



ZIRCON-X Analysis: TLX250-CDx Impacts Clinical Decision Making for Almost Half of Patients with Indeterminate Renal Masses

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MELBOURNE, Australia and INDIANAPOLIS, Nov. 20, 2025 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today announces results from the ZIRCON-X study which finds that almost half of all patients imaged with TLX250-CDx (Zircaix®¹, ⁸⁹Zr-DFO-girentuximab) PET/CT² would have undergone a change in clinical management, when compared with baseline standard of care (SOC) imaging. The data will be presented at the 26th Annual Meeting of the Society of Urologic Oncology (SUO) being held in Phoenix, AZ, December 2 – 5, 2025.

ZIRCON-X was a non-interventional, prospective, post-hoc study sponsored by Telix – using imaging data from Telix's parent pivotal Phase 3 ZIRCON study³ – that assessed the impact of TLX250-CDx imaging on clinical decision-making versus SOC contrast-enhanced diagnostic imaging in 294 patients with indeterminate renal masses (IRMs)⁴. The study found that 143 patients (48.6%) would have undergone a change in clinical management if imaged with TLX250-CDx, and over 20% of these patients (31 out of 143) could have potentially avoided invasive biopsy⁵.

Of all evaluable patients, more than one third (110 out of 294, or 37.4%) would have had a major change in clinical management based on defined categories (see table below), with approximately 30% having their treatment escalated or de-escalated. A subset of 18 patients initially selected for active surveillance would have been escalated to immediate treatment⁵.

Most common major changes in clinical management ⁵	n
Biopsy to surgery (partial or total nephrectomy)	24
Surgery (partial or total nephrectomy) to biopsy	19
Additional diagnostic to surgery (partial or total nephrectomy)	18
Partial nephrectomy to total nephrectomy	8
Surgery (partial or radical nephrectomy) to additional diagnostic test	7
Total nephrectomy to partial nephrectomy	6

In patients whose planned surgery was changed, TLX250-CDx provided greater clarity on spatial localization of ccRCC within the kidney; thus allowing the physician to determine the most appropriate surgical procedure.

Professor Karolien Goffin, staff member of nuclear medicine at the University Hospital Leuven, Chair of the EANM Oncology & Theranostics Committee and a Principal Investigator on the ZIRCON and ZIRCON-X studies commented, "These are compelling results which demonstrate that TLX250-CDx PET/CT has significant potential to impact clinical decision making in the diagnostic work-up of patients presenting with small IRMs and give physicians greater confidence in clinical planning."

Dr. David N. Cade, Group Chief Medical Officer at Telix, added, "This analysis is another demonstration of the potential clinical usefulness of TLX250-CDx, Telix's breakthrough⁶ precision diagnostic candidate, which has recently been added to international guidelines for renal imaging⁷. These results indicate that TLX250-CDx may deliver on an unmet need for better non-invasive diagnostic work-up for ccRCC that can improve risk stratification and minimize overtreatment and undertreatment."

About ZIRCON-X

ZIRCON-X was a non-interventional, prospective, post-hoc study assessing imaging data collected during Telix's parent pivotal Phase 3 ZIRCON study. The primary objective was to assess whether TLX250-CDx PET/CT has an impact on clinical decision-making versus SOC conventional contrast-enhanced diagnostic imaging in patients presenting with an IRM.

Four multi-disciplinary teams⁸ (MDTs) at four separate institutions⁹ evaluated ZIRCON data from 294 evaluable patients in two steps:

- Step 1:** MDTs issued a patient management decision based on SOC conventional imaging and clinical/laboratory data (excluding histology)
- Step 2:** After a minimum 4-week interval, MDTs reassessed the same cases, this time informed by the TLX250-CDx PET/CT imaging results and the same clinical/laboratory data¹⁰

Clinical management for each individual patient was determined by MDT consensus. Data will support Telix's planned marketing authorization application for TLX250-CDx in Europe.

About TLX250-CDx

TLX250-CDx is an investigational PET agent that is under development for the diagnosis and characterization of ccRCC. It works by specifically binding to carbonic anhydrase IX (CAIX), a validated target protein expressed on >95% of ccRCC cells¹¹, to produce images with high tumor-to-background ratio and high intra- and inter-reader consistency. Telix's pivotal Phase 3 ZIRCON trial evaluating TLX250-CDx in 300 patients, of whom 284 were evaluable, met all primary and secondary endpoints, including showing 86% sensitivity and 87% specificity and a 93% positive predictive value (PPV) for ccRCC across three independent radiology readers¹². Telix believes this demonstrated the ability of TLX250-CDx to reliably detect the clear cell phenotype and provide an accurate, non-invasive method for diagnosing and characterizing ccRCC.

For more on TLX250-CDx and Telix's theranostic kidney cancer program, click [here](#).

TLX250-CDx has not received a marketing authorization in any jurisdiction.

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals and associated medical technologies. Telix is headquartered in Melbourne, Australia, with international operations in the United States, United Kingdom, Brazil, Canada, Europe (Belgium and Switzerland), and Japan. Telix is developing a portfolio of clinical and commercial stage products that aims to address significant unmet medical needs in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (NASDAQ: TLX).

Visit www.telixpharma.com for further information about Telix, including details of the latest share price, ASX and U.S. Securities and Exchange Commission (SEC) filings, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on [LinkedIn](#), [X](#) and [Facebook](#)

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¹ Brand name subject to final regulatory approval.

² Positron emission tomography/computed tomography.

³ Zirconium in Renal Cancer Oncology, ClinicalTrials.gov ID: [NCT03849118](https://clinicaltrials.gov/ct2/show/study/NCT03849118).

- ⁴ Evaluable patient population of 294 differs from main ZIRCON patient population of 284 since histology was not required in ZIRCON-X.
- ⁵ Telix ZIRCON-X SUO 2025 abstract, available at: <https://suo-abstracts.secure-platform.com/a/gallery/rounds/24/details/4869>
- ⁶ Telix ASX disclosure 1 July 2020. TLX250-CDx granted Breakthrough Therapy designation by U.S. FDA.
- ⁷ SNMMI/EANM/ACNM Procedure Standard/Procedure Guideline on the Use of Molecular Imaging for Renal Mass Characterization (October 2025), available at: <https://jnm.snmjournals.org/content/early/2025/10/09/jnumed.125.271332.abstract>
- ⁸ Each MDT comprised at least three board-certified physicians, one nuclear medicine physician and two urologists.
- ⁹ University of California, Los Angeles (U.S.); University Hospitals Leuven (Belgium); Royal Free London (United Kingdom); European Institute of Oncology (Italy).
- ¹⁰ MDTs did not have access to the Step 1 outcomes during the Step 2 reading.
- ¹¹ Stillebroer et al. *Eur Urol.* 2010.
- ¹² Telix ASX disclosures 7 November 2022. Shuch et al. *Lancet Oncology.* 2024.