



Insights from the Illuccix launch

Telix Pharmaceuticals (ASX:TLX)

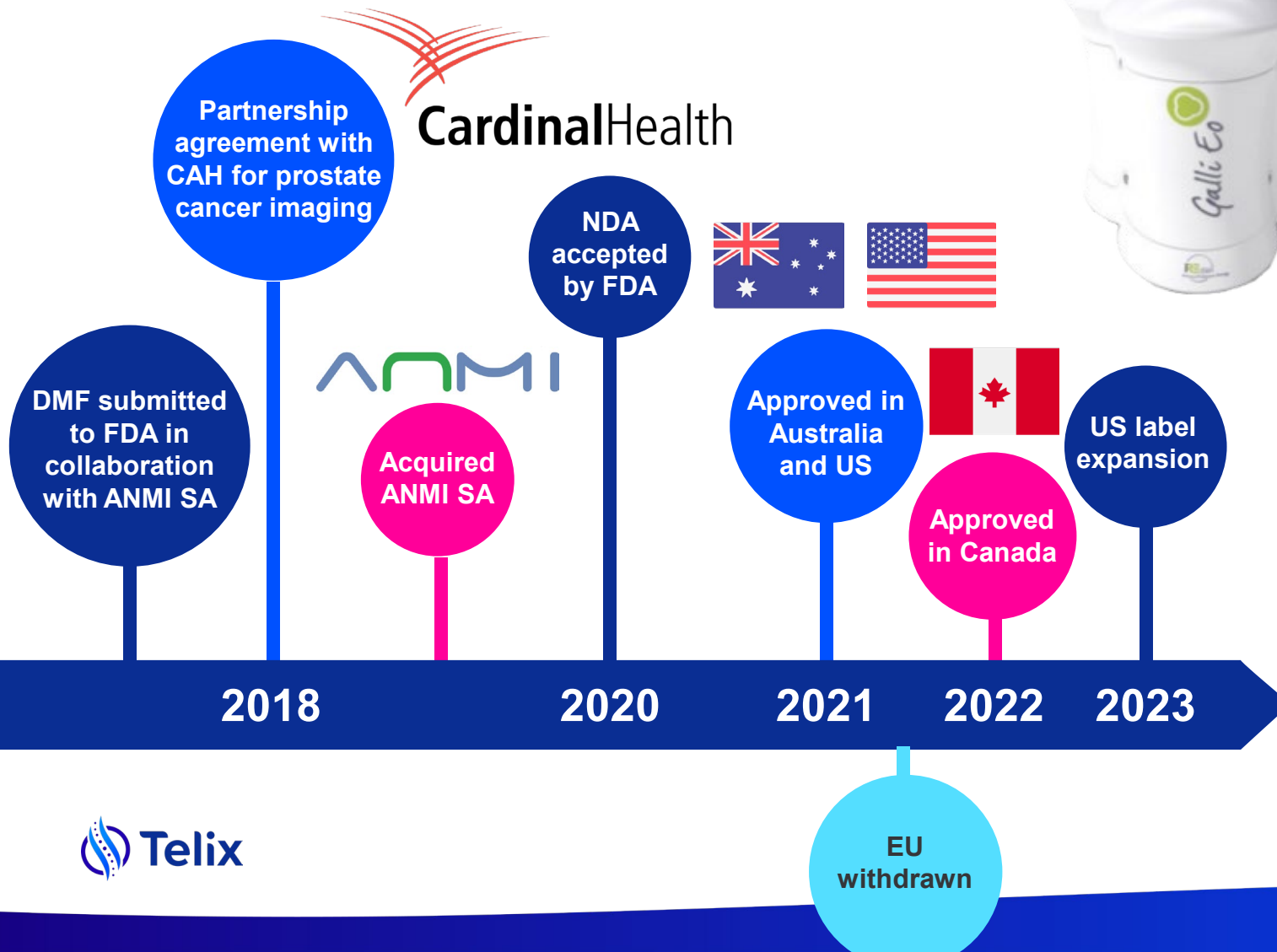
Bioshares Biotech Summit, 24 July 2023

Dr Christian Behrenbruch, Managing
Director and Group CEO



Illuccix[®]

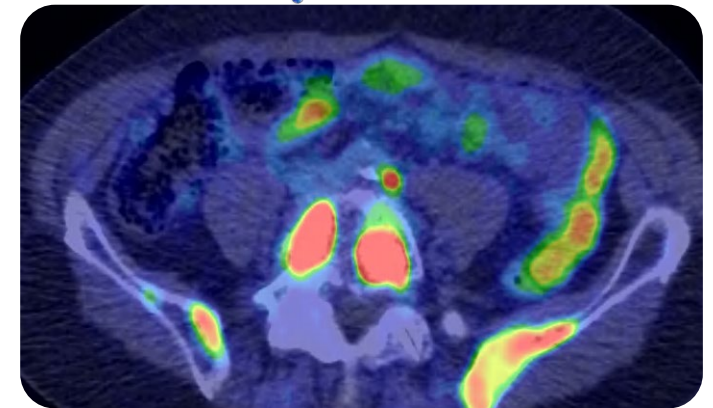
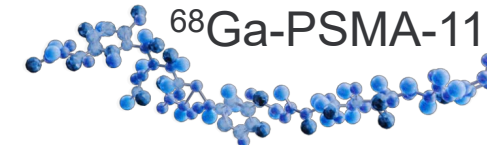
The story so far...



Generator

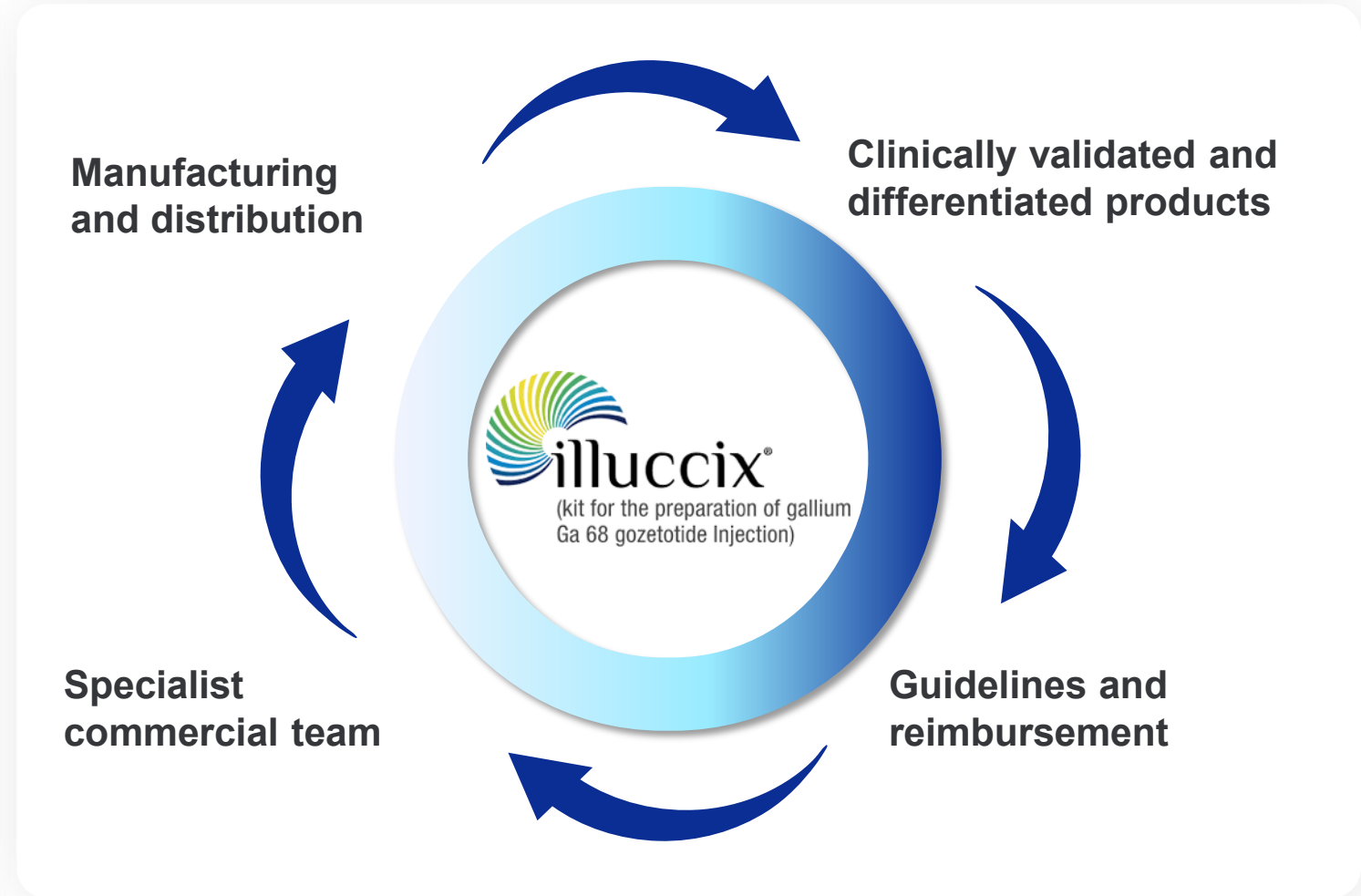
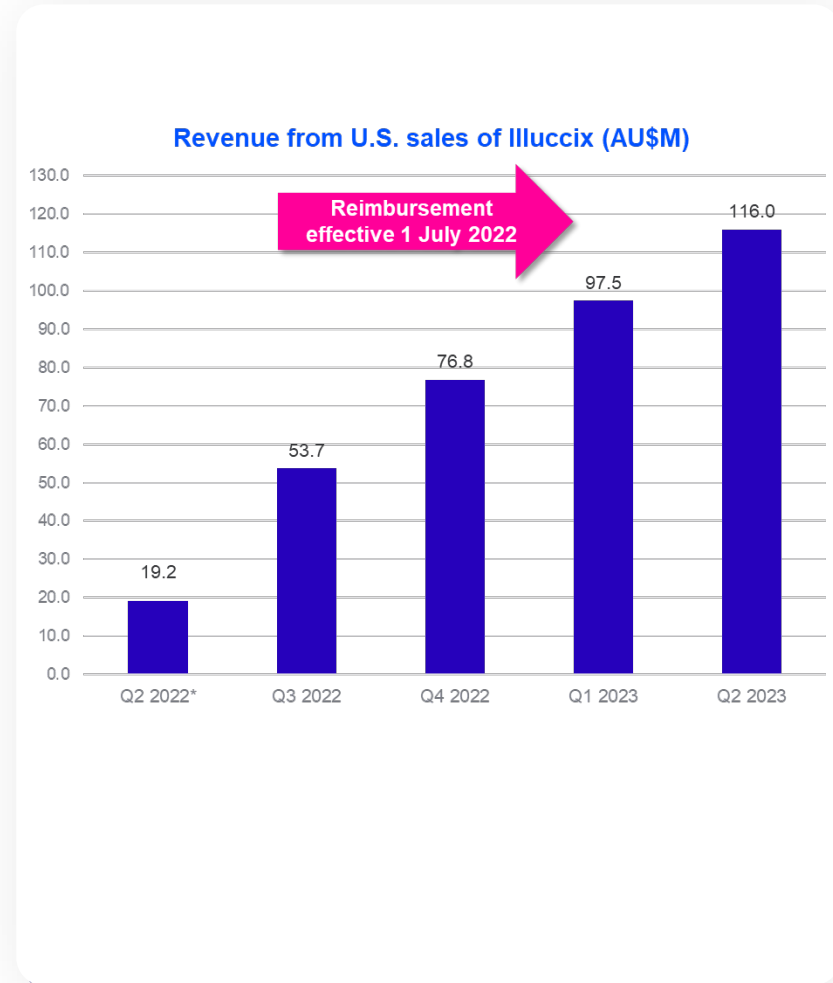


Kit



How did we get from launch to here?

Key elements of our pre-launch and market engagement



The Illuccix® difference

Reliable dose availability and flexible scheduling

Access to existing customer base

- Local market knowledge & deep account level relationships
- Motivated business partners

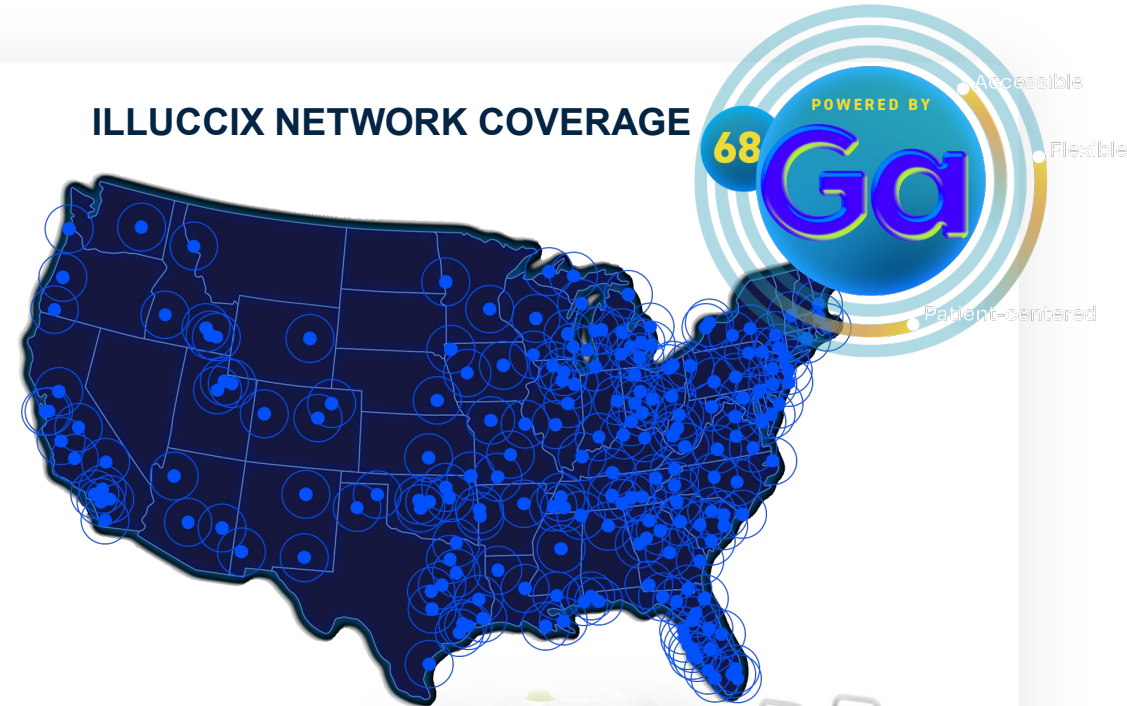
Reliable dose delivery

- Expansive distribution network >200 pharmacies
- Exceptional on-time delivery (+99%)

Convenience and scheduling flexibility

- Widest injection window & <30 min scan time
- ⁶⁸Ga production can meet flexible scheduling demands

ILLUCCIX NETWORK COVERAGE

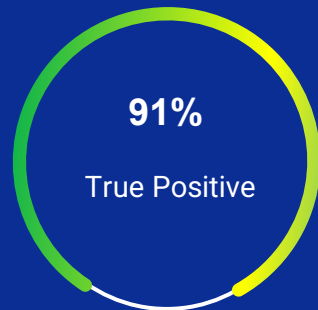


The Illuccix® difference

Robust clinical data, written into the major guidelines

Illuccix efficacy was established at BCR even at low PSA levels¹

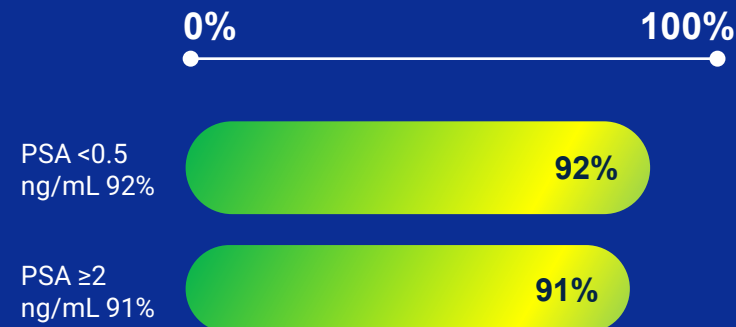
Low False Positive Rate



91% of the evaluable patients (192/210) were found to be true positive in one or more regions against the composite reference standard (95% CI: 88%-95%)

Trial Design: The pivotal PSMA-BCR trial, was a prospective 2-center study of patients with biochemical evidence of recurrent prostate cancer after definitive therapy (N=635).

Correct Localization Rate (CLR) at Different PSA Levels



CLR is defined as the true positive percentage among all positive PET scans with reference standard

CLINICAL ACCURACY

Pinpoint micrometastases at the earliest signs across stages of prostate cancer in a broad range of patients

HIGH-QUALITY IMAGES

High-quality images across vital regions, with scan time ≤30 minutes and trained specialists ready to help

ENDORSED IN THE GUIDELINES

NCCN® Guidelines recommended PSMA-11 PET/CT as preferred for imaging of bone and soft tissue²

END-TO-END SUPPORT

Dedicated industry-leading support at every step, including onsite onboarding, educational resources, and ongoing training

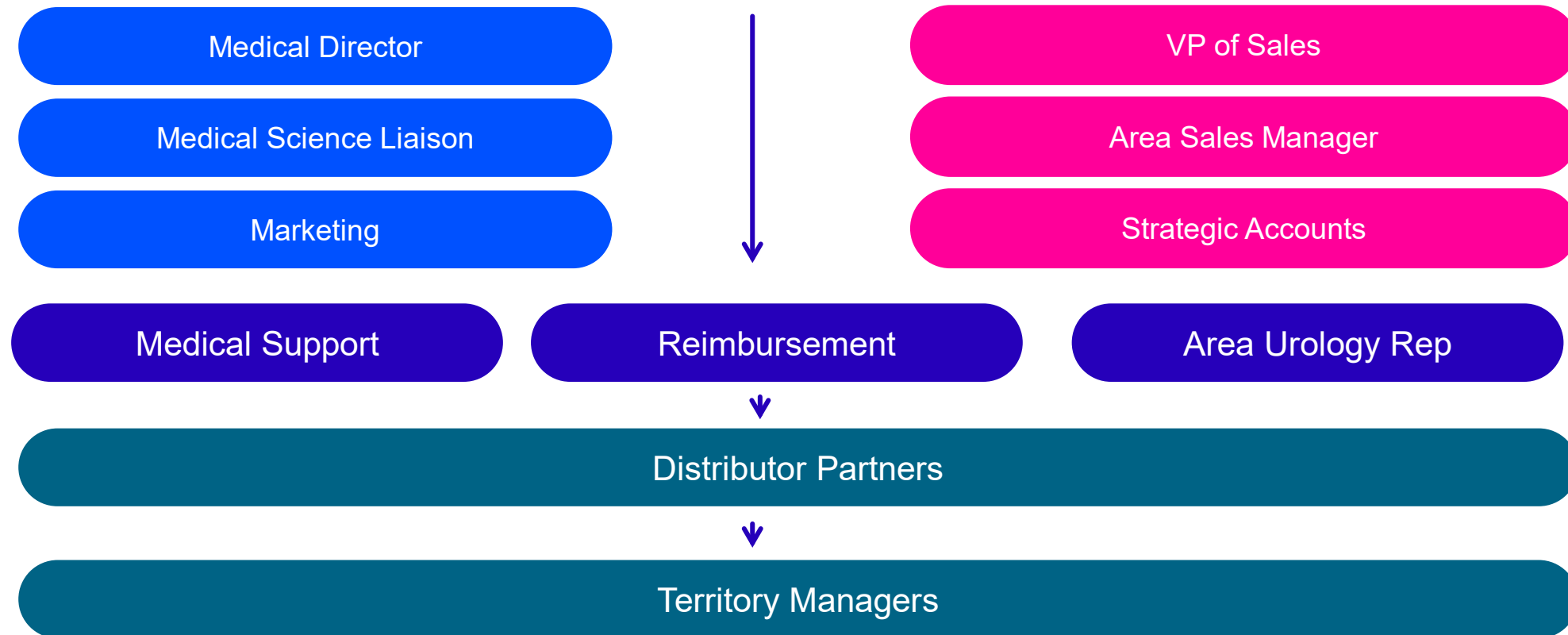
1. Hope et al. JAMA Oncol. 2021.

2. National Comprehensive Cancer Centre Guidelines prostate cancer V2.2023

Breadth and depth of the field organization

Deploying a world-class customer facing team

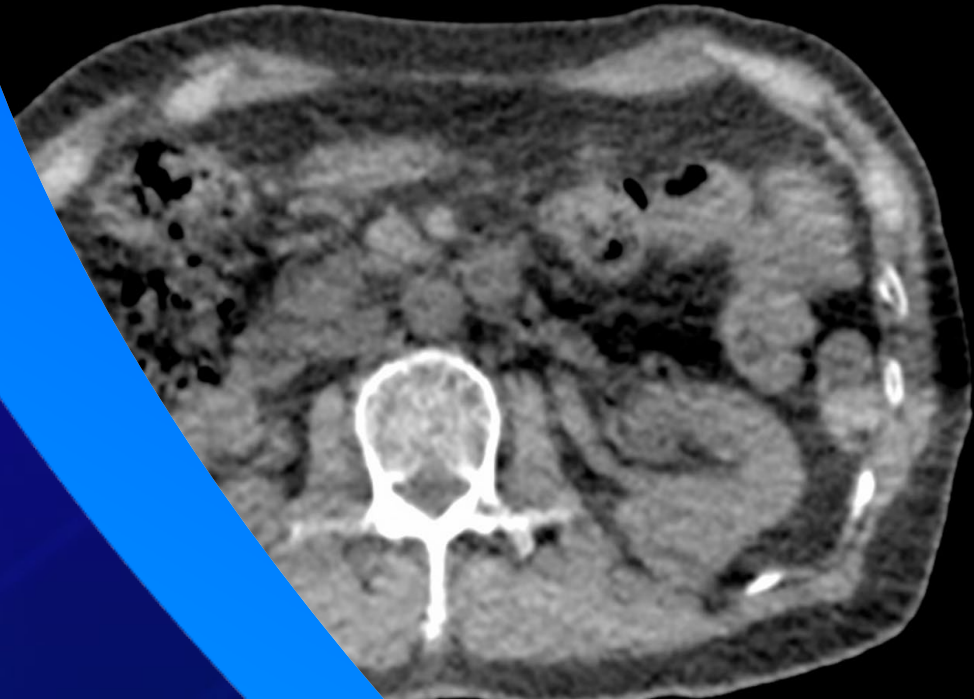
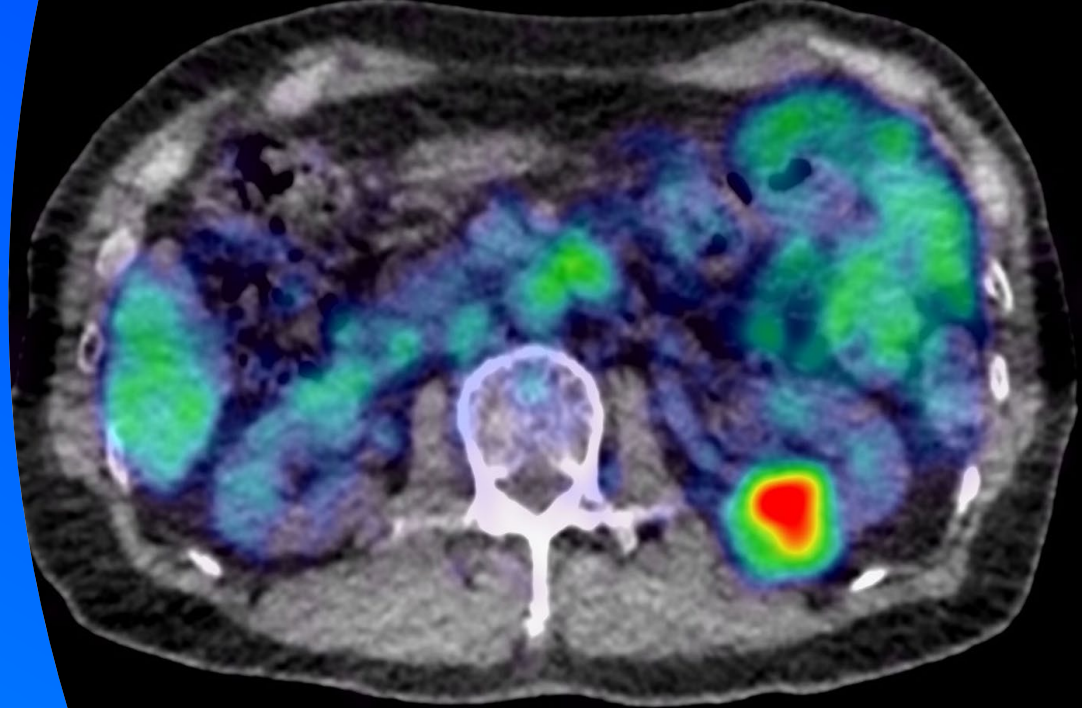
Modular functions that will also be utilised for TLX250-CDx and TLX101-CDx





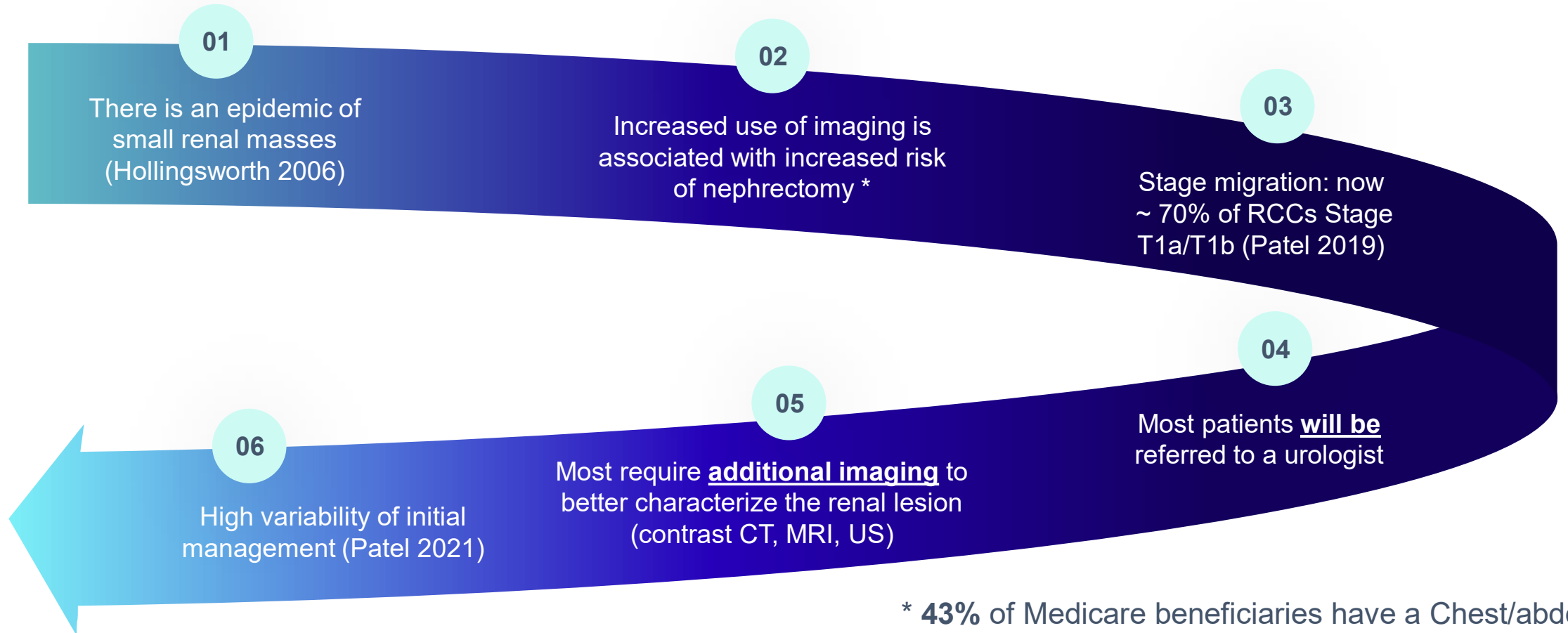
Part B:

**The path forward for
TLX250-CDx**



The patient journey

The indeterminate renal mass “epidemic”



* **43%** of Medicare beneficiaries have a Chest/abdomen CT within 5 years (Welch 2018)

Challenges with renal mass biopsy

Many surgeries are performed unnecessarily

10-15%

Insufficient tissue, 10-15% of cases non-diagnostic and doesn't stage

Error

Biopsies are invasive, subject to sampling errors.

~70%

- **NPV is ~70%** when distinguishing between benign oncocytomas and chromophobe RCC
- **>6,000** benign renal masses removed each yr (2015 data)

pT3

Upstaging to pT3 disease is increased in those with a biopsy (Hazard Ratio 1.69, 95% CI 1.17–2.44; $p < 0.01$).

COMPLICATIONS

Hematoma ~40%

Transfusion 1%

Pneumothorax 0.6%

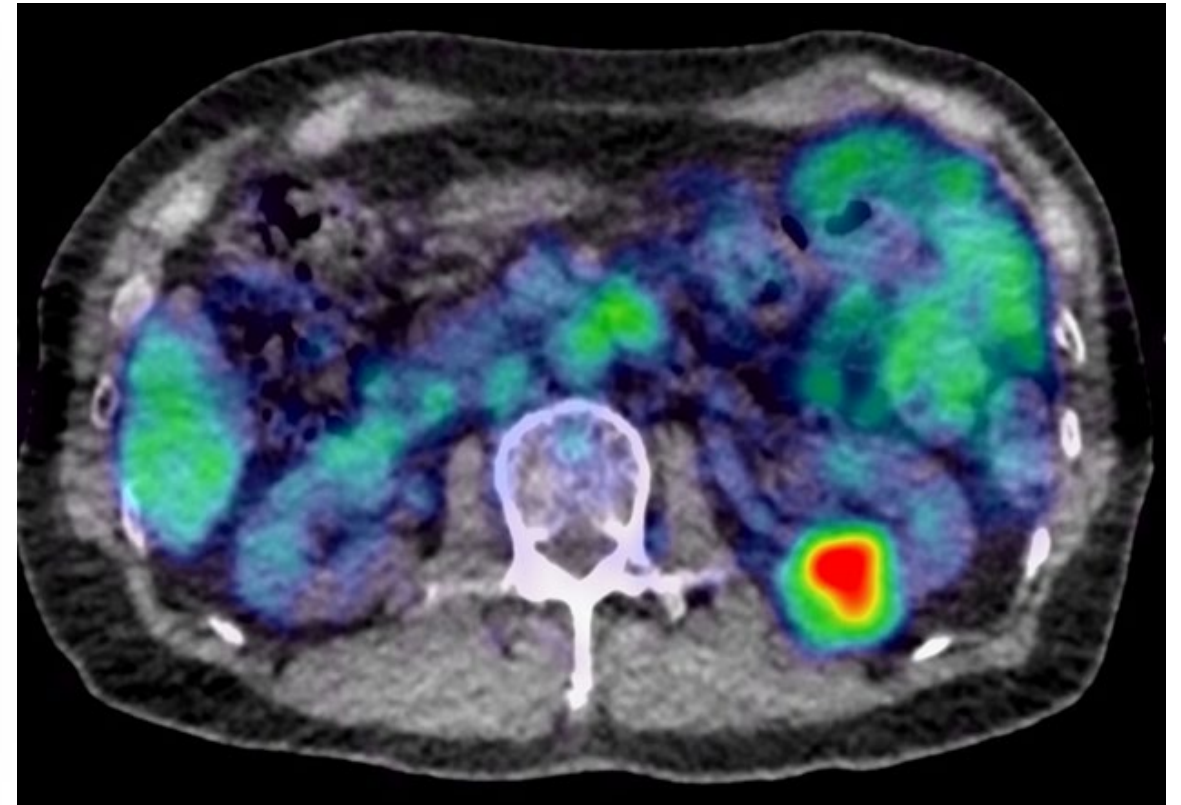
Biopsy tract seeding 1.2%

TLX250-CDx delivers on a major unmet medical need

Potential to change standard of care in the diagnosis and management of ccRCC

Highly positive Phase III data² suggests this imaging agent could be as ground-breaking as PSMA-PET has been in prostate cancer

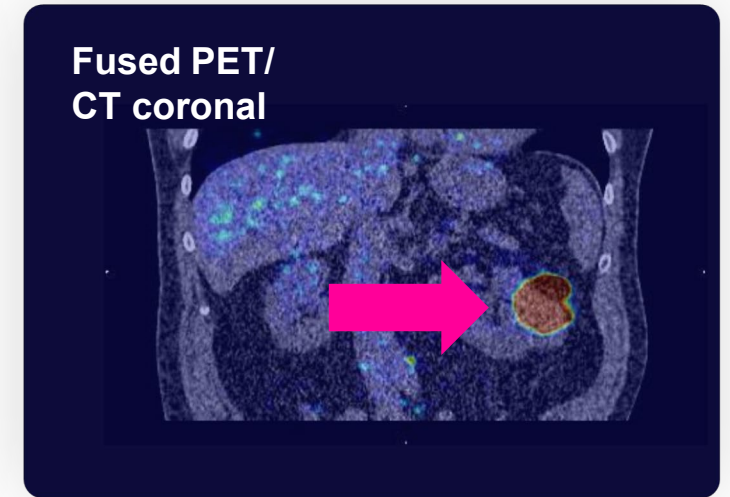
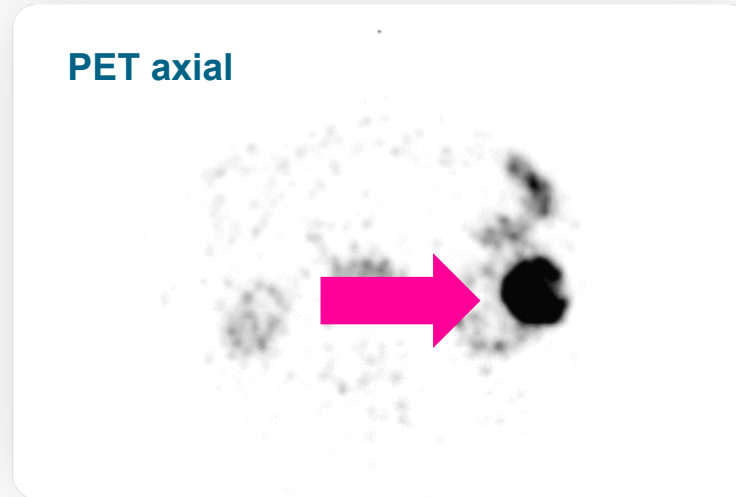
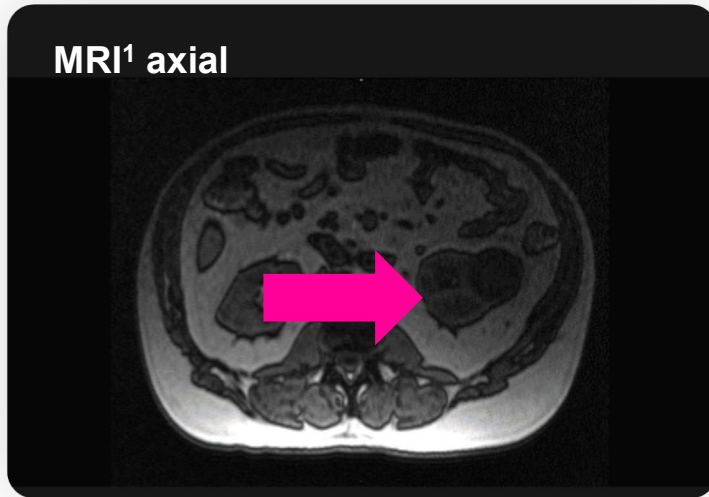
- **Primary endpoint met:** Sensitivity of $\geq 84\%$ and specificity of $\geq 84\%$ in all three readers (86% / 87% overall)
- Considerably exceeds confirmatory trial sensitivity and specificity success target of 70%
- **Key secondary endpoints met**, namely sensitivity and specificity targets in small renal masses (less than 4cm)
- Excellent data in **very small renal lesions ($\leq 2\text{cm}$):** Sensitivity 84% for all three readers, specificity 92.3% to 100%³



1. Clear cell renal cell carcinoma
2. ASX disclosure 7 November 2022.
3. ASX disclosure 1 May 2023.

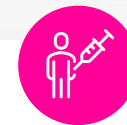
ZIRCON clinical case in a complex cyst

Potential support for clinical decision making



Diagnostic challenge:

- 42 yr male
- 3.1 cm (cT1a) left kidney mass
- ⁸⁹Zr-girentuximab PET scan clearly positive → ccRCC highly likely



Clinical management:

- Surgery - radical nephrectomy
- ccRCC confirmed by central pathology
- Low/Focal CAIX expression by IHC²



TLX250-CDx distribution model

Pharmacy distribution (US)



TLX250-CDx: U.S. market opportunity

Identification and characterisation of ccRCC

New incidental renal mass

- Estimated 73,994 incidental findings
- Over 1/3 of IDRM are non-ccRCC¹
- >45% of small renal masses <1cm are benign²

Renal cancer diagnosis

- 79,000 patients will be diagnosed with RCC in 2022 in the U.S.³
- 80% of patients with RCC are clear cell⁴
- Over 60% of ccRCC is found incidentally⁵

Of total patient population ~ 110,000 expected to be suitable for imaging with TLX250-CDx

Initial addressable market

>US\$500M
in the U.S.

Active surveillance for known renal mass

- Prevalence unknown
- Active surveillance is recommended for patients with select renal masses (e.g. older patients, <2cm)
- A 6-monthly, then annual, CT/MRI scan is currently recommended in the NCCN Guidelines® kidney cancer v3.2023

Previously treated ccRCC high risk

- 599,000 patients living with kidney cancer in the U.S.³ in 2019



1. Telix: Data on file from ZIRCON study (patients with IDRM diagnosed every year).
2. Johnson et al., 2015.
3. SEER. (2022). Cancer Stat Facts: Kidney and Renal Pelvis Cancer: <https://seer.cancer.gov/statfacts/html/kidrp.html>.
4. STATPEARLS Rahul D. Arora 2020;11(3):79-87.
5. Vasudev et al. BMJ 2020.

Note: TLX250-CDx pricing estimate based on Illuccix.

Potential new tumour targets and combinations

Reinforces potential of CAIX as a therapeutic target

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 tumors for future indications II

Current clinical studies of TLX250



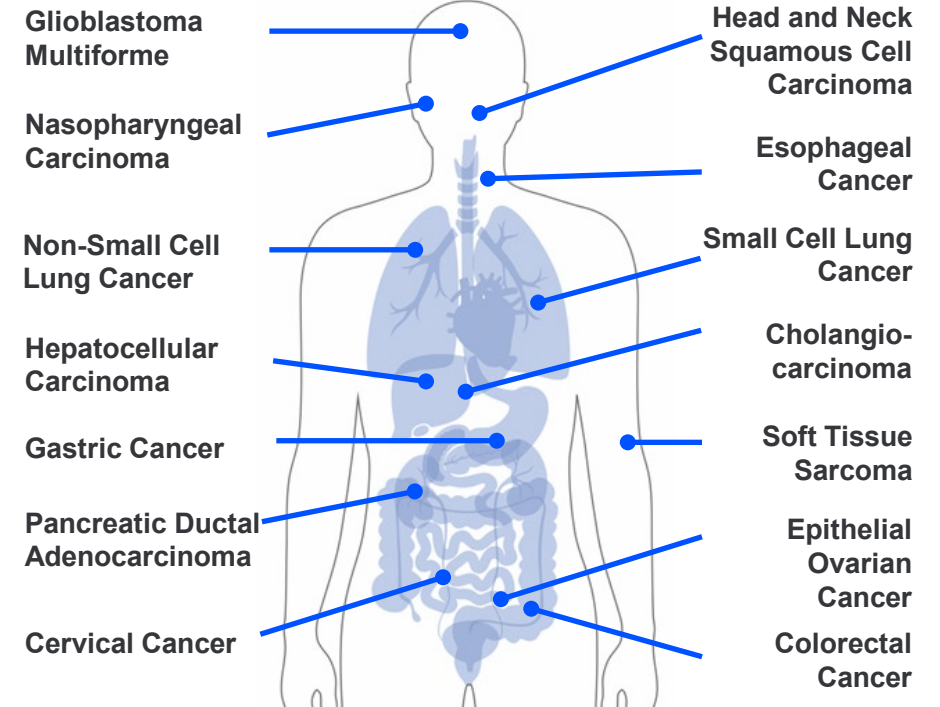
STARLITE² Combination I-O² therapy studies

- STARLITE-1: TLX250 + cabozantinib and nivolumab in naïve advanced ccRCC patients
- STARLITE-2: TLX250 + nivolumab in patients that have progressed on I-O therapy

MERCK Combination study (STARSTRUCK)

- TLX250 + Merck KGaA DNA Damage Response Inhibitor (DDRi)

Potential for indication expansion: Literature reports of CAIX expression



1. Investigator-initiated trial.
2. Immuno-oncology.

Thank you & questions

Kyahn Williamson

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