy

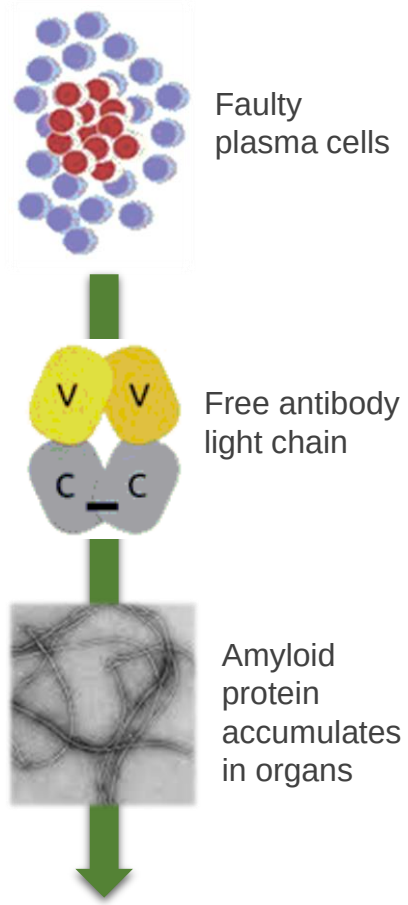
1. Glioblastoma Multiforme.
2. External beam radiation therapy.
3. Maximum tolerated dose.

TRALA Phase I trial of ^{90}Y-besilesomab (TLX66) in SALA[1]

Targeted Radiotherapy for Amyloid Light Chain Amyloidosis (TRALA)[2]

- **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[3] in US and 'EU5'
- Current standard of care comprises induction therapy (cyclophosphamide, bortezomib, dexamethasone) plus high dose melphalan BMC[4], followed by HSCT[5, 6]

- **TRALA study**
  - ✓ **Primary endpoint:** Safety and toxicity of ^{90}Y-besilesomab as the sole BMC regime for autologous HSCT in patients with SALA
  - ✓ Study complete, preliminary data (9 pts) demonstrated 100% engraftment and high PR/CR rate (5/2)



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.

Outlook

Summary

Momentum and focus leading into key inflection points

Launch Illuccix®

US FDA decision (goal date)
23 December 2021
(+ 3-month PDUFA extension)

- ✓ Launch ready
- ✓ TGA approval received

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 BLA 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 (CTN/ethics)
- ✓ US/EU site selection underway
- ✓ Expanded ProstACT program launched to support future indication expansion

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	OPALESCENCE	TLX250-CDx	Dx
I	Emory University	TLX591-CDx	Dx

Lung Cancer

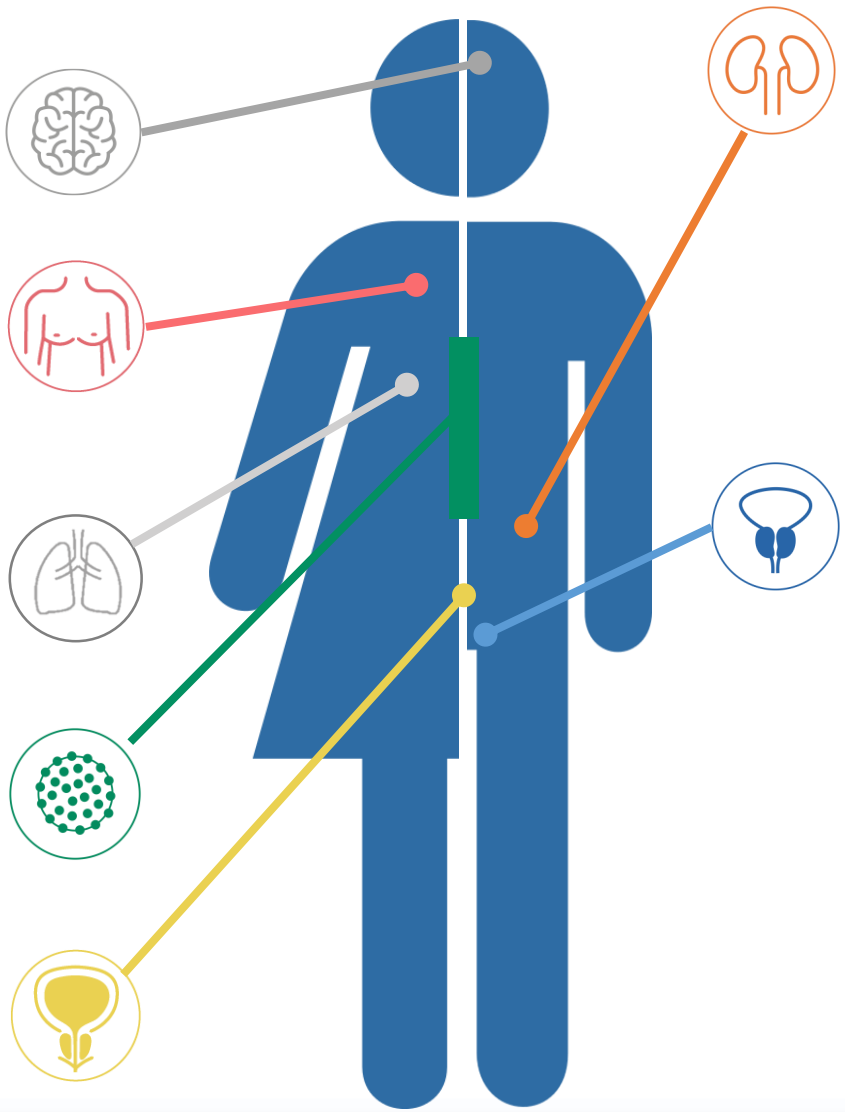
Ph	Name	Asset	Dx/Tx
I	Royal Adelaide (IIT)	APOMAB	Dx/Tx

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*	NOBLE	TLX599-CDx	Dx
III	PROSTACT	TLX591	Tx
I	CUPID	TLX592	Tx

*Registry study

Precision Oncology.
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