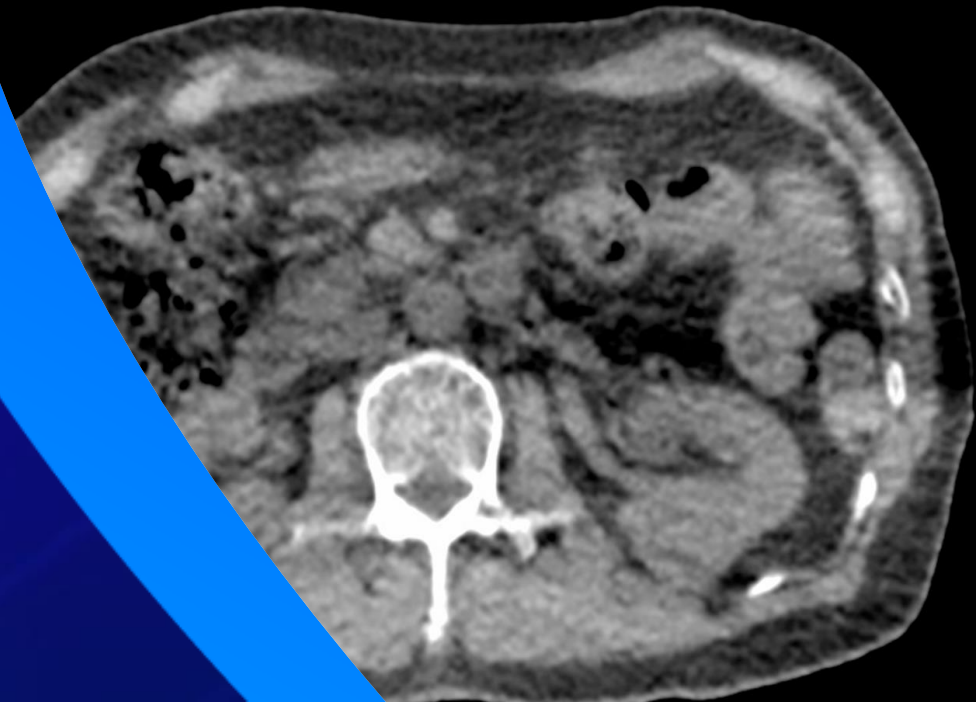
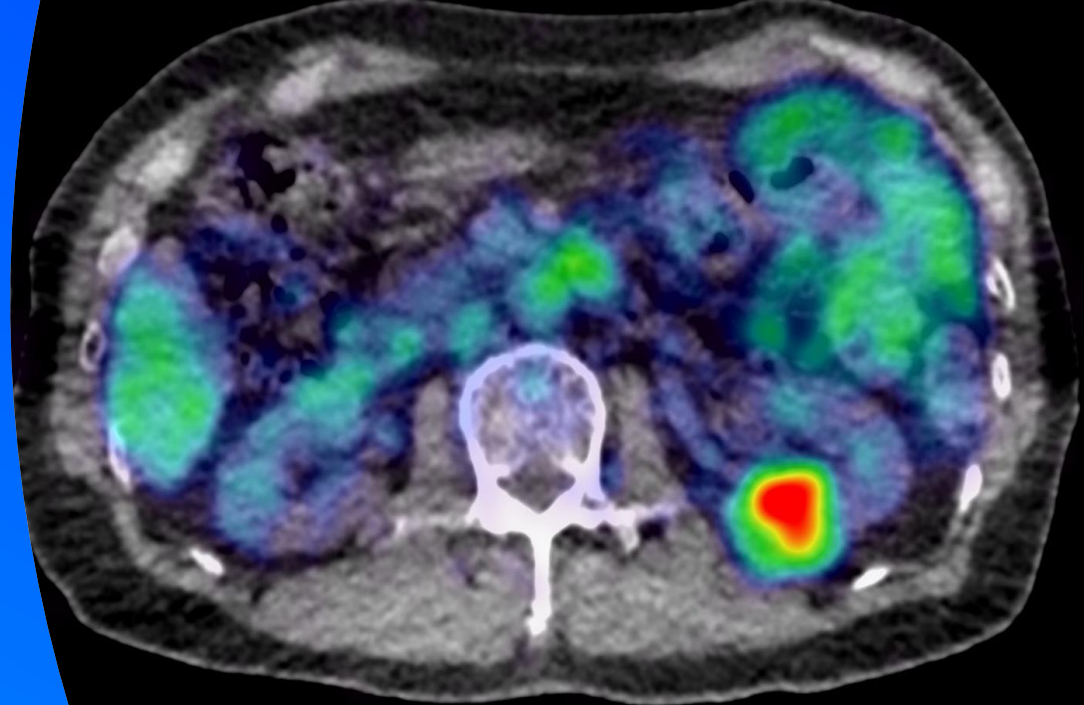




ZIRCON Phase III Study Top-Line Data

Telix Pharmaceuticals (ASX:TLX)

7 November 2022



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TLX250-CDx has not received a marketing authorisation in any jurisdiction. Telix’s lead product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been approved by the Australian Therapeutic Goods Administration (TGA), the U.S. Food and Drug Administration (FDA), and Health Canada. Full United States prescribing information for Illuccix can be found at <http://illuccixhcp.com/s/illuccix-prescribing-information.pdf>

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ZIRCON

A confirmatory, prospective, open-label, multi-centre phase III study to evaluate diagnostic performance of ^{89}Zr -labelled girentuximab (^{89}Zr -TLX250) to non-invasively detect clear cell renal cell carcinoma (ccRCC) by positron emission tomography/CT (PET/CT) imaging in patients with indeterminate renal masses.

(Zirconium Imaging in Renal Cancer Oncology)

Summary: ZIRCON Phase III study meets primary endpoints

Highly positive results support potential for TLX250-CDx to change standard of care

Top-line data

- **Primary endpoint met:** Sensitivity of $\geq 84\%$ and specificity of $\geq 84\%$ in all three readers (86% / 87% overall)
- Considerably exceeds confirmatory trial sensitivity and specificity success target of 70%
- **Key secondary endpoints met,** namely sensitivity and specificity targets in small renal masses (less than 4cm) has also been exceeded

TLX250-CDx is being developed as a PET/CT imaging agent for use in the characterisation of indeterminate renal masses previously identified on CT or MRI as clear cell renal cell carcinoma (ccRCC) or non-ccRCC

Key takeaways

- Positive results demonstrate that TLX250-CDx provides a way to non-invasively diagnose clear cell renal cell carcinoma – delivering on a major unmet medical need
- Data strongly validates that the CAIX target is potentially as ground-breaking in ccRCC, as PSMA has been for prostate cancer
- Potential to change standard of care in the diagnosis of renal masses
- An effective non-invasive tool can potentially reduce reliance on invasive biopsy or surgery for diagnosis
- Telix will pursue global regulatory approvals for TLX250-CDx based on clinical data obtained in the U.S., Canada, European Union, United Kingdom and Australia

Carbonic Anhydrase IX (CAIX) program

Phase III imaging study complete, potential to develop as a pan-cancer target

Product Candidate

TLX250-CDx (⁸⁹Zr-DFO-girentuximab)
“Breakthrough Designation” from the U.S. Food and Drug Administration (FDA)

Targeting Molecule

Monoclonal antibody (mAb)

Indication

Clear cell renal cell carcinoma (ccRCC)

Target

Carbonic anhydrase IX (CAIX)
Cell surface antigen

Scientific Rationale

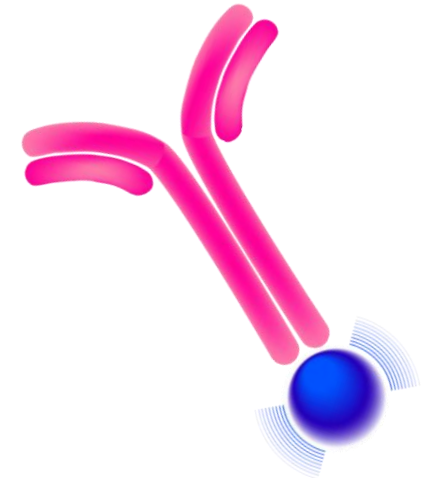
- TLX250-CDx has high affinity for CAIX, a tumour-associated antigen expressed in up to 95% of ccRCC and many hypoxic solid tumours, with low expression in normal tissue
- Hypoxia correlates with progression and resistance to therapy
- ⁸⁹Zr half-life optimal for detection of small tumour lesions with this class of targeting agent

Clinical Rationale

- Detection of renal masses increasing due to widespread use of cross-sectional imaging
- Diagnostic challenge: current imaging cannot reliably distinguish benign or malignant lesions from ccRCC
- TLX250-CDx excellent target localisation enables a wide window (several days) for PET scanning, potential for scheduling flexibility for patient convenience
- TLX250-CDx may offer improved surgical staging, aid decision making and avoid unnecessary biopsy / surgery

Targeting Agent:
girentuximab

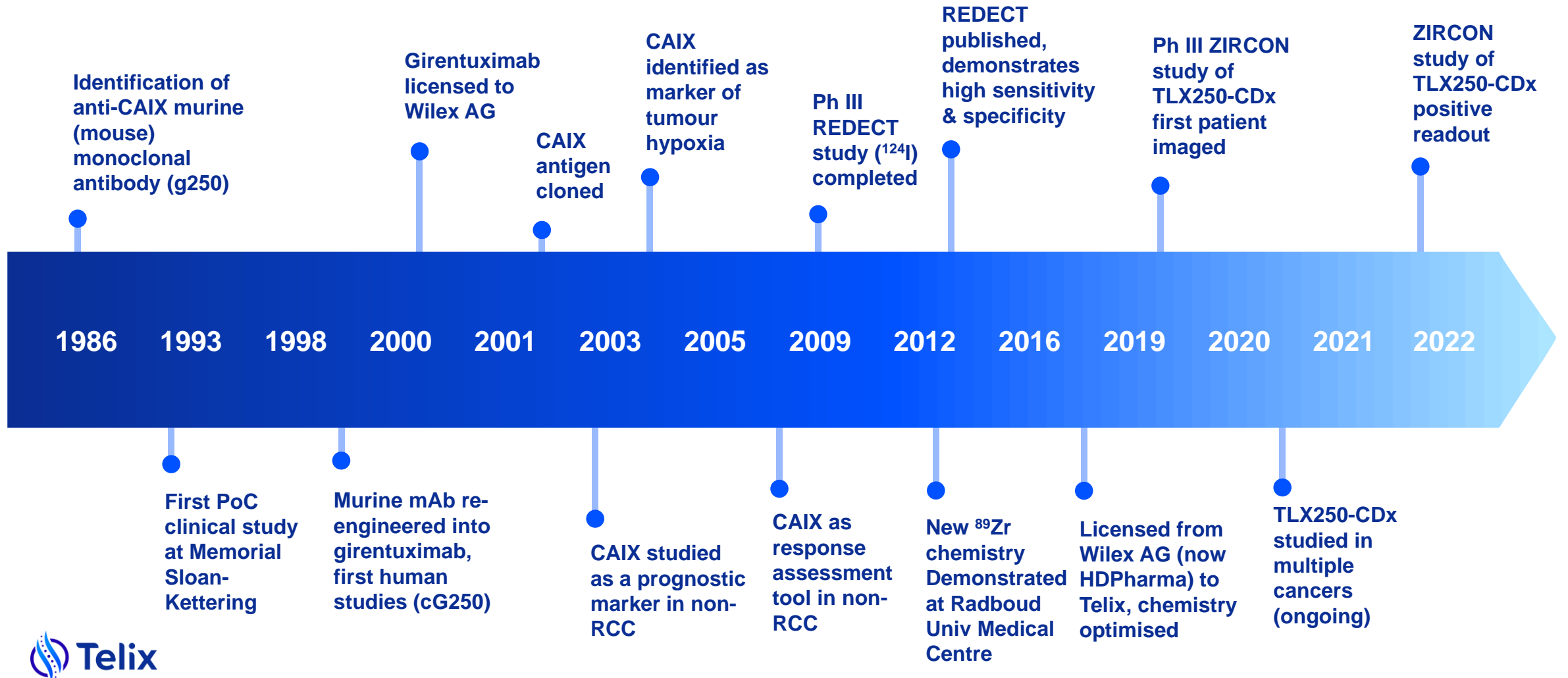
IgG1 monoclonal antibody



Payload: ⁸⁹Zr
Positron emitter
T_{1/2} 3.3 days

Targeting CAIX: the scientific journey

TLX250-CDx builds on a strong scientific pedigree



ZIRCON study overview

Study design and goals

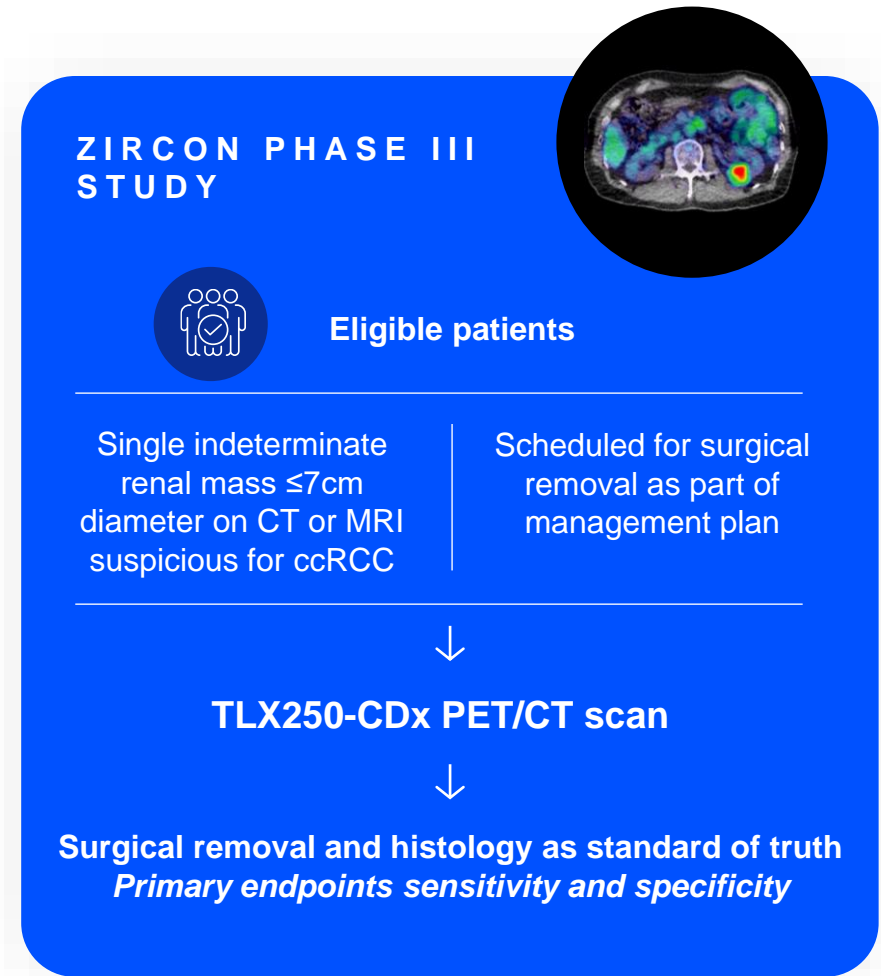
Primary endpoint: Sensitivity and specificity of PET/CT imaging with TLX250-CDx to detect ccRCC in patients with renal masses, using histology from surgical resection as standard of truth

Study goal: A sensitivity/specificity threshold of 70% was agreed with the FDA as a confirmatory trial objective (independent readers must demonstrate $\geq 70\%$ sensitivity/specificity)

Key secondary endpoint: Commensurate sensitivity and specificity in patient sub-group with small renal masses of ≤ 4 cm in diameter (T1a classification)

Study outcomes:

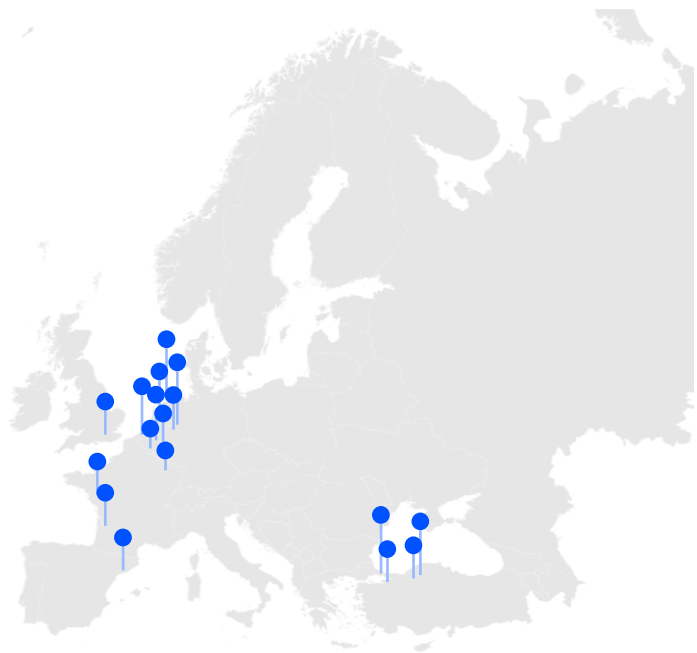
- Primary endpoint met: Sensitivity of $\geq 84\%$ and specificity of $\geq 84\%$ in **all three** readers (86% / 87% overall)
- Key secondary endpoint met: Sensitivity/specificity were also exceeded (85% / 89% overall) in T1a patient subgroup
- 93% positive predictive value (secondary endpoint)
- Full clinical data to be presented a major medical congress in Q1 2023



ZIRCON study participation

A large-scale global study

300 patients enrolled | **36 sites** | **9 countries**



Europe | 17 sites



North America | 13 sites



Australia | 6 sites

What do clinicians around the world say?

Results reinforce the broad clinical applicability and potential of TLX250-CDx



**A/Prof. Brian Shuch,
MD**

Director, Kidney Cancer Program, UCLA Institute of Urologic Oncology

“A positive result from the study is a critical step in better diagnosing clear cell renal cancer. Having an imaging product like TLX250-CDx will be so important in managing the continued increase incidence of small renal masses and reducing the need for unnecessary invasive surgery for lesions that in the prior era were often found to be benign at the time of surgery.”



**Mr Gregory Jack,
F.R.A.C.S.**

General Urological Surgeon, Austin Health and Olivia Newton John Cancer Centre

“Kidney cancer is a diagnostic dilemma for the majority of our patients. Without biopsy or surgery, we can’t currently give them the information they need. Based on this result from the ZIRCON Phase III study, TLX250-CDx may help us to be more accurate in who we treat, whilst also providing reassurance for those patients who don’t need treatment.”



**Prof. Françoise
Kraeber-Bodéré, MD,
PhD**

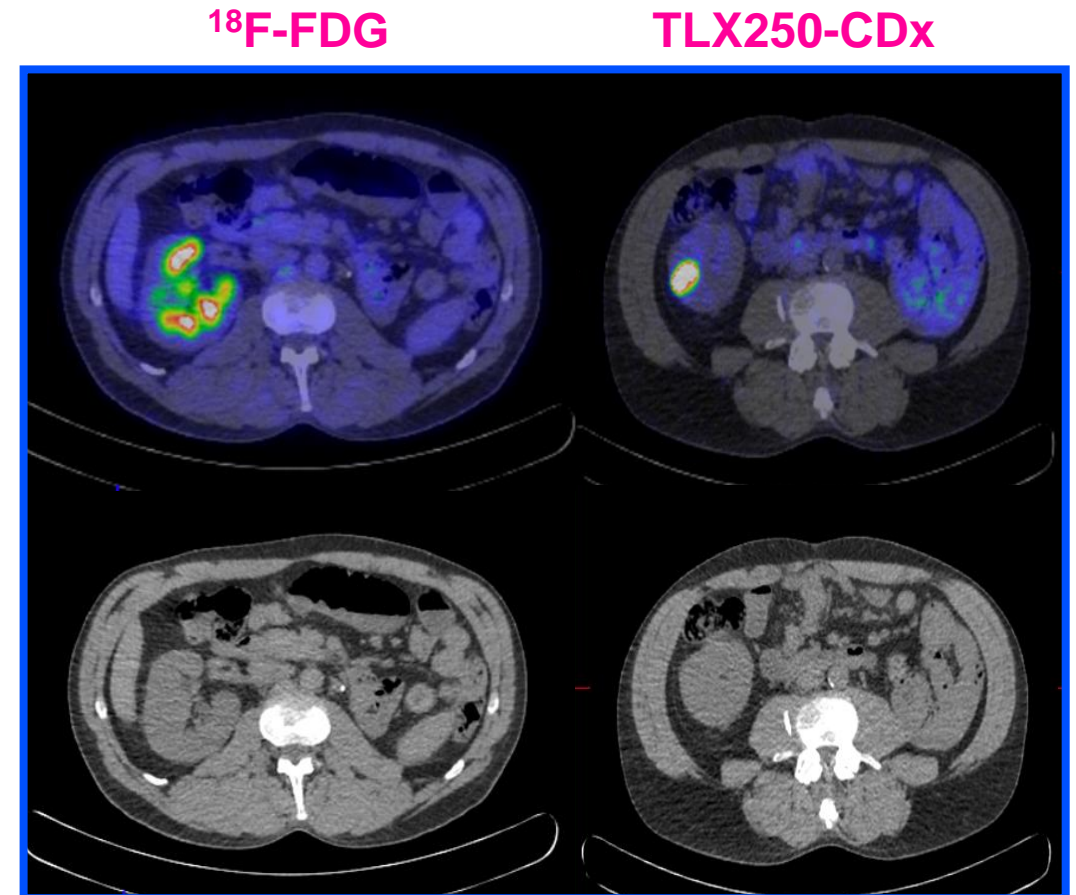
Nuclear Medicine Department - CHU Nantes

“Results from the Phase III ZIRCON study of TLX250-CDx should represent a major milestone in the management of small renal lesions and the diagnosis of clear cell renal cell carcinoma. There is so much potential in optimal targeting of CAIX, paving the way for better staging of this neoplasia and a theranostic approach.”

TLX250-CDx in action: a case study

Austin Health (Melbourne, Australia)

- 57-year-old male with a single kidney (prior nephrectomy)
- FDG scan was equivocal
- FDG is typically of limited value in understanding of renal cell carcinoma owing to high urinary clearance, decreased contrast between renal lesions and normal tissue that can mask renal pathology
- Imaging with TLX250-CDx non-invasively diagnosed a solitary ccRCC lesion in the kidney
- This allowed the patient to receive a partial nephrectomy (localised resection), preserving remaining renal function

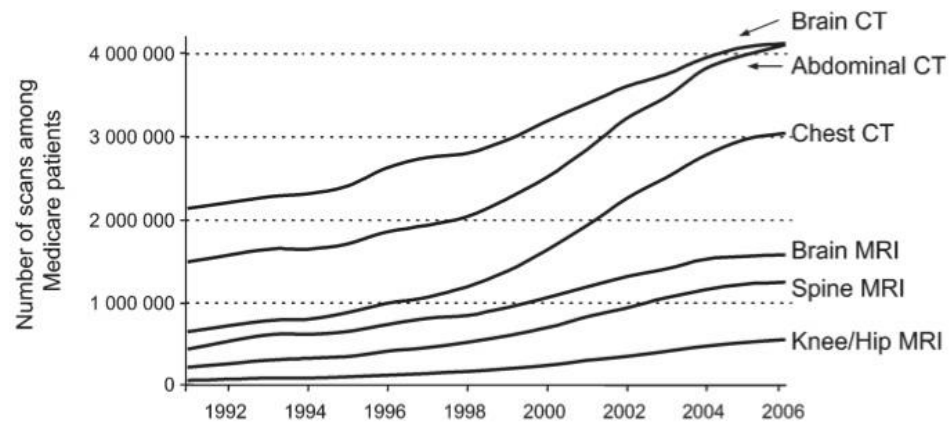


The clinical and commercial opportunity



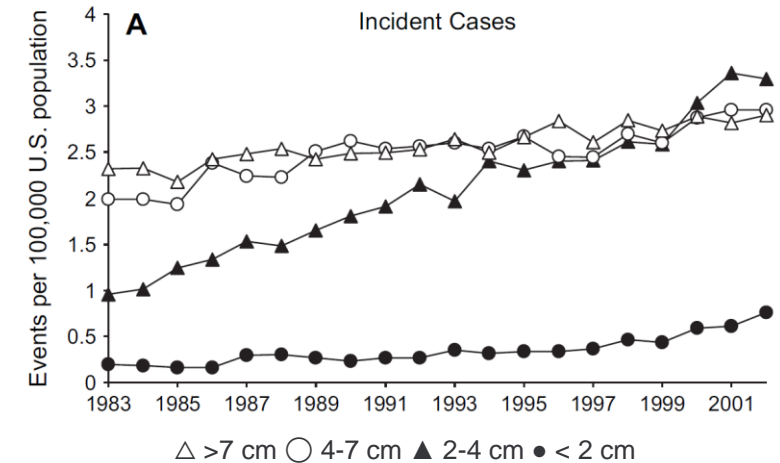
The indeterminate renal mass “epidemic”

Widespread imaging has led to an increase in incidental detection of renal masses



Since the 1980s – incidental detection of renal masses has increased – in line with greater use of CT for abdominal imaging

- The majority of these are asymptomatic and unrelated to why imaging was performed
- Current imaging provides anatomic information but does not diagnose renal cancer

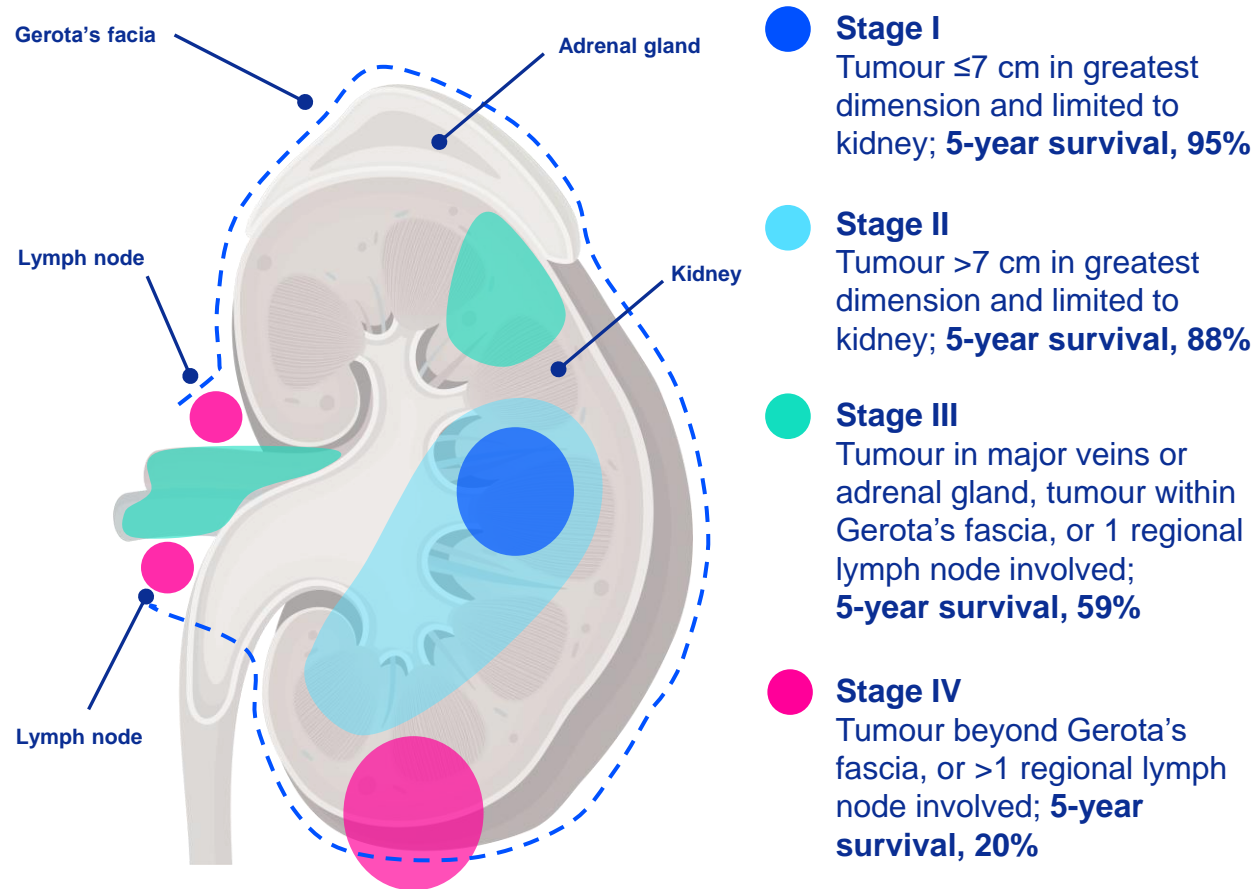


There is an “epidemic” of indeterminate small renal masses

- Asymptomatic and difficult to confidently diagnose as benign or malignant at the time of discovery
- Prevalent in patients > 50 years old
- Age, obesity, diabetes, hypertension and smoking are key risk factors for renal masses

Improving outcomes for patients with small renal masses

Five-year survival rates increase dramatically if diagnosed early



Early disease is often asymptomatic, can be targeted surgically or with ablative therapy, survival rate is high if targeted accurately

The diagnostic dilemma

- Overtreatment or undertreatment could affect both survival and quality of life
- Small masses, in particular ≤ 4 cm, pose the greatest dilemma – invasive biopsy is not always conclusive and carries risk

Late stage needs accurate assessment and complete tumour burden to properly plan treatment

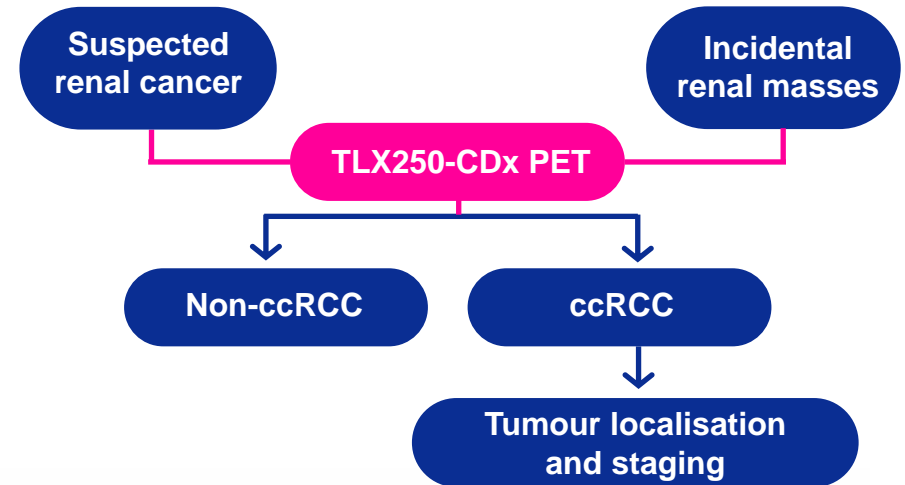
The role of TLX250-CDx in the patient journey

- Most patients will be referred to a urologist for additional imaging study to better characterise a renal mass – but a biopsy or surgery is currently the only method to diagnose cancer
- There are many subtypes of kidney cancer – ccRCC is the most aggressive and the most prevalent (approx 80%)
- Small renal masses represent the biggest diagnostic challenge

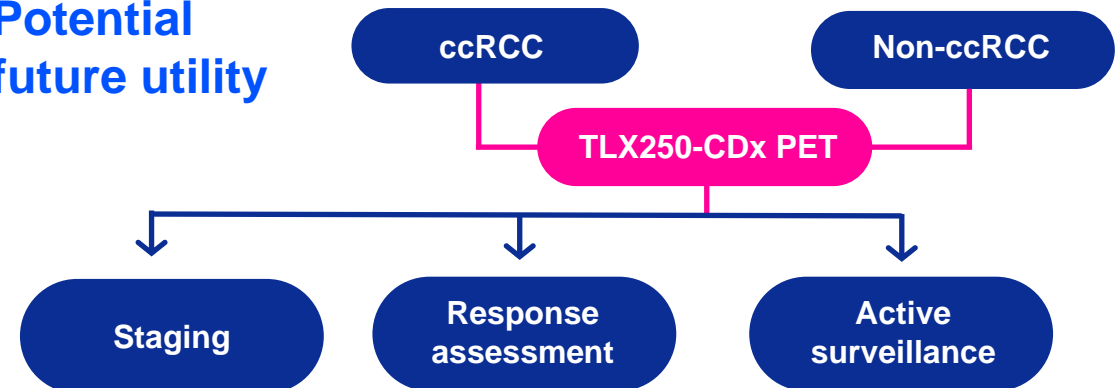
Potential indications

- Under the “breakthrough designation” the initial indication is for use in the characterisation of indeterminate renal masses previously identified on CT or MRI as ccRCC or non-ccRCC
- Potential future utility could include active surveillance, staging and response assessment

Core indication

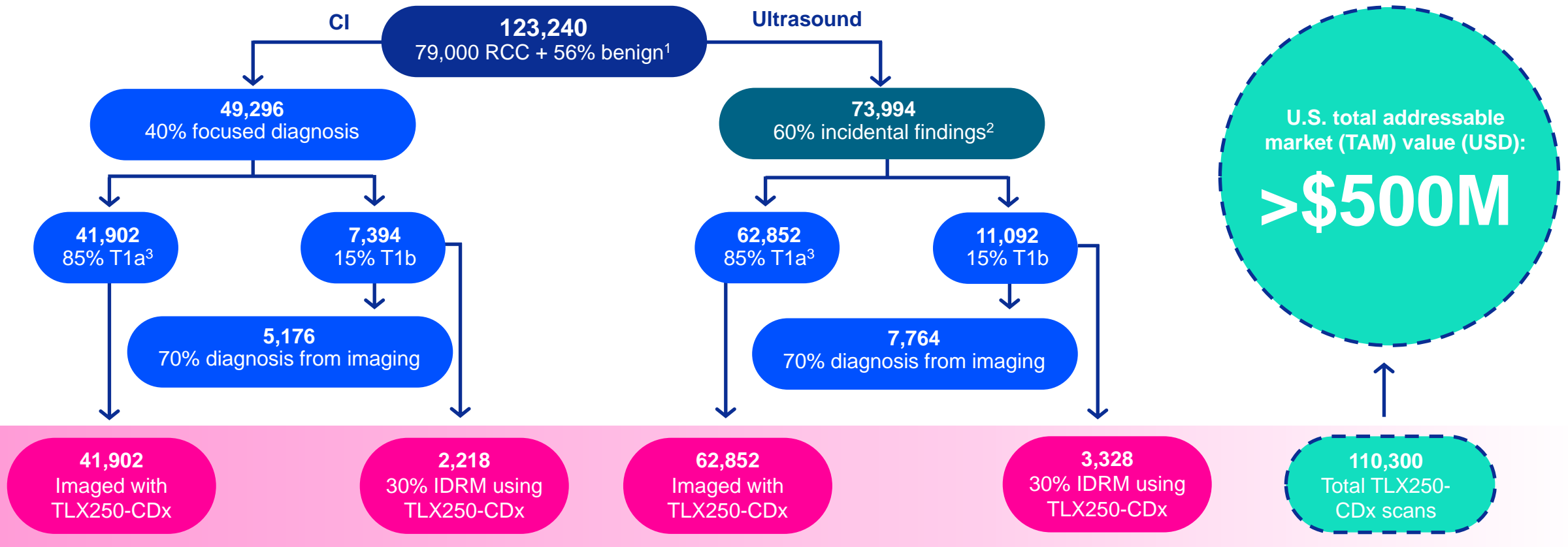


Potential future utility



U.S. market opportunity

Potential for clinical and commercial leadership



1. Thompson RH, Journal of Urology 2009.





2. Vasudev et al. BMJ 2020.

3. Haliloglu AH, Int. J. Nephrol 2011.

TLX250-CDx indication expansion

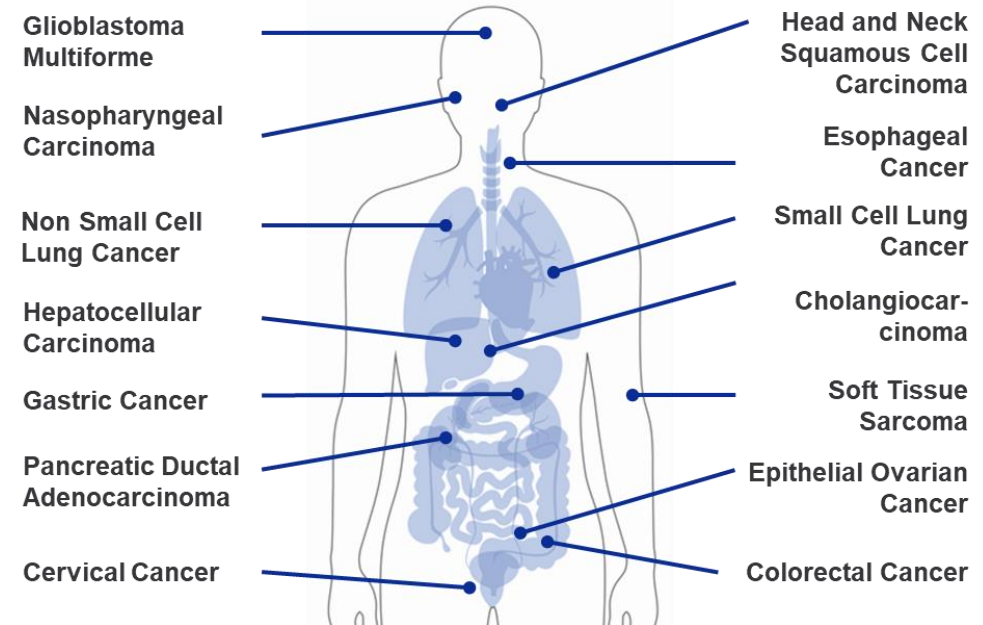
Potential for applications beyond kidney cancer

Current clinical studies of TLX250-CDx

	OPAESCENCE (IIT)¹	PHASE
	Triple Negative Breast Cancer	II
	PERTINENCE (with Atonco) (IIT)	PHASE
	Non muscle invasive bladder cancer	I
	Zip-UP (IIT)	PHASE
	Bladder or urothelial cancer	I
	STARBURST (Telix sponsored)	PHASE
	Multiple solid tumours (see diagram) for future diagnostic and therapeutic applications (<i>IND submitted</i>)	II

Telix's Planned Phase II 'STARBURST' study will explore TLX250-CDx in other tumour types

A prospective, open-label, Phase II study to explore CAIX expression through ⁸⁹Zirconium-labelled girentuximab deferoxamine (⁸⁹Zr-girentuximab) PET/CT imaging in patients with solid tumours.



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