Investor Presentation

JP Morgan Virtual Healthcare Conference, January 2022

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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 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 the US and Australia and Scintimun®, none of Telix's products have received a marketing authorisation in any jurisdiction.

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

An established global leader in radiopharmaceuticals

Extensive portfolio of diagnostic and therapeutic assets with compelling clinical data

12,150 patient doses in past 12 months[1]

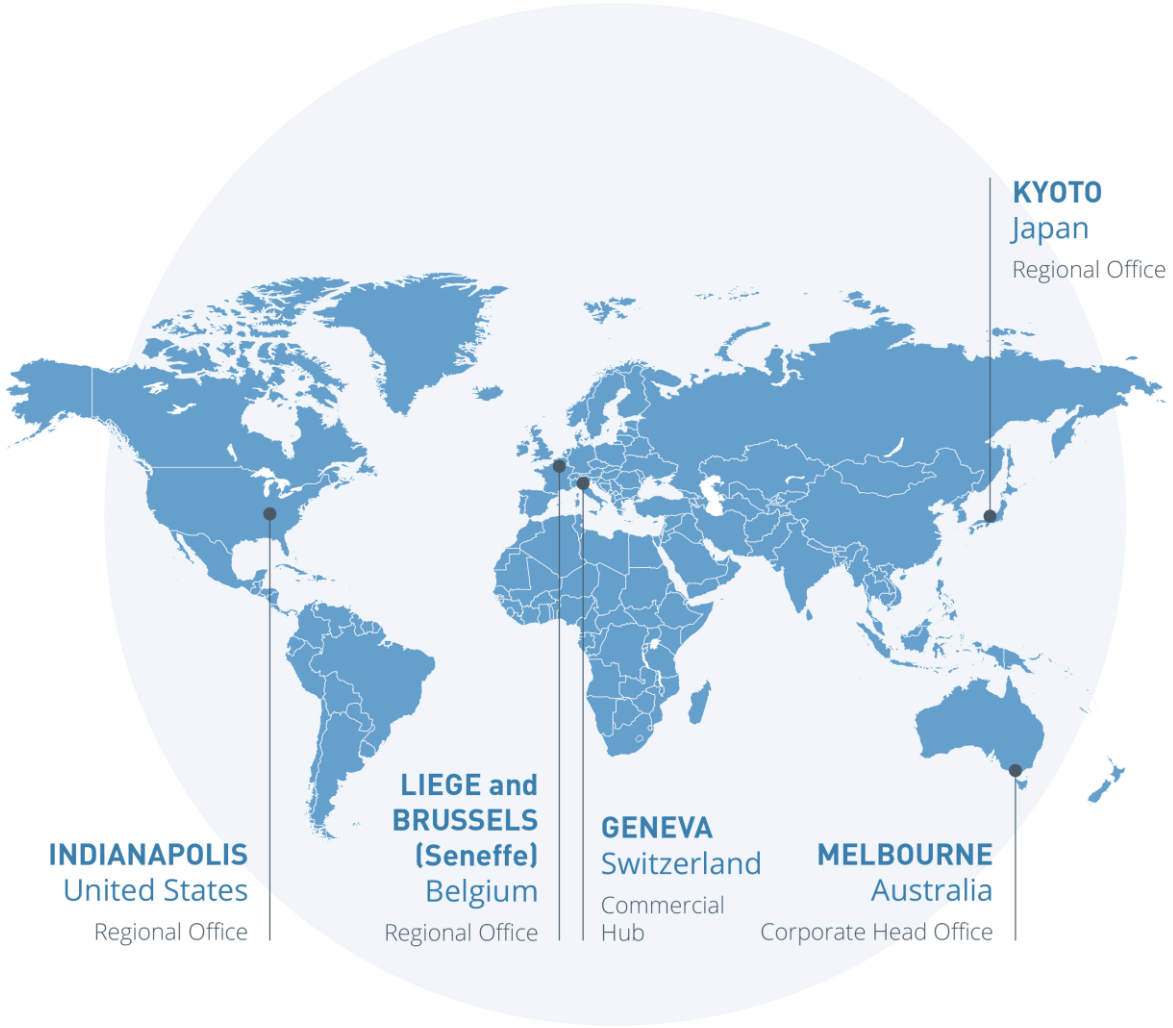
FDA approval for TLX591-CDx (Illuccix®)[2]

18 active clinical studies (8 indications)[3]

Leading supply chain and distribution network

80 countries in the Telix distribution network

11 countries with a manufacturing footprint

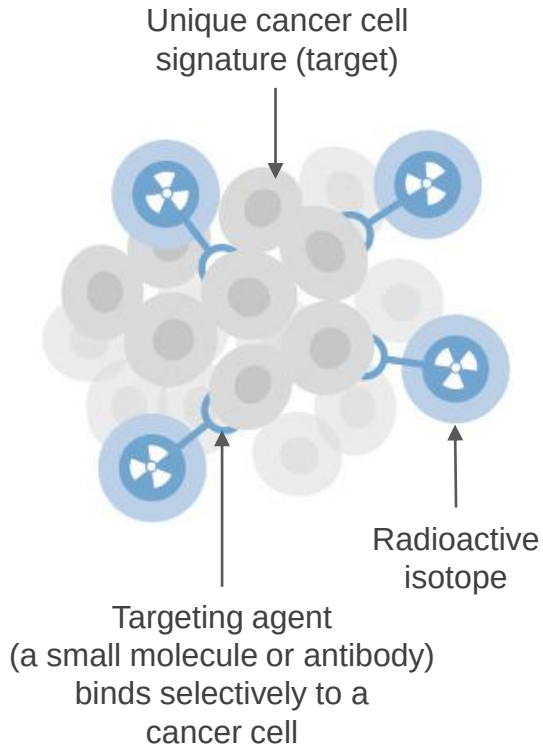


1. Clinical trial doses and magisterial / compassionate use of TLX591-CDx. 12 months from Q4 2020
2. United States Food and Drug Administration – ASX 20/12/21
3. Includes partnered investigator-led studies.

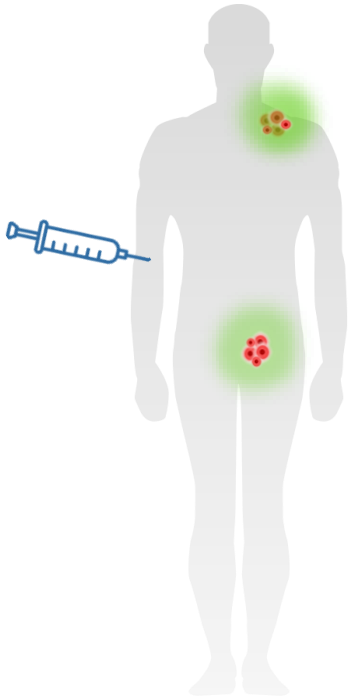
Our strategy: *See It. Treat it.*

Personalised, precision medicine

Targeted radiation delivery



Systemically administered



Imaging

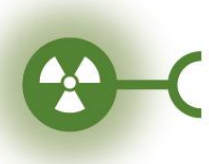
^{68}Ga, ^{89}Zr
(diagnostic isotopes)

Enables **PET images** of cancer

PET[1] scanner

TLX591-CDx[2]
(Prostate cancer)

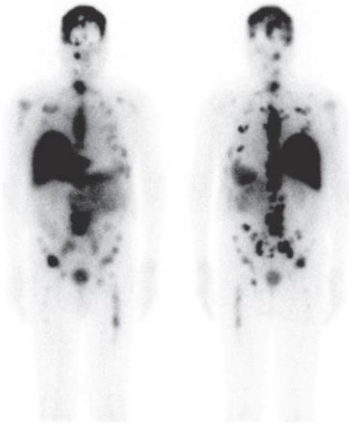
Therapy



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

Enables precise **radiation delivery** to the cancer

TLX591
(Prostate cancer)



1. Positron emission tomography
2. Courtesy of Ammar Chaudhry MD, City of Hope, Duarte CA, USA.

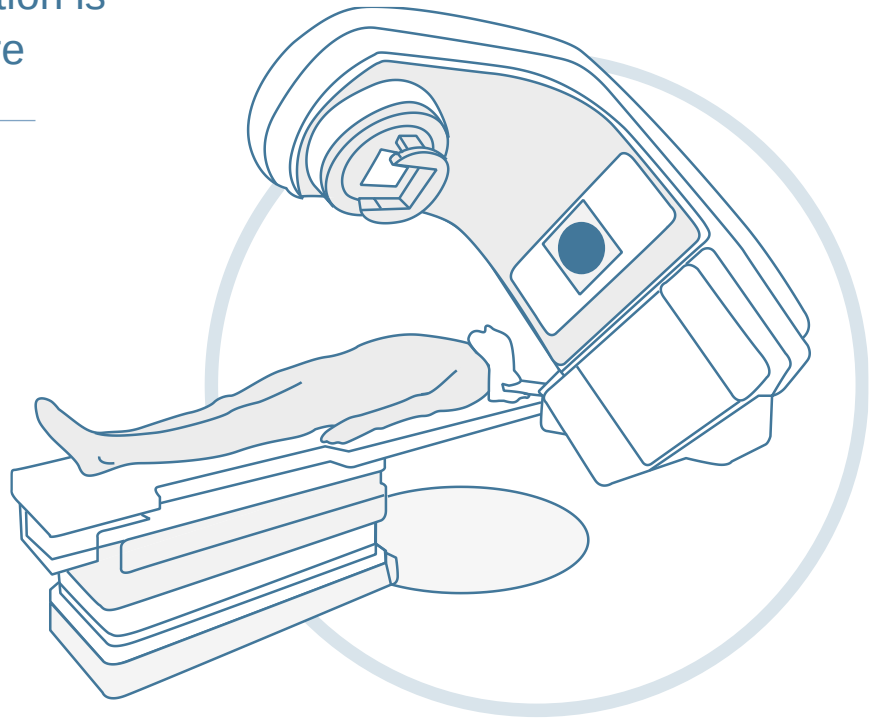
Radiation has never been more important in cancer care

Underpinned by the shift from radiation “in a box” to radiation “in a shot”

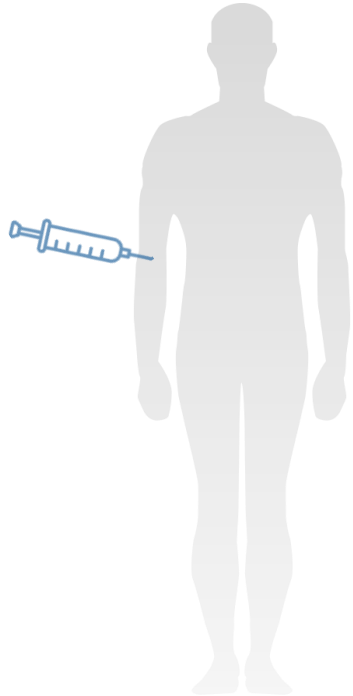
The evolution from external-beam radiation to **systematically-delivered** and **targeted** radiation is transforming the role of radiation in cancer care

- 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

From a ‘box’



To a ‘shot’



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

Telix is pioneering a new cancer modality

Glioblastoma

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

Breast Cancer

Ph	Name	Asset	Dx/Tx
II	OPALESCENCE (IIT)	TLX250-CDx	Dx
I	Emory University (IIT)	TLX591-CDx	Dx

Lung and Ovarian Cancers

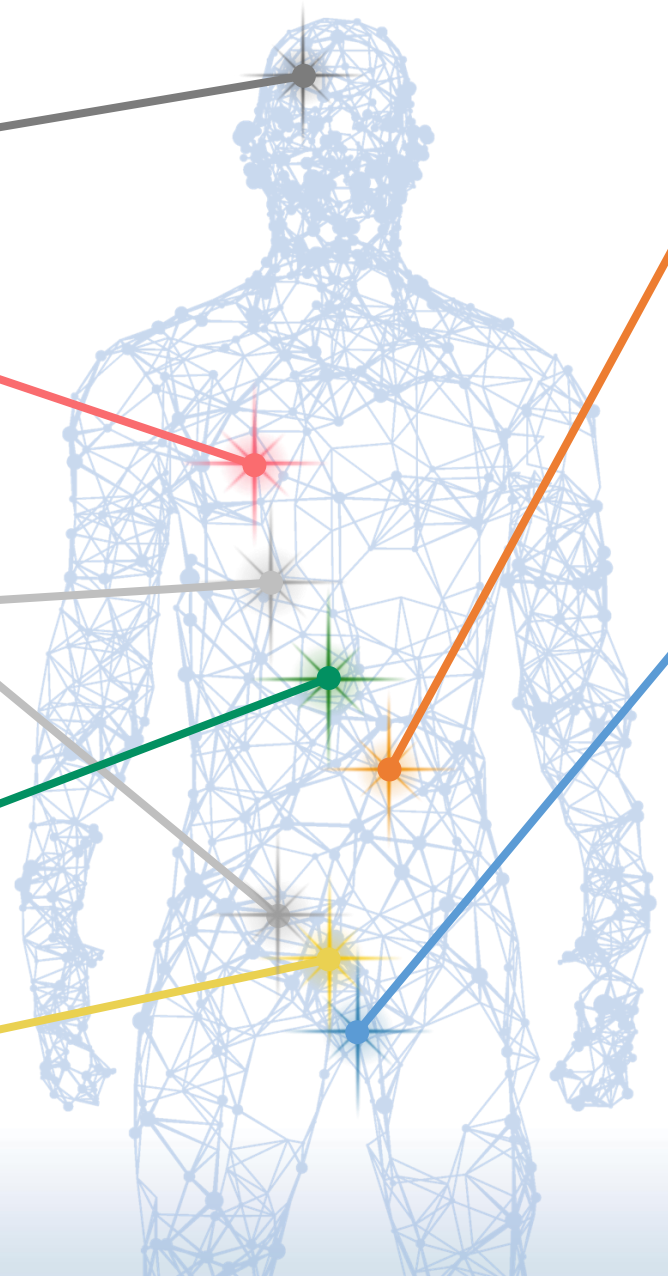
Ph	Name	Asset	Dx/Tx
I	Royal Adelaide (IIT)	APOMAB	Dx/Tx

Bone Marrow Conditioning

Ph	Name	Asset	Dx/Tx
I/IIa	TRALA (IIT)	TLX66	Tx

Bladder Cancer

Ph	Name	Asset	Dx/Tx
I	ZiP-UP (IIT)	TLX250-CDx	Dx
I	PERTINENCE (IIT)	TLX250-CDx	Dx



Kidney Cancer

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

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-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. *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.

Strategic Priorities

Use Illuccix as a commercial launchpad

Establish Telix's leadership in urologic oncology

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

Novel targets, clinical applications and manufacturing technologies

Focus for 2022

Unlocking the value in our pipeline

Illuccix global rollout

- US reimbursement
- Additional global approvals including EU/UK, Canada
- Commercial launch from late Q1 (US and AU)

Commercialise diagnostics

- Kidney cancer (TLX250-CDx) Phase III readout
- Prepare for US regulatory filing for TLX250-CDx
- US filing planned for brain cancer imaging product

Advance core therapeutics

- ProstACT studies active globally
- Kidney cancer combination therapy Phase II studies
- Initiate Phase II studies in TLX101 and TLX66

Pipeline & manufacturing

- Seneffe manufacturing / R&D buildout to commence
- Focus on strategic deals and in-licensing
- Advance early-stage alpha therapy programs

Recent milestones and near-term catalysts

Recently completed milestones

- Illuccix regulatory approvals granted in US and Australia
- HCPCS[1] reimbursement submitted for Illuccix in the US
- ProstACT patient recruitment commenced
- Distributors finalised for major EU markets (subject to regulatory approval)
- FDA Investigational New Drug (IND) granted for STARLITE 1 & 2 studies

Upcoming milestones: Q1 2022

- Illuccix commercial launch US and AU
- US reimbursement for Illuccix:
  - Pass-through code submission (March 2022)
  - HCPCS code for US reimbursement expected 1 April 2022
- Illuccix EU marketing authorisation decision
- ZIRCON Phase III study enrolment completed
- IPAX-2 Phase II study launched (glioblastoma)
- STARLITE Phase II kidney cancer therapy studies progressed

1. Healthcare Common Procedure Coding System

Illuccix® Imaging

Launching in Q1 2022

Illuccix® is now approved in the United States
Indication and usage information

Illuccix is a kit for the preparation of gallium-68 (^{68}Ga) gozetotide (also known as PSMA-11) injection, a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in patients with prostate cancer with:

- Suspected metastasis who are candidates for initial definitive therapy;
- Suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

Important Safety Information:
https://www.illuccixhcp.com/important-safety-information

Please see full Prescribing Information at
http://illuccixhcp.com/s/illuccix-prescribinginformation.pdf

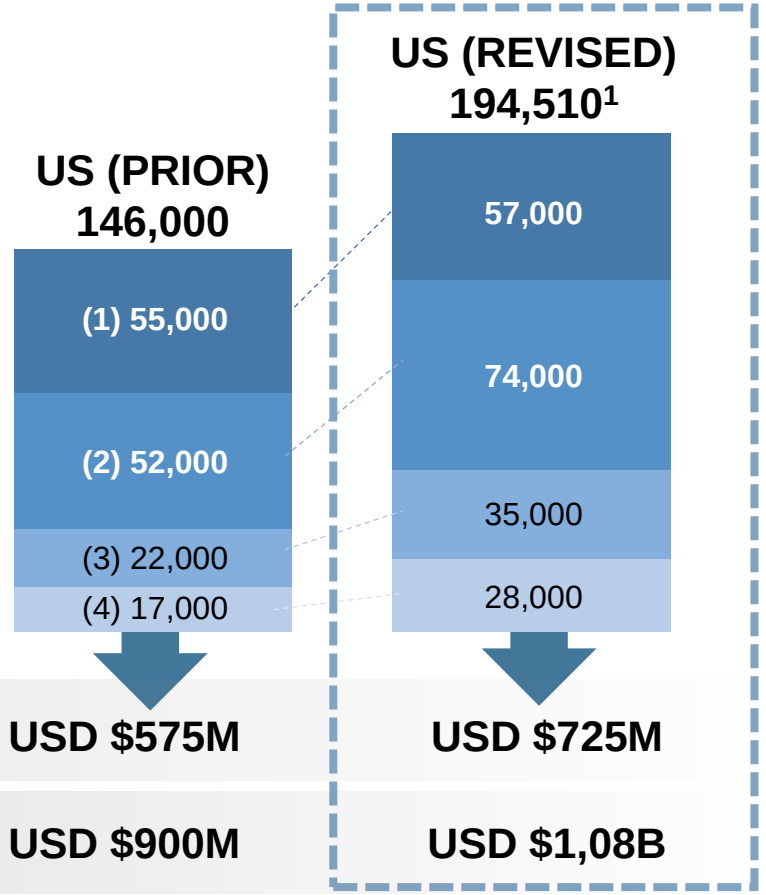
illuccix®
(kit for the preparation of gallium Ga 68 gozetotide Injection)

Market opportunity for prostate imaging is expanding

Due to growing incidence rates and practice guidelines

Potential clinical utilisation:

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



US total addressable market (TAM) value	USD $575M	USD $725M
TAM value including EU[2]	USD $900M	USD $1,08B

1. American Cancer Society. Cancer Facts & Figures 2021. Atlanta, GA: American Cancer Society; 2021.
2. EU countries included in MAA submission to Danish Medicines Authority on 30 April 2020.

Commercial launch plans - US

Commercial ramp up during Q1 2022

Positioned to capture meaningful market share

- **Access** to ~90% of eligible PET sites
- **Distribution network** holds 60% market share of nuclear medicine market in the US
- **On-demand** pharmacy-based production with a high yield product
- **Customer** and patient scheduling flexibility

Market access strategy in place, commercial launch underway

- Q1 focus on early adopters – imaging centers and veteran affairs
- 400 imaging centres pre-qualified
- Telix + partners will have one of the largest commercial teams (including sales, market access, MSL) to service the US prostate imaging market

On track for reimbursement in H1 2022

- HCPCS[1] code expected 1st April 2022
- Transitional Pass-Through (TPT) status expected 1st July 2022

Telix / partner sites

Current competitor sites (4 November 2021)

1. Healthcare Common Procedure Coding System

PSMA-PET imaging emerging as standard of care in prostate cancer

Inclusion in guidelines are driving clinical adoption and reimbursement

- National Comprehensive Cancer Network Guidelines® (NCCN 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
  - Aligns with indication for 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) recognises 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*

National Comprehensive Cancer Network®

AIM SpecialtyHealth®

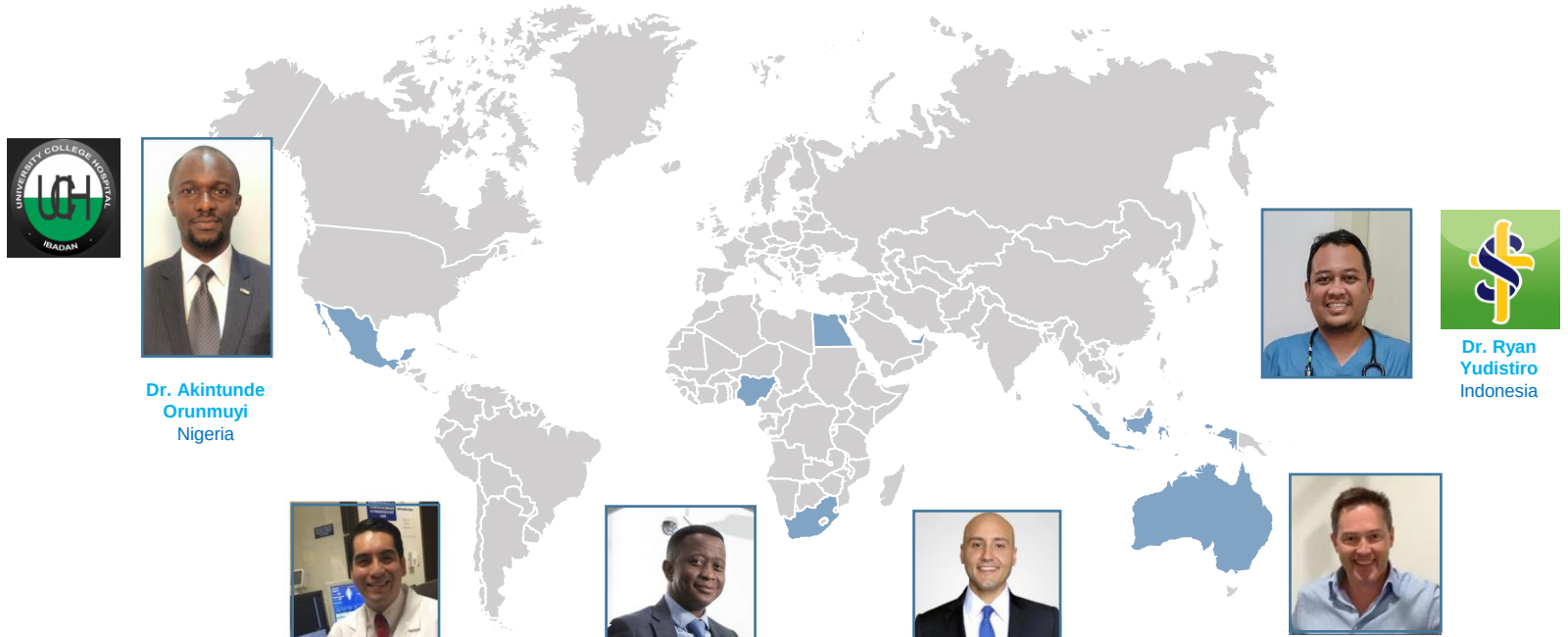
NIA Magellan℠

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)

The NOBLE Registry (TLX599-CDx): Nobody left behind

Improving access to PSMA imaging – *beyond* Illuccix

- Collaboration to investigate utility of ^{99m}Tc-iPSMA SPECT[1] 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 limited[2]
- Isotope (^{99m}Tc) supply chain well established and inexpensive
- Rapid expansion planned including APAC

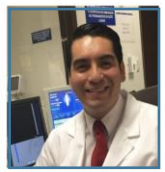


Dr. Batool Albalooshi
Ambassador | UAE

Chair

Dr. Akintunde Orunmuyi
Nigeria

Dr. Ryan Yudistiro
Indonesia



Dr. Ivan E. Diaz Meneses
Ambassador | Mexico

Dr. Mike Sathekge
South Africa

Dr. Yehia Omar
Ambassador | Egypt

Peter Tually
Australia

1. Single photon emission computed tomography
2. Worldwide SPECT cameras outnumber PET by 4:1 (MEDraysintell 2021)

Renal cancer program

A clinical leadership opportunity in diagnostics and therapy

TLX250-CDx / TLX250 overview

An exciting target, with potential application beyond kidney cancer

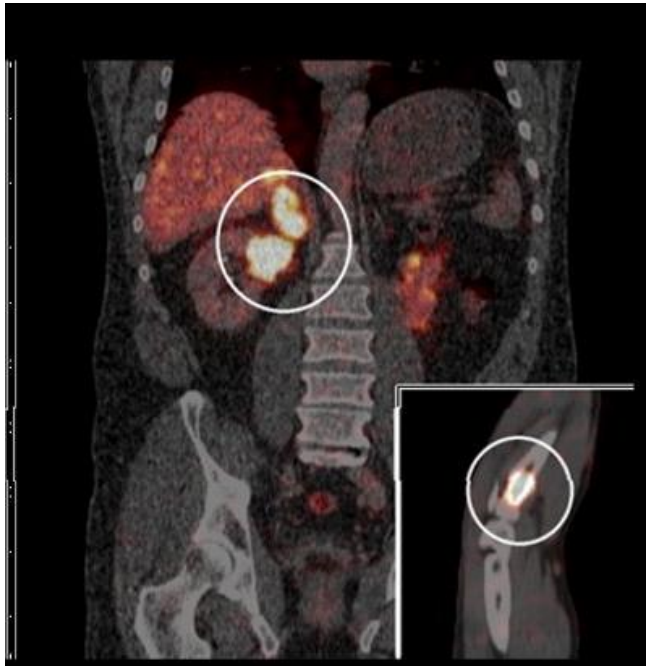
- **Target:** Carbonic Anhydrase IX (CAIX / CA9)
- **Indication:** Kidney cancer (clear cell renal cell carcinoma, ccRCC)
- **Development status:**
  - TLX 250-CDx: Phase III ZIRCON diagnostic imaging study nearing completion
  - TLX250: Phase II STARLITE 1 & 2 therapeutic studies (in combination with immunotherapy) initiated
- **Rationale:**
  - CA9 is over-expressed in mutated ccRCC and many hypoxic solid tumors, with low expression in most normal tissue.
  - Tumour hypoxia correlates with progression and resistance to therapy
  - Potential for targeted radiation to enhance the effect of existing ccRCC therapies such as immunotherapy
  - Limited competition in imaging, optimises surgical management

Target: CAIX / CA9	Dx (TLX250-CDx)	Tx (TLX250)
Targeting molecule	Antibody	Antibody
Targeting agent	DFO-girentuximab	DOTA-girentuximab
Radionuclide	^{89}Zr	^{177}Lu

Building a high-value diagnostics portfolio

"Breakthrough Therapy" designation, clinical leadership opportunity

- **Biologics License Application (BLA) consultation process has commenced, Phase III study in final stages of enrolment**
- 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 avoid unnecessary surgical intervention
- Opportunity to follow prostate cancer imaging, with a second high-value product for the genitourinary (GU) oncology field



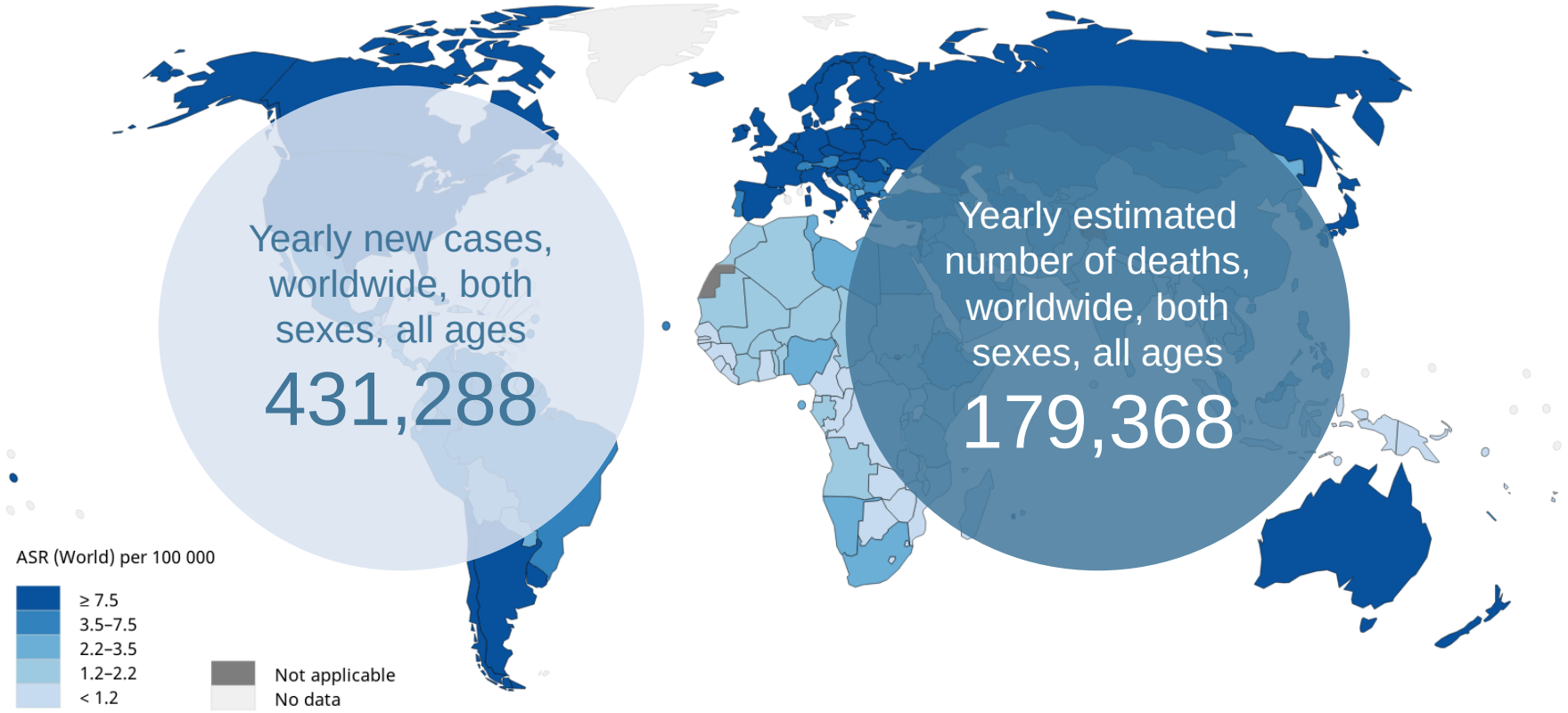
An example of PET/CT imaging showing the uptake of ^{89}Zr-girentuximab in a primary renal mass. The insert shows the identification of a metastatic lesion of the proximal radius, confirmed as ccRCC upon biopsy.[1]

1. Hekman et al, *European Urology.* 2018.

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

- **Total addressable market value in US and Europe estimated at US$300-400M**
- **Potential for market leadership, given limited patient options**
- **Addresses a major unmet medical need for more accurate patient staging**

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

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

Study overview

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

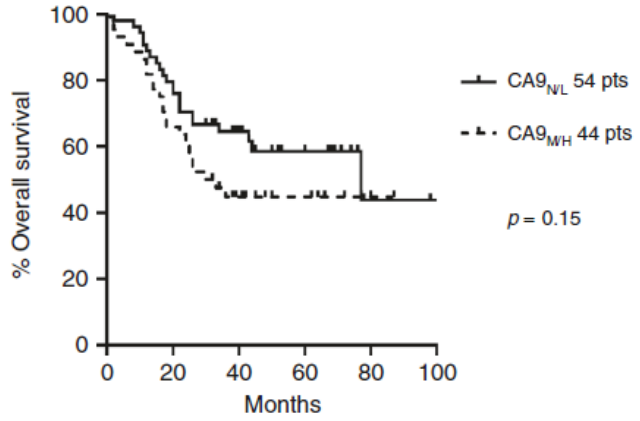
→ TLX250-CDx PET/CT scan → Surgical removal & histology as standard of truth

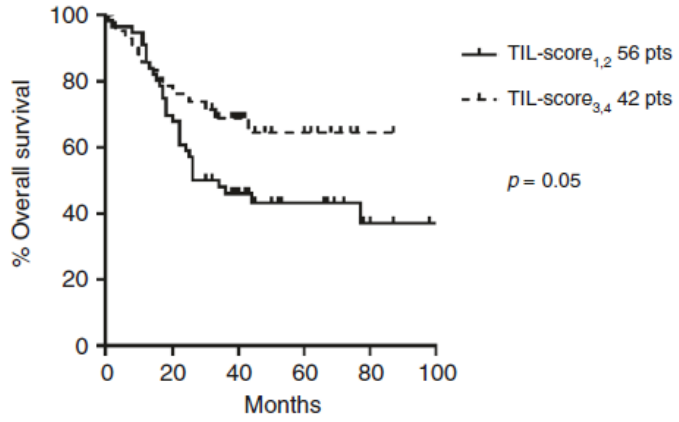
- International, multi-centre, Phase III trial in ~252 patients with an indeterminate renal mass suspicious of ccRCC
  - **Primary endpoint:** Sensitivity and specificity of PET/CT imaging with TLX250-CDx to non-invasively detect ccRCC in patients with indeterminate renal masses, using histology as standard of truth (after surgical removal)
- 35 sites participating
  - > 85% 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

STARLITE 2 Phase II trial of TLX250 for Treatment of ccRCC

TLX250 in combination with immunotherapy

- **STARLITE 2 now actively recruiting (screening patients)**
- 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) – 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 177Lu-girentuximab (TLX250) 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 (awaiting ethics approval)





CA9 expression is correlated with the presence of tumour-infiltrating lymphocytes, which may confer resistance to immunotherapy.[1]

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

CA9 indication expansion

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 in tumours including bladder or urothelial, breast, brain, cervix, colon, esophagus, head and neck, lung, ovarian, pancreatic and vulval cancers
- Imaging is being used to “indication scout” for future therapy applications, highlight the value of a “theranostic” approach

Potential Indication	Status
Bladder or Urothelial Cancer	Commenced
Triple Negative Breast Cancer	Commenced
Lung Cancer	Planned
Ovarian Cancer	Planned
Colorectal Cancer	Planned
Head and Neck Cancer	Planned
Pancreatic Cancer	Planned

Prostate cancer therapy

Our vision for prostate cancer

Prostate cancer therapy assets overview

Next-generation therapy to follow TLX591

- **Target:** Prostate Specific Membrane Antigen (PSMA)
- **Indication:** Prostate cancer
- **Clinical status:**
  - TLX591: ProstACT GLOBAL Phase III + ancillary studies recruiting
  - TLX592: CUPID study enrolling patients for imaging initially – next-generation PSMA-directed alpha therapy
- **Rationale:**
  - Unmet need for treatment options for late-stage, metastatic patients specifically target both soft tissue and bony lesions
  - Antibody-based PSMA treatment may deliver superior efficacy and side-effect profile compared to small molecule
  - TLX592 a potential adjuvant for high-risk patients that may have early metastatic disease. May also have utility in patients progressing from conventional ^{177}Lu-PSMA Tx

Target: PSMA	TLX591	TLX592
Targeting molecule	Antibody	Engineered Antibody
Targeting agent	DOTA-rosopatamab	RADmAb®
Radionuclide	^{177}Lu	^{225}Ac

ProstACT program overview

Multiple opportunities to deliver insights into TLX591

Radiogenomics study

- ~50 patients
- 1st line metastatic prostate cancer (mCRPC)
- Rapid recruitment

PROSTACT SELECT

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

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

- 390 patients
- 2nd line mCRPC

PROSTACT GLOBAL

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

SELECT (Ph I) – radiogenomics study enhances patient selection and supports indication expansion based on a “theranostic” approach

TARGET (Ph II) – 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 Phase III study

Pivotal trial

PROSTACT TARGET

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

Eligible Patients

- PSMA avid (defined by TLX591-CDx)
- mCRPC[1]
- Progressed despite prior therapy with NAAD[2]

TLX591 + Standard of care therapy

Standard of care therapy alone

- 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)
  - **Primary endpoint:** radiographic progression-free survival (rPFS)
  - **Secondary endpoints include:** overall survival, quality of life, safety
- 2:1 randomisation and enrichment of study population, patient selection with TLX591-CDx
- **Status: ProstACT GLOBAL 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**

1. Metastatic castrate-resistant prostate cancer
2. Novel androgen axis drug

ProstACT SELECT Phase 1 study

Enhances patient selection and supports indication expansion

PROSTACT TARGET

Treat the scan

Correlation between imaging and therapy to optimise patient selection

Eligible Patients

- PSMA avid (defined by TLX591-CDx)
- mCRPC
- Progressed despite prior therapy with NAAD

TLX591 + Standard of care therapy

Comparative imaging between ^{68}Ga-PSMA and ^{177}Lu -PSMA

- Ph I study of TLX591 for the treatment of mCRPC
- Multi-centre, multinational Phase I radiogenomics study in Australia and New Zealand in ~50 patients, comparing ^{68}Ga-PSMA and ^{177}Lu-PSMA, specifically confirming the similarity of small molecule and antibody-based targeting
- Radiogenomics study to enhance patient selection for ProstACT GLOBAL and support indication expansion for Telix's PSMA therapeutic portfolio, based on a "theranostic" approach
  - **Primary endpoints:** biodistribution, safety and tolerability
  - **Secondary endpoints include:** correlation between imaging and therapy molecules, radiographic progression-free survival, PSA response
- **Status: Actively recruiting (screening patients)**

ProstACT TARGET Phase II study

Expanding clinical data to include a front-line setting

PROSTACT TARGET

Early data in front line care

Efficacy data in patients in their first recurrence

In partnership with:

GenesisCare

Eligible Patients
• PSMA avid (defined by TLX591-CDx) • Oligometastatic early recurrence

→ TLX591 + External Beam Radiation Therapy (EBRT)

- Single arm Phase II study in Australia in 50 patients with PSMA-expressing biochemically recurrent oligometastatic prostate cancer, in combination with external beam radiation therapy (EBRT)
- To determine the efficacy, biodistribution and combination dosimetry of TLX591 plus EBRT, including dose to tumour
  - **Primary endpoint:** radiographic progression-free survival
  - **Secondary endpoints include:** overall survival, quality of life, safety
- **Status: Patient screening to commence early 2022 (subject to ethics approval)**

TLX591 differentiation

Potential advantages with PSMA antibody approach

Efficacy	Potential for improved overall survival (OS) in advanced metastatic disease, with 40+ months OS reported to date[1]
Patient comfort	Reduced potential for off-target 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	Significantly lower ^{177}Lu isotope requirements with commensurate reduction in COGS, expected to also be available in “cold kit” format

1. Tagawa et al, Cancer 2019.

TLX591 patient experience

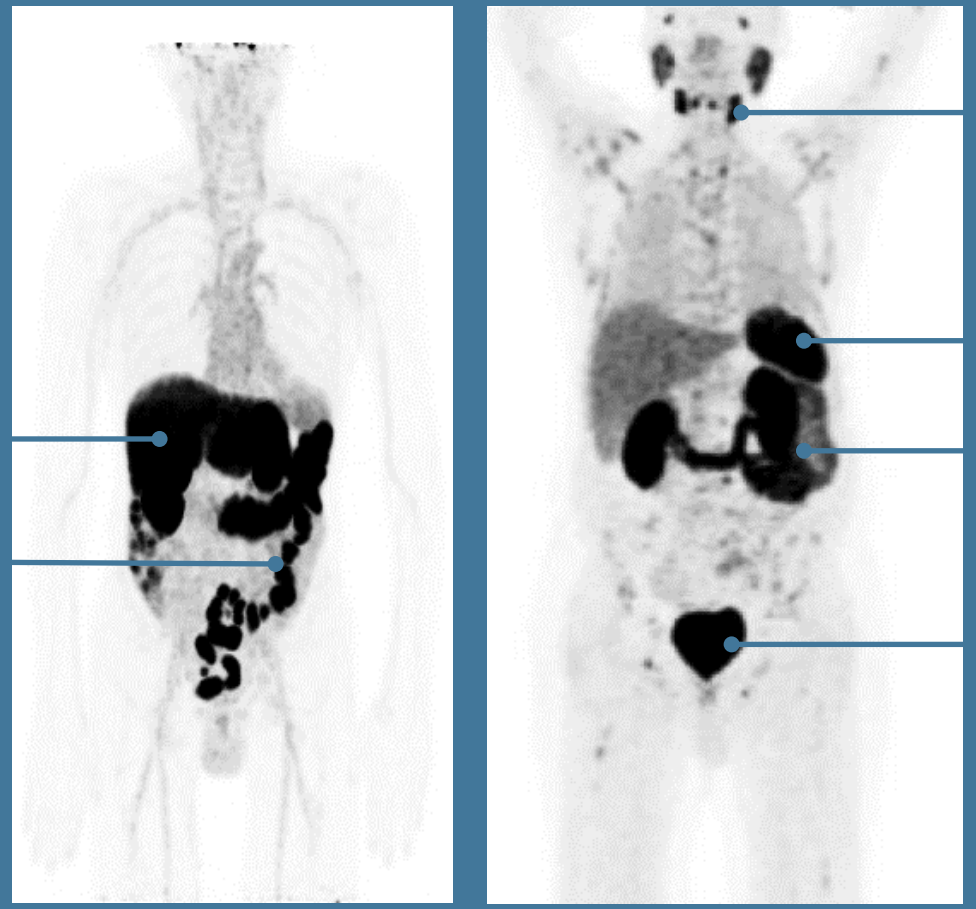
Off-target irradiation – quality of life matters

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 long-term vision for prostate cancer

Improving access, imaging and treatment options for patients

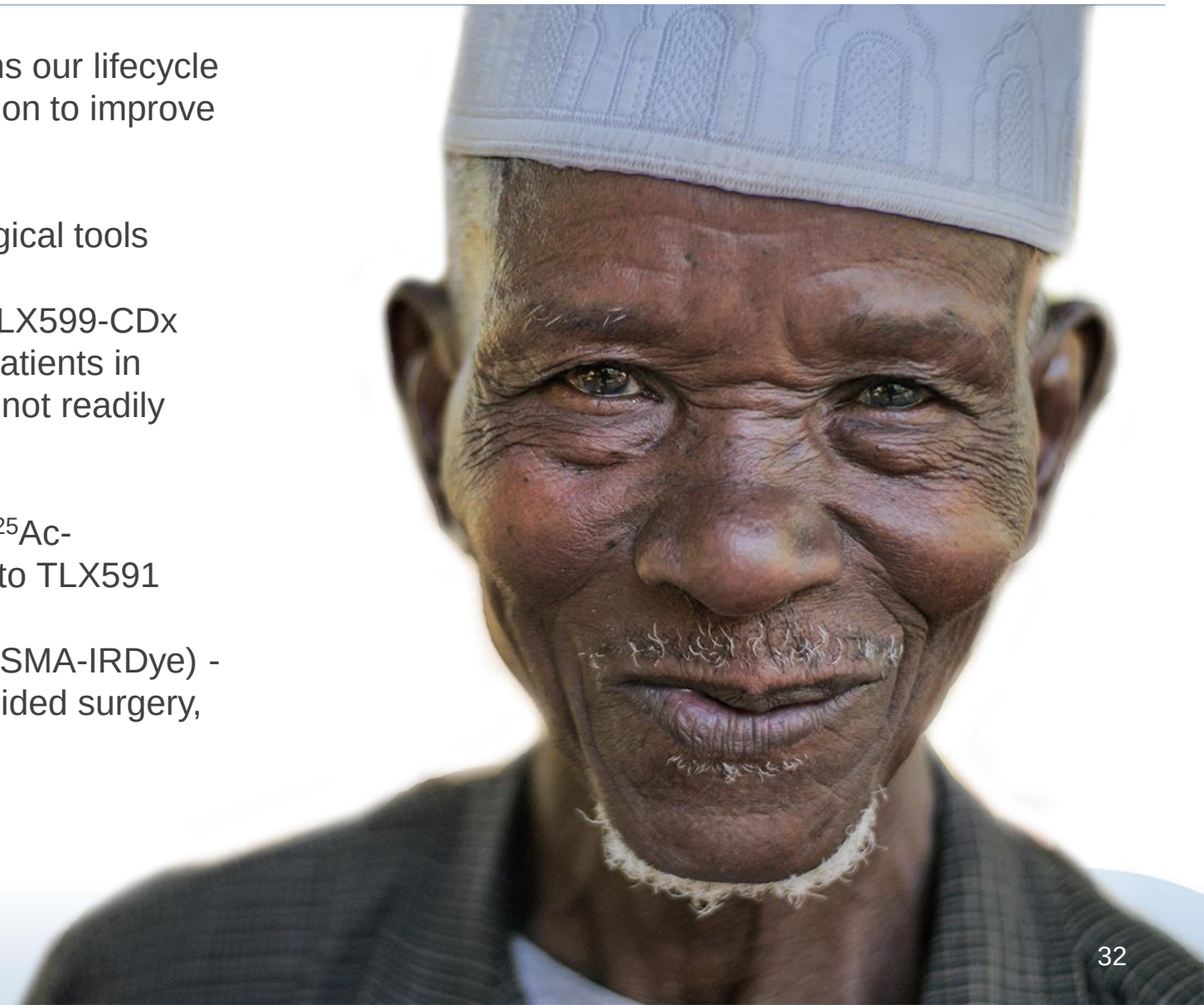
- Further development of the PSMA target underpins our lifecycle management strategy for prostate cancer and vision to improve patient outcomes

- 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

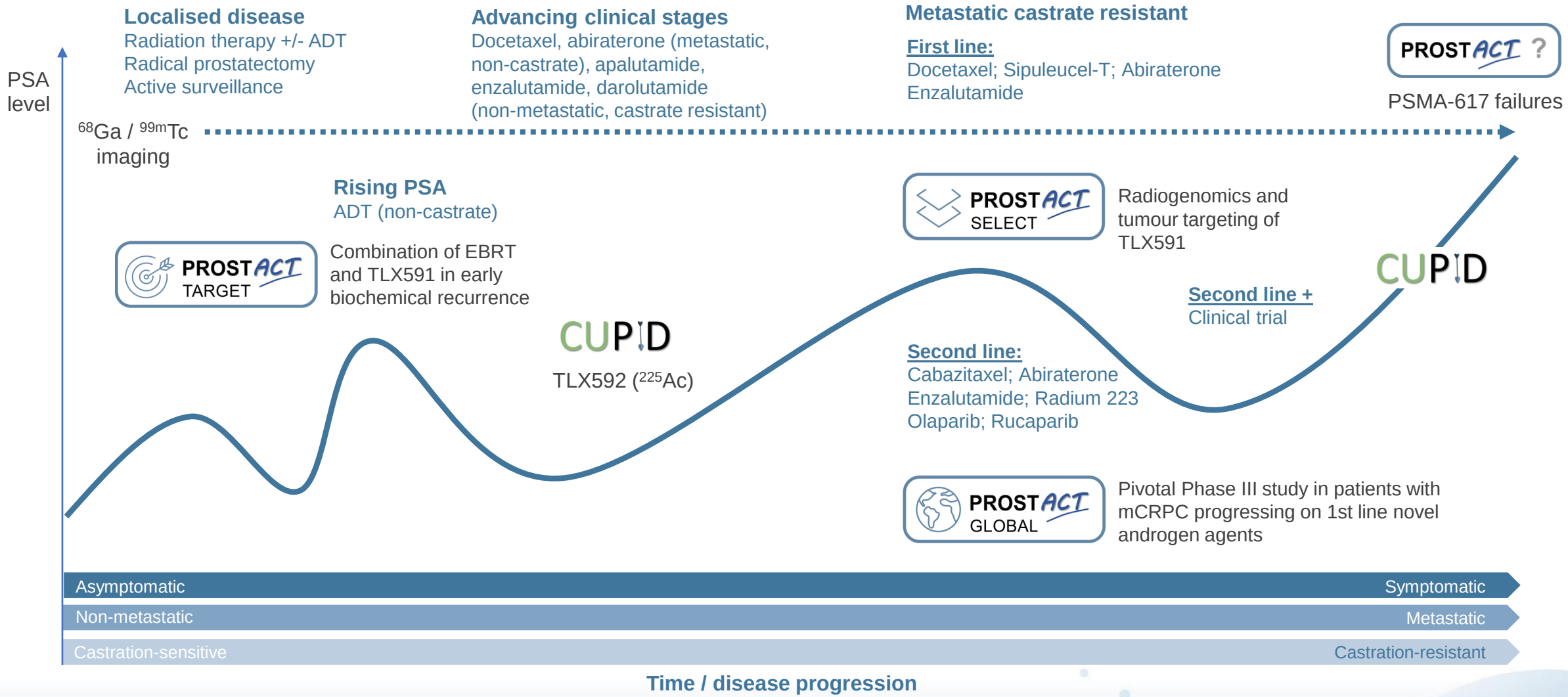
    - **Next-generation alpha therapy:** TLX592 (^{225}Ac-RADmAb®) – high potency, complementary to TLX591

    - **Image guided surgery:** TLX591-Sx (^{68}Ga-PSMA-IRDye) - dual-labelled PET-optical tracer for image guided surgery, enables real-time cancer detection[1]



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

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



CUPID trial

Next-generation alpha therapy, complements TLX591

CUPID

Study with ^{64}Cu-TLX592 to show biodistribution and tumour targeting prior to targeted alpha therapy (TAT) with ^{225}Ac-TLX592

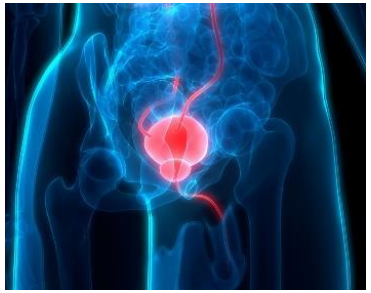
Eligible Patients

- Prostate cancer patients with low-burden metastatic disease at ≤ 5 sites as detected using PSMA PET/CT scanning (TLX591-CDx)

→ ^{64}Cu-TLX592 PET/CT scan →

^{225}Ac-TLX592 TAT

Subject to positive outcomes with ^{64}Cu



- TAT is becoming an important area of PSMA therapy research, particularly in men that are no longer responding to ^{177}Lu
- TLX592 antibody re-engineered to clear ~10x faster from the body, while maintaining specificity for tumour-expressed PSMA (liver cleared, no exocrine uptake)
- Designed for delivering TAT (^{225}Ac) intended for:
  - i) Early-stage metastatic disease (e.g. biochemical recurrence (BCR)) and
  - ii) Late-stage disease when ^{177}Lu-PSMA therapy is no longer providing treatment efficacy
- Single arm, open-label, first-in-human (FIH) study of ^{64}Cu-TLX592 in men with metastatic prostate cancer using PET
  - **Primary endpoint:** Determine the safety and tolerability, pharmacokinetics, whole body biodistribution and radiation dosimetry of ^{64}Cu-TLX592 using PET as a proxy for ^{225}Ac-TLX592 TAT
- **Status: Actively recruiting – multiple patients dosed in imaging phase**

Rare diseases program
High potential, high impact

TLX101-CDx / TLX101 overview

Orphan designation status granted for imaging and therapy candidates

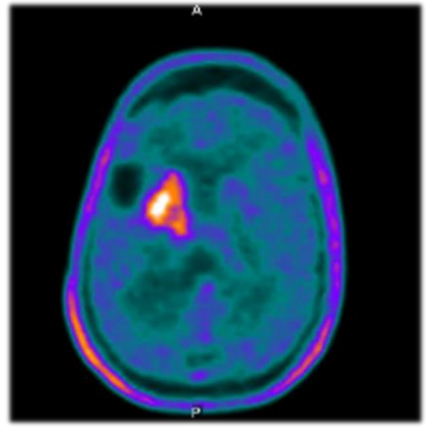
- **Target:** Large amino acid transporter 1 (LAT-1)
- **Indication:** Glioblastoma multiforme (GBM)
- **Clinical status:**
  - TLX101-CDx: Progressing towards new drug application (NDA) filing in 2022
  - TLX101: IPAX-2 follow-on Phase I/II study in newly diagnosed patients commencing in 2022
- **Rationale:**
  - TLX101-CDx: FET-PET demonstrated to provide greater diagnostic sensitivity compared to standard imaging procedures
  - TLX101: Poor prognosis with few treatment options. Promising overall survival data in IPAX-1 study warrants further investigation in earlier stage patients

Target: LAT-1	Dx (TLX101-CDx)	Tx (TLX101)
Targeting molecule	Small molecule	Small molecule
Targeting agent	Fluoroethyl)-L-tyrosine (FET)	4-L-[^{131}I] Iodo-Phenylalanine
Radionuclide	^{18}F	^{131}I

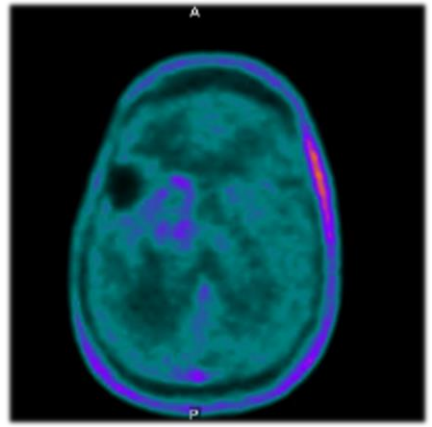
IPAX-I Phase I/II trial of TLX101 for the treatment of GBM[1]

TLX101 in combination with EBRT[2]

- 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
- 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
  - 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

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

Building on the IPAX-1 experience

IPAX-2 will evaluate TLX101 in newly-diagnosed patients

- **Progression of TLX101 program into front-line setting, Phase I/II study expected to commence in Q1 2022**
- 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 radio-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 rates
  - Progression free survival at a range of treatment intervals
- Single-arm, multi-centre trial, expected to enrol 12-15 patients in Phase I
- Patients to be treated and monitored for up to 64 weeks

TLX66 CD-X / TLX66 overview

Application across a range of conditions requiring bone marrow conditioning

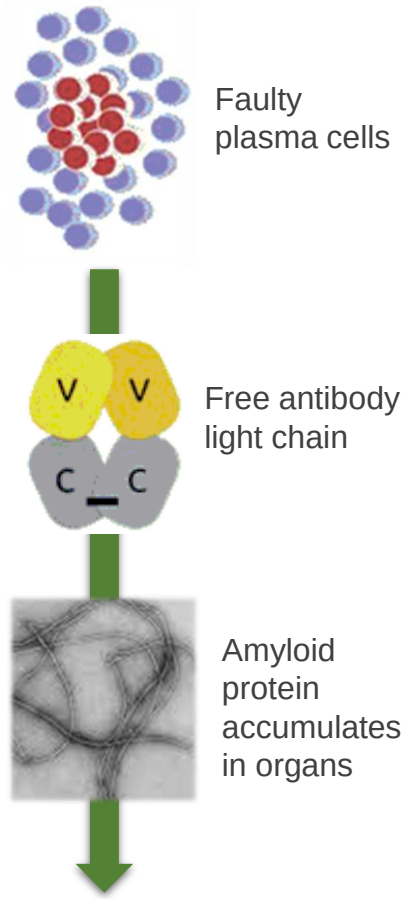
- **Target:** CD66 (Cluster of differentiation 66)
- **Indication:**
  - **TLX66-CDx:** Scintigraphic bone imaging
  - **TLX66:** Bone marrow conditioning for systemic amyloid light chain amyloidosis
- **Development status:**
  - TLX66-CDx (Scintimun®): Approved in EU
  - TLX66: Phase I TRALA study completed in 2021, planning for Phase II study in progress
- **Rationale:**
  - TLX66-CDx: Lower cost, faster than white blood cell labelling (current standard). Data from >100,000 patients in Europe to support regulatory filing in US.
  - TLX66: Significantly reduced toxicity and tolerability compared to chemo-ablative approaches, potential to treat patients ineligible for SoC (e.g., older patients, co-morbidities, children)

Target: CD66	Dx (TLX66-CDx)	Tx (TLX66)
Targeting molecule	Antibody	Antibody
Targeting agent	besilesomab	DOTA-besilesomab
Radionuclide	^{99m}Tc	^{90}Y

New hope in a rare disease

Progressing development of TLX66 in bone marrow conditioning

- SALA[1] 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 TAM[2] in US and ‘EU5’
- Current standard of care comprises induction therapy (cyclophosphamide, bortezomib, dexamethasone) plus high dose melphalan BMC[3], followed by HSCT[4, 5]
- 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 ^{90}Y-besilesomab (TLX66) in SALA
  - **Primary endpoint:** Safety and toxicity of ^{90}Y-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

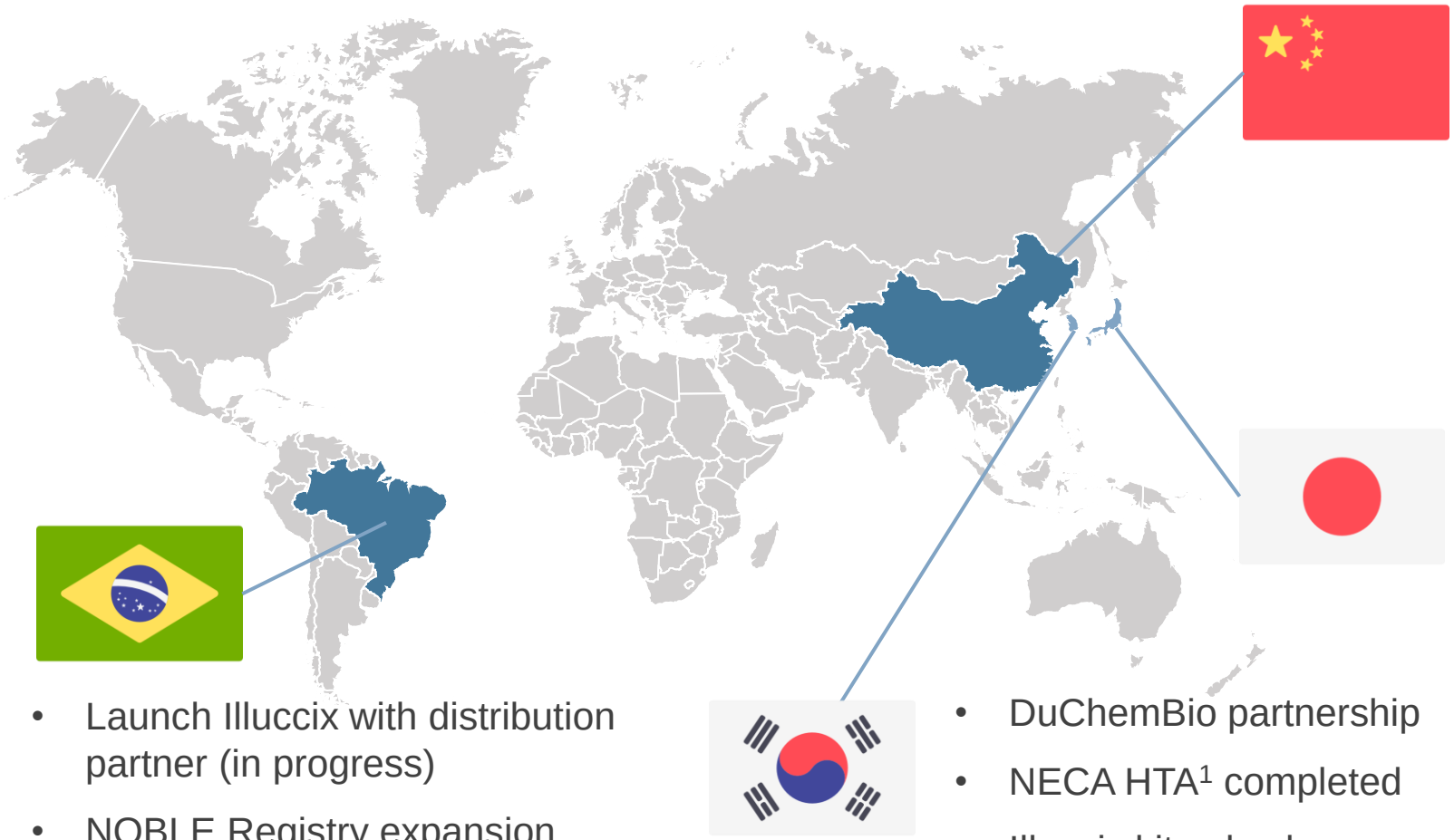


1. Systemic amyloid light chain amyloidosis.
2. Total addressable market.
3. Bone marrow conditioning.
4. Hematopoietic stem cell transplant.
5. Venner C, et al. Blood. (2012) 119 (19): 4387–4390.
6. https://www.clinicaltrialsregister.eu/ctr-search/trial/2015-002231-18/GB

Future value creation
Focus on innovation and growth markets

Near-term growth opportunities

Expansion into new geographic markets



- 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)

- Launch Illuccix with distribution partner (in progress)
- NOBLE Registry expansion

- DuChemBio partnership
- NECA HTA[1] completed
- Illuccix kit sales have commenced, pursuing reimbursement

1. National Evidence-based Healthcare Collaborating Agency. Health Technology Assessment.

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 ^{131}I-based products for export (i.e. TLX101) using Belgian-sourced isotopes (Belgium is a major global supplier)
  - Provides certainty / control over supply chain
- Seneffe will be an integral part of Telix's EU R&D capability
- Enables the capture of intellectual property that is intrinsic in manufacturing scale-up of this class of products
  - First legacy cyclotron removed October 2021, second in November 2021
  - New buildout has commenced

Future research and innovation focus

Targeted alpha therapy

"Next Generation" therapeutics with alpha-emitting radioisotopes

MTR[1] + immuno-oncology

MTR sets the “groundwork” for cancer immuno-therapy in combination

Tumour microenvironment

Combining MTR with standard of care treatments for improved efficacy with biomarker-driven patient selection

Artificial intelligence (AI)

Tools to maximise clinical insights gained from imaging, link to therapeutic outcomes

Radio-guided surgery

Bringing molecular imaging into the operating room (OR)

1. Molecularly targeted radiation

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