TELIX PHARMACEUTICALS

Precision Oncology

Clinical Trial Program Update
Q3 2019

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Executive summary

- ZIRCON Ph III (renal cancer imaging) : EU/AUS recruiting, US to start Q1 ‘20
  - *Expect completion of enrolment Q2 2020*
- ZIRDAC Japan (Ph I/II bridging study to ZIRCON) : Study approved – first patient in expected next month (December ‘19)
- ENHANCING study (prostate cancer imaging) : Recruiting to plan
- Multiple investigator studies using prostate imaging kit – excellent US and EU reference sites for market launch next year
- IPAX-1 study Ph I/II (brain cancer imaging) : Five sites actively recruiting, final site to open during Q4 2019
  - *Clinical update on initial patient experience by end-year (December ‘19)*
- Renal cancer Ph II and Prostate cancer Ph III therapy protocols in final preparation for regulatory submissions (FDA)

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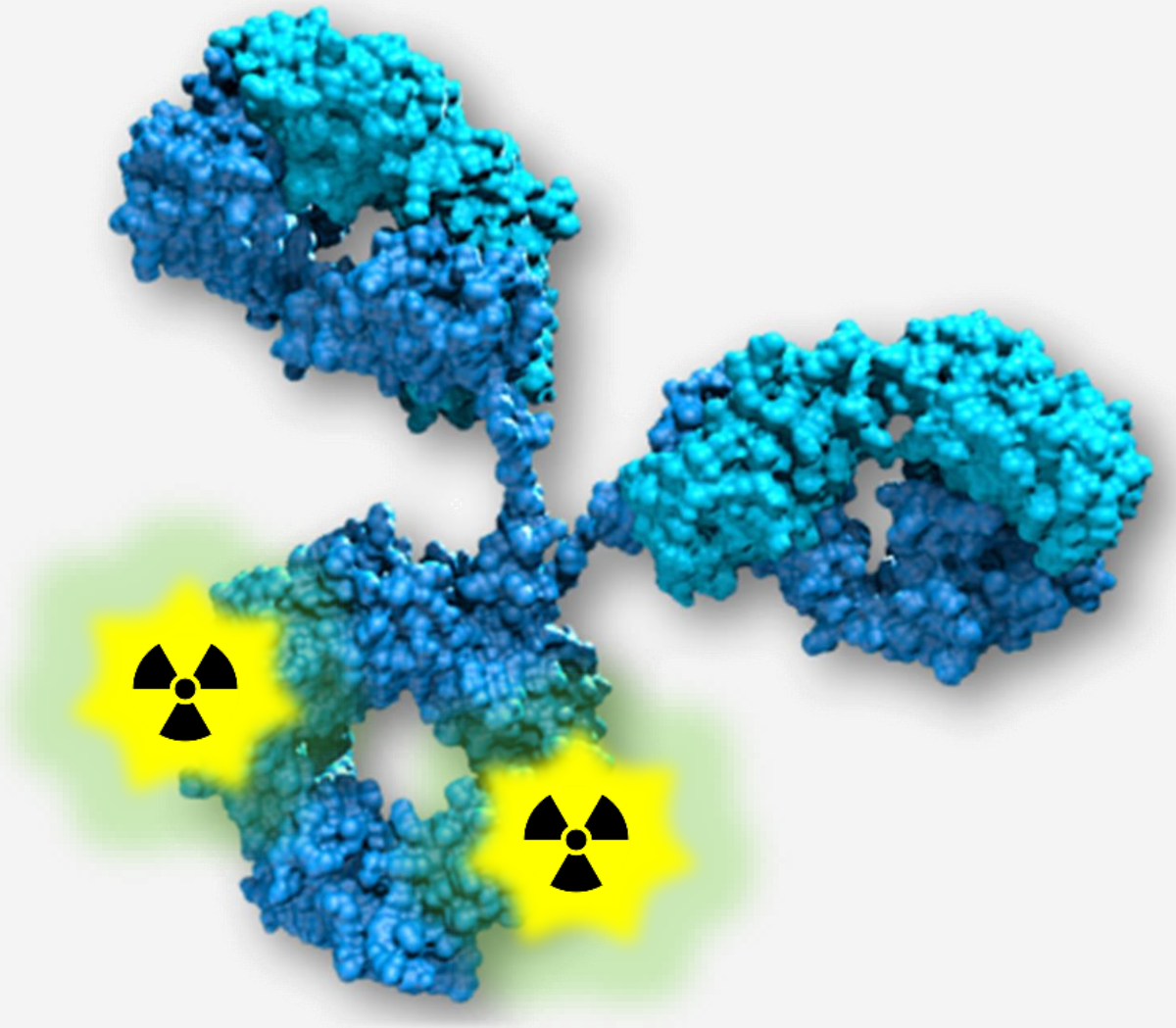
Technology and Product Overview



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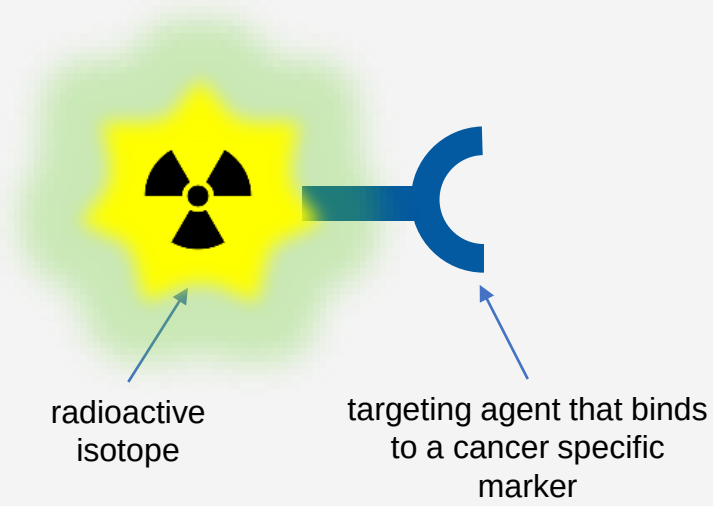
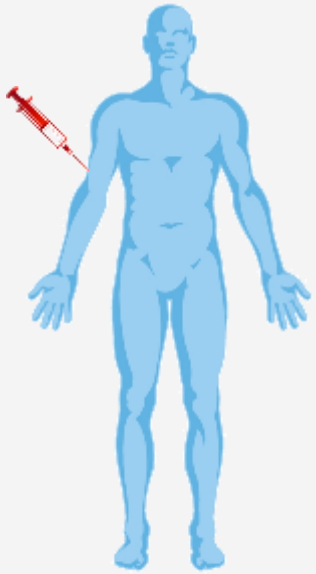
Telix's core technology is Molecularly Targeted Radiation (MTR)

MTR



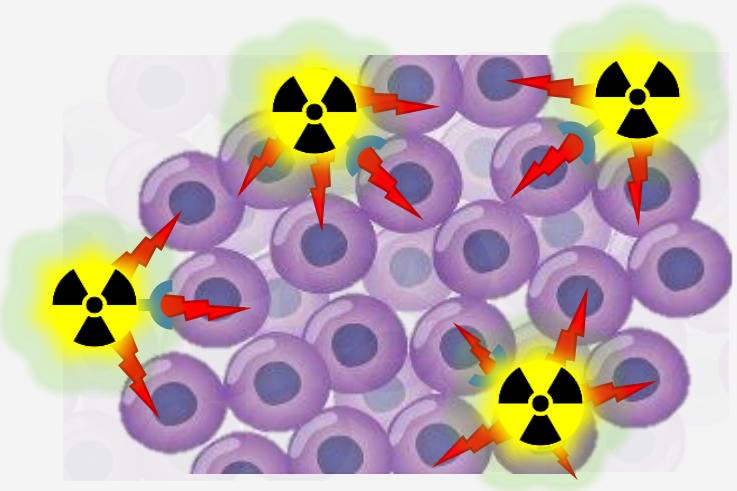
Unique markers or "targets" on cancer cells are the "address" to which the radioisotope is delivered

Systemic administration



MTR is administered via the blood stream and attaches to cancer cells, wherever they are, including tiny metastases

Targeted delivery of radiation to cancer cells



MTR precisely targets cancer cells.

- Low doses are used to image the patient ("*See the cancer*")
- High doses destroy the cancer cells ("*Treat the cancer*")

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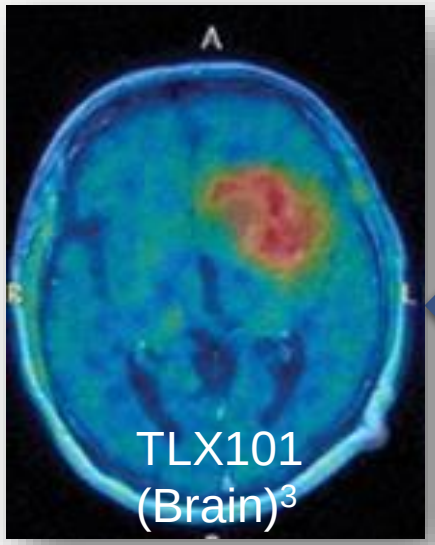
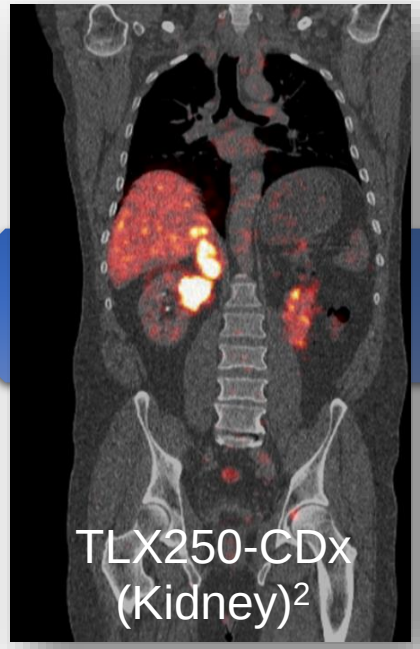
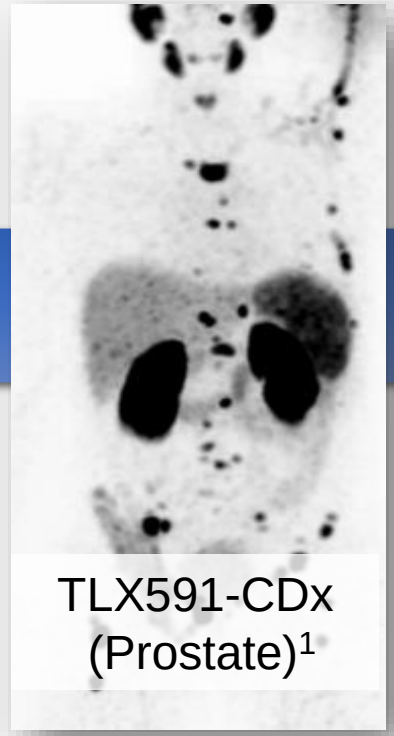
MTR enables precise imaging of the cancer

- ✓ Patient selection – ensuring the patient receives the right therapy
- ✓ Therapy optimisation – tailoring the radiation dose to the patient's actual disease burden
- ✓ Early revenue generation – imaging product development is faster than therapy product





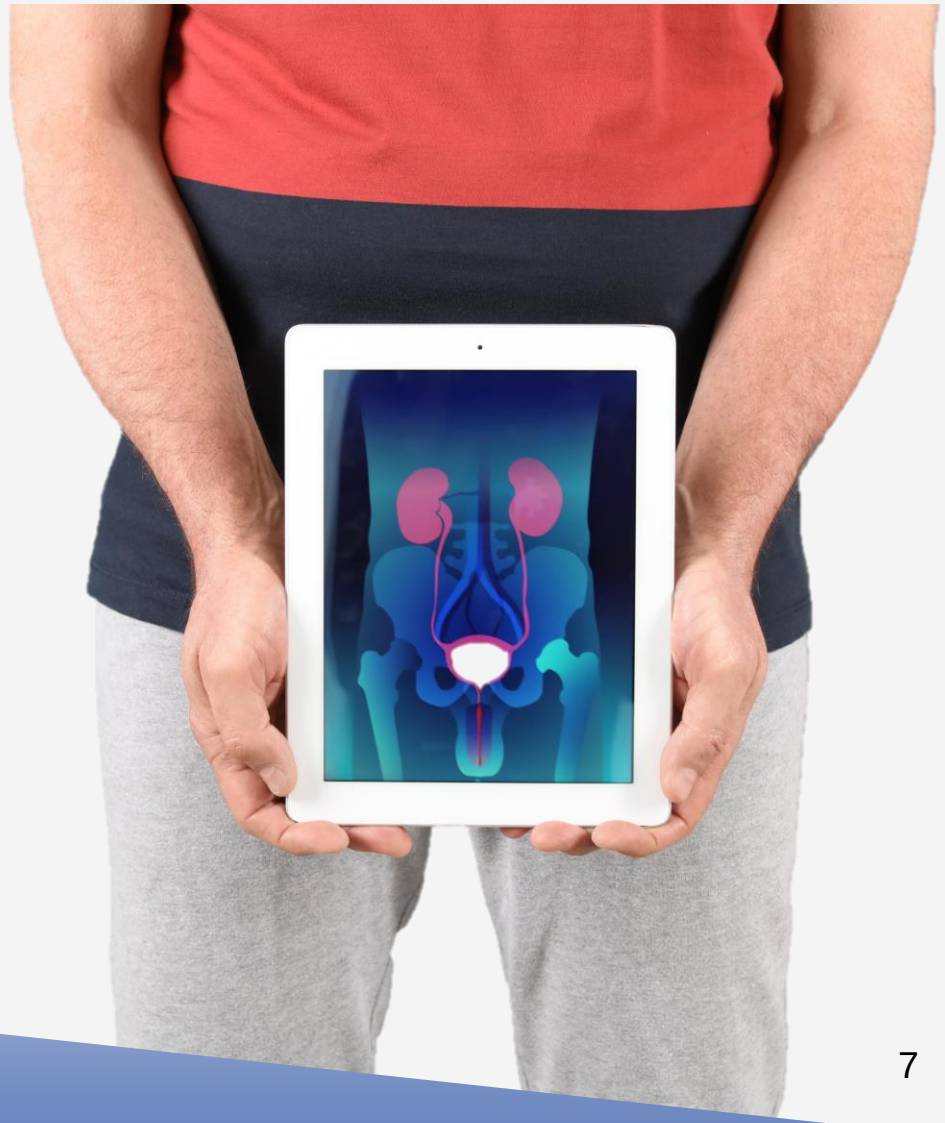


Positron Emission Tomography – "PET" Imaging

[1] Courtesy of Dubai Nuclear Medicine & Molecular Imaging Center, UAE
[2] Courtesy of Radboud University Medical Centre, Netherlands
[3] Courtesy of ZentralKlinik Bad Berka, Germany

Telix's strategy for developing clinically-validated MTR therapeutics

- ✓ Focus on MTR technologies that are well validated by existing data – manage clinical risk
- ✓ Combine with companion imaging agent targeting the same cancer-specific marker
- ✓ Integrate with the existing standard of care for cancer treatment to gain acceptance
- ✓ Establish a global supply chain that ensures product availability, establish confidence



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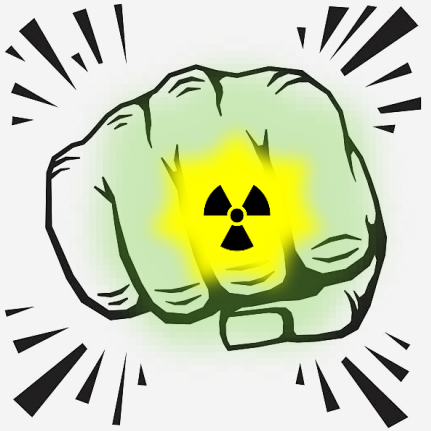
Why is MTR so effective at treating cancer?

Benefit	Impact
Precise	Minimal “off-target” damage to surrounding healthy tissues / organs
Systemic	Targets cancer cells wherever they are in the body
Durable	Targets cancer cells and also destroys the tumour micro-environment
Multi-modal	Directly kills cancer cells as well as mobilises the immune system
Personalised	Imaging enables patient selection and treatment optimisation
Synergistic	Compatible and often synergistic with other cancer treatments



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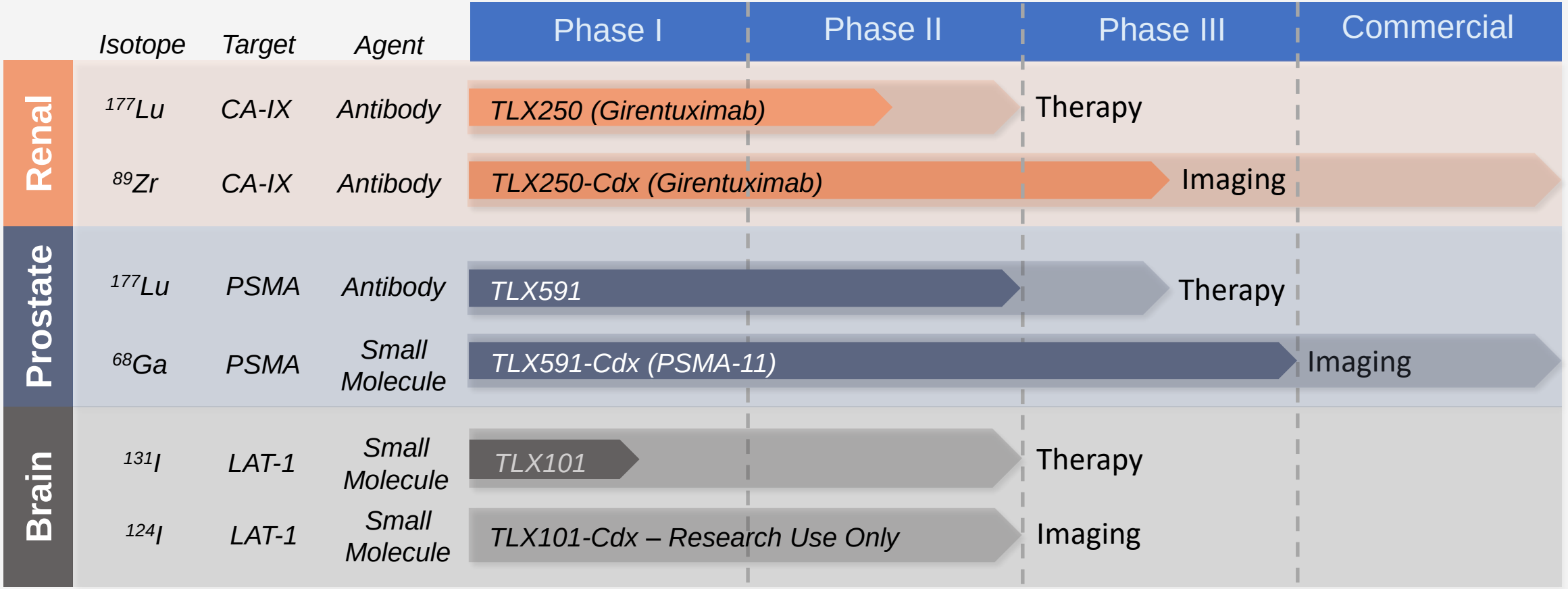
Telix's clinical pipeline focuses on three main cancers



Shaded arrows indicate the company's development objectives over the next 12 months
CDx denotes "Companion Diagnostic"

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Summary

- ✓ Late stage pipeline of Molecularly Targeted Radiation (MTR) imaging and therapy products assets, significantly de-risked by extensive existing clinical data
- ✓ Three main focus areas : prostate, kidney and brain cancer
- ✓ Development of both imaging and therapy indications to optimise therapy delivery and achieve early revenue
- ✓ Precision medicine approach inherent to MTR is the future of medicine

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Clinical Program Update

Telix clinical trials

Trial	Locations	Indication	Status
ZIRDOSE	Netherlands	Kidney (Imaging)	Complete (Ph I)
IPAX-1	EU (NL/AT/BE), Australia	Brain / GBM (Therapy)	Recruiting (Ph I/II)
ENHANCING Enzalutamide-Enhanced Imaging	Australia	Prostate (Imaging)	Recruiting (Ph II)
ZIRDAC Japan	Japan	Kidney (Imaging)	Recruiting (Ph I/II)
STARLITE-1	USA	Kidney (Therapy)	Pending (Ph II)
STARLITE-2	USA	Kidney (Therapy)	Pending (Ph II)
ZIRCON	EU, Turkey, Canada, USA	Kidney (Imaging)	Recruiting (Ph III)
PROSTACT	Australia, US	Prostate (Therapy)	Pending (Ph III)

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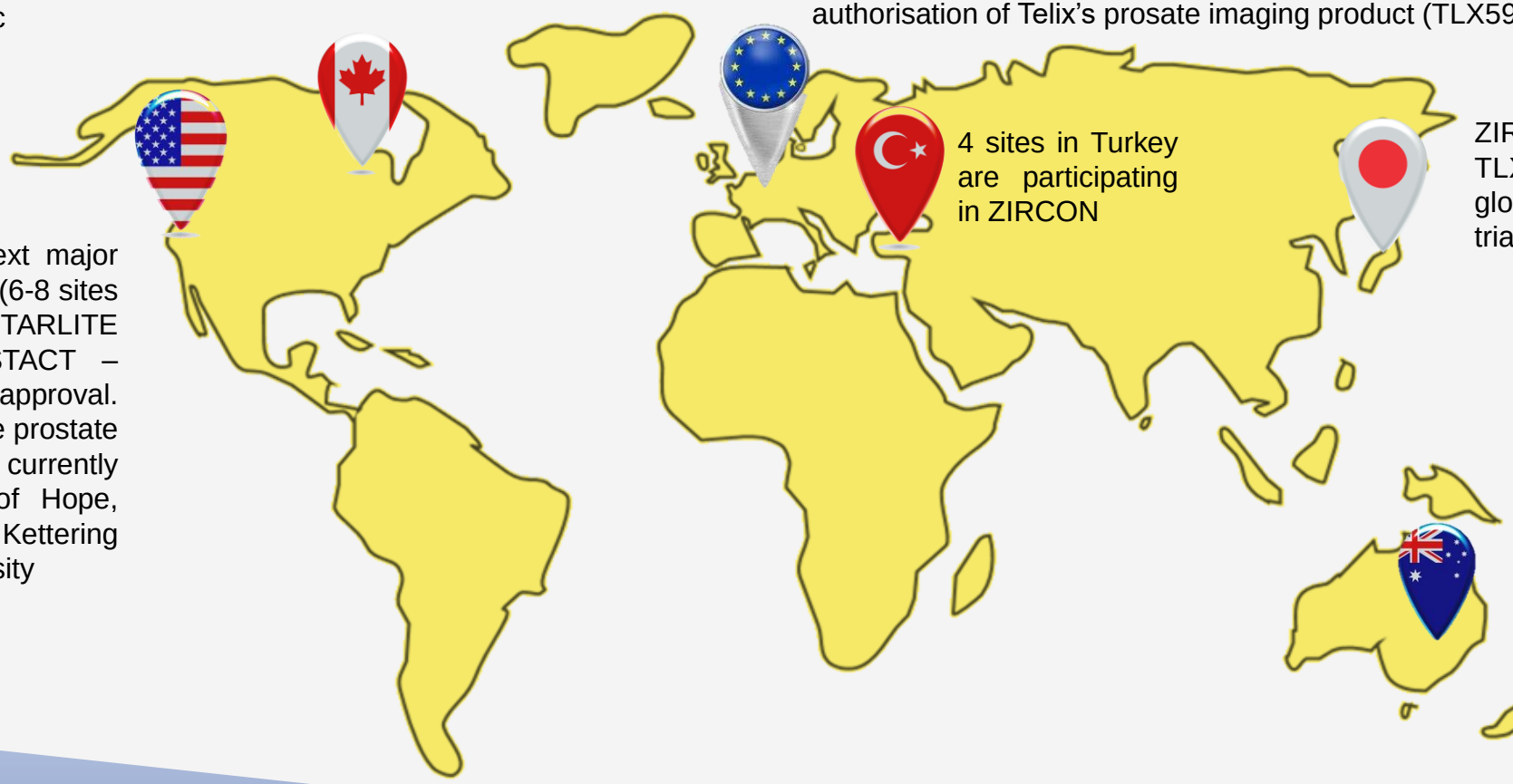
Key clinical activity overview by geography

At least two sites in Canada are planned for ZIRCON, subject to HealthCanada approval. TLX250-CDx drug product is also manufactured in Canada by Isologic

Europe is the dominant recruitment territory for ZIRCON and IPAX-1 (19 centres across both trials). Europe is also key for additional clinical data collection to support the marketing authorisation of Telix's prosate imaging product (TLX591-CDx)



4 sites in Turkey are participating in ZIRCON

ZIRDAC trial – Phase I/II for TLX250-CDx to bridge to global Phase III ZIRCON trial

The US is the next major focus for ZIRCON (6-8 sites planned), the STARLITE trials and PROSTACT – subject to FDA approval. Three collaborative prostate imaging INDs currently running at City of Hope, Memorial Sloan Kettering and Emory University

IPAX-1 and ZIRCON trials are active in Australia. ENHANCING prostate imaging study in collaboration with GenesisCare

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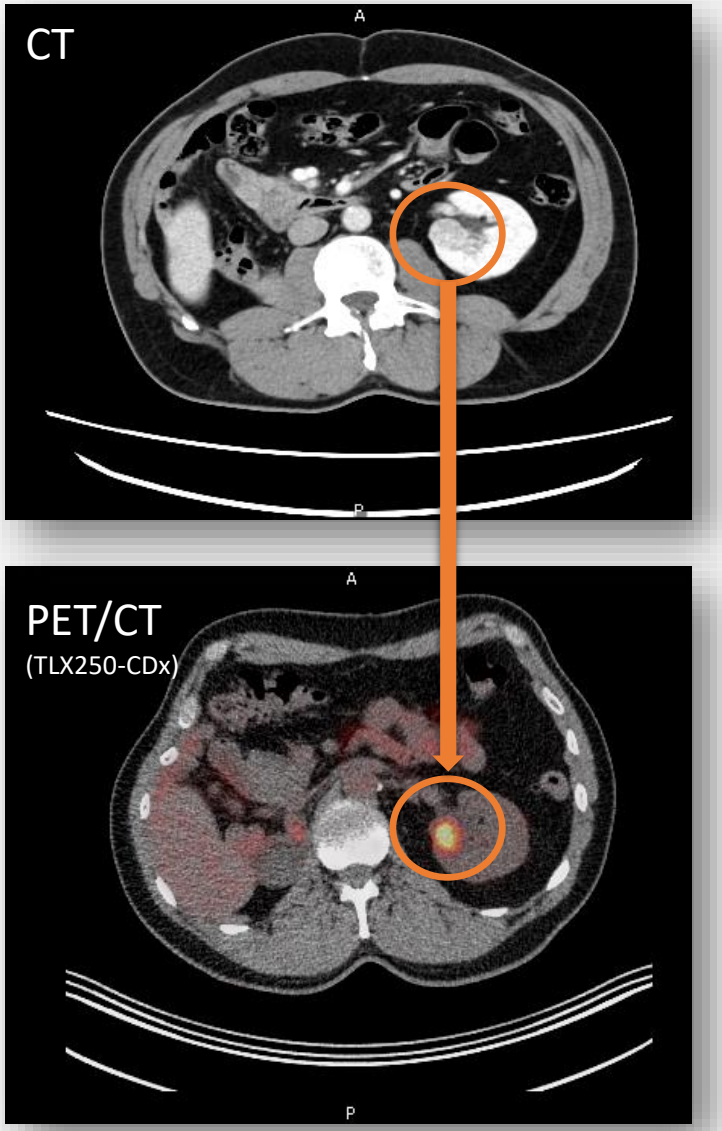
Renal cancer program status

Imaging : ZIRCON Phase III study progressing nicely

- Initial Australian and EU sites have launched well – adding patients weekly
- All AU/EU sites will be fully online by end-Nov (21 sites in total)
- US/Canadian regulatory submission expected to be completed by end-Nov (following successful pre-IND meeting with FDA earlier this year)
- Targeting completion of enrolment by late Q1 / early Q2 next year – slightly delayed (3-4 months) due to US regulatory submissions
- Japanese bridging study (ZIRDAC) will start first patients in December ‘19

Therapy : Regulatory documentation in preparation

- STARLITE protocols nearly finalised with US clinical sites – rapidly moving “standard of care” has delayed finalisation
- Manufacturing of antibody conjugate complete, currently validating radiolabelling process to finalise manufacturing package
- IND preparation in progress with submission planned early 2020



Courtesy of Radboud University Medical Center (RUMC), Netherlands

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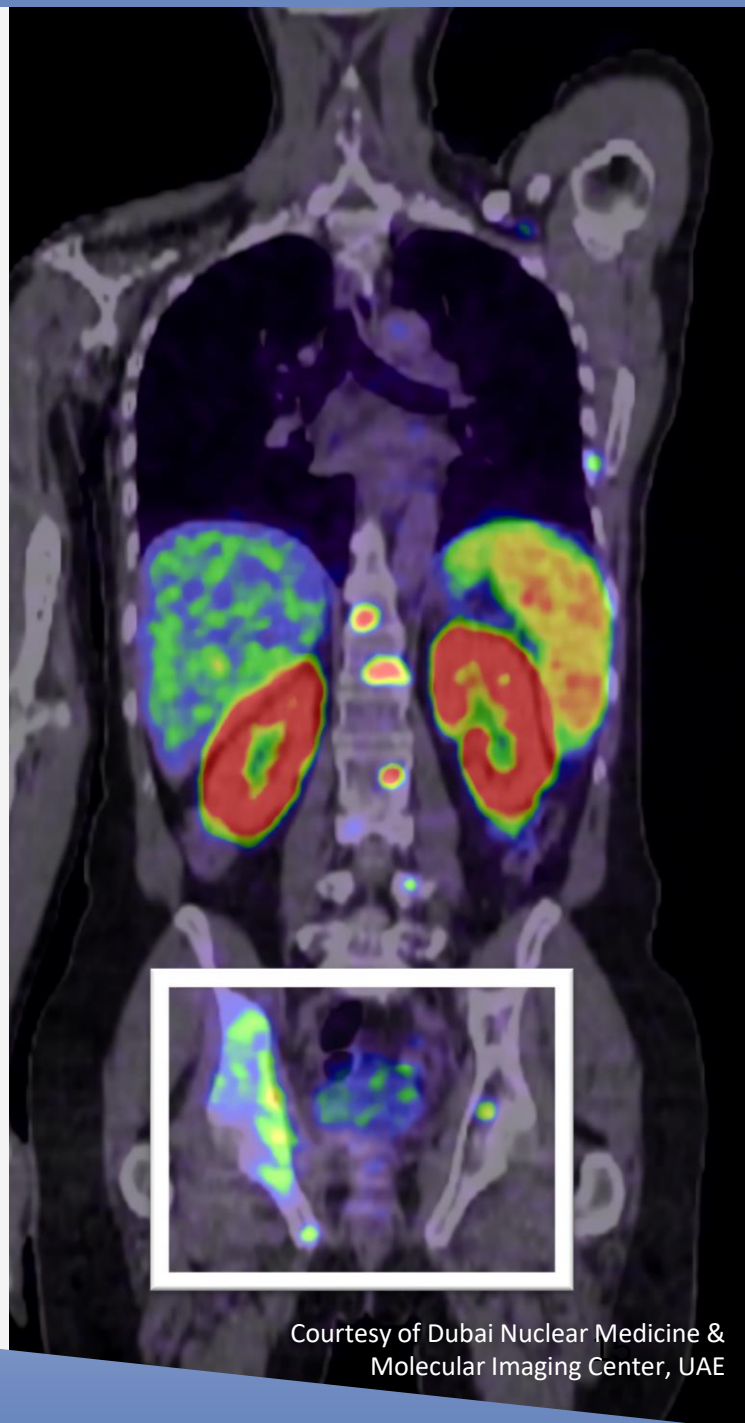
Prostate cancer program status

Imaging : Preparing for market launch

- Focus is on data collection building reference sites for market launch
- Clinical/data collaboration with Bologna, Linz and Université libre de Bruxelles to support EU marketing authorisation
- Three collaborative US academic INDs with City of Hope, Memorial Sloan Kettering and Emory University – key reference sites in the US (recruiting well)
- ENHANCING study with GenesisCare (Australia) has recruited initial patients – to inform combination prostate therapy trial design for Phase III (ProstACT)

Therapy : Clinical trial design readiness for FDA review

- ProstACT Phase III protocol is nearly complete – in final review
- Pre-Phase III meeting FDA meeting request to be submitted January, subject to clinical advisory board sign-off
- Significant commercial interest in the ProstACT study



Courtesy of Dubai Nuclear Medicine & Molecular Imaging Center, UAE

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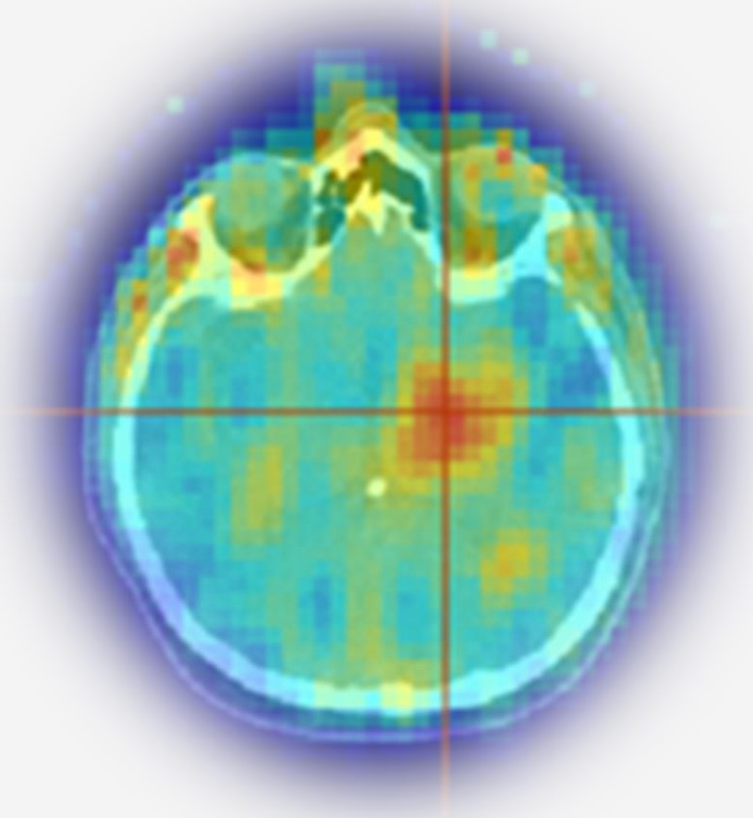
Brain cancer (glioblastoma) program status

Therapy : Successfully recruiting

- 5/6 sites up and running (remaining EU site online before year-end, one site dropped)
- Dosing for both single and triple fraction regimens has commenced
- Some site initiations were delayed by EU summer - recruitment now tracking at expected rate
- Interim clinical update by end-December (initial dosing experience)
- Phase II portion of the study expected to commence mid-2020

US Activity

- Extensive US clinical interest in TLX101
- Drug Master File (DMF) will be filed with the FDA before year-end to support potential US clinical collaborations
- First US investigator-led study in planning for 1H 2020



Actual brain scan from an IPAX-1 patient showing TLX101 drug targeting in a tumour (Courtesy Keppler University Clinic, Linz AT)

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Commercialisation of prostate imaging product

US and EU marketing authorisations are a major focus

- Successful pre-NDA meeting with the FDA and consultations with key EU competent authorities – clear guidance given
- US New Drug Application (NDA) submission imminent
- EU marketing authorisation submission planned Q1 2020
- Expecting several temporary EU authorisations in the next few months

Market Launch Planning

- Currently augmenting US and EU distribution agreements to support a commercial product roll-out (as opposed to just the “kit”)
- Coding / reimbursement readiness – in progress
- Building sales training and education packages to support launch

^{68}Ga–PSMA-11

illumet™

Kit for the preparation of ^{68}Ga-PSMA-11 Injection

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Summary

- Excellent progress over the last quarter, across all programs (globally)
- Telix-sponsored trials are recruiting well alongside investigator-led studies to establish further clinical experience in advance of market launch for prostate cancer imaging (TLX591-CDx/ *illumet*™)
- Notable upcoming clinical milestones:
  - ✓ US Ph III ZIRCON IND submission (Nov)
  - ✓ Submission of US Drug Master File for TLX101 (Nov)
  - ✓ US NDA submission for TLX591-CDx (Nov/Dec)
  - ✓ First Japanese patient in ZIRDAC / TLX250 (Dec)
  - ✓ Initial reporting of IPAX-1 glioblastoma therapy experience (Dec)
  - ✓ Submission of TLX591 Ph III clinical protocol to FDA (Jan)

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