TLX250-CDx (Zircaix) Included in Leading International Guidelines for Renal Imaging

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MELBOURNE, Australia and INDIANAPOLIS, Oct. 23, 2025 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today welcomes updated guidelines from the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM) and The American College of Nuclear Medicine (ACNM) that, for the first time, include the use of Telix's investigational PET[1] agent, TLX250-CDx (Zircaix®[2], ^{89}Zr-DFO-girentuximab), for molecular imaging of renal masses.

Published on the SNMMI website[3] and in *The Journal of Nuclear Medicine*[4], the guideline panel[5], comprising internationally renowned and multidisciplinary expert key opinion leaders, concludes that "the emerging use of molecular imaging for risk stratification of indeterminate renal masses offers the opportunity to more effectively characterize such lesions and optimize patient management decisions".

The panel asserts that antibody-based radiotracers exhibit lower renal clearance, thereby improving visualization of renal masses. It emphasizes that TLX250-CDx PET "appears to be a well-tolerated and accurate method for non-invasive identification of ccRCC[6]" and notes by contrast, the high renal excretion with ^{18}F-FDG PET, which obscures accurate lesion detection.

The panel references data from Telix's pivotal Phase 3 ZIRCON trial[7], which met all primary and secondary endpoints, demonstrating a sensitivity of 86%, specificity of 87% and a positive predictive value (PPV) of 93% for ccRCC, including in very small, difficult-to-detect lesions[8]. TLX250-CDx works by specifically binding to carbonic anhydrase IX (CAIX), a validated target protein expressed on >95% of ccRCC cells[9], to produce images with high tumor-to-background ratio and high intra- and inter-reader consistency.

Professor Brian Shuch, MD, Director of the Kidney Cancer Program and the Alvin & Carrie Meinhardt Endowed Chair in Kidney Cancer Research at UCLA Institute of Urologic Oncology and guideline author, commented, "The recognition of ^{89}Zr-girentuximab PET in the SNMMI/EANM/ACNM clinical guidelines reflects a shift toward precision medicine in renal cancer, providing clinicians with a more accurate tool for diagnosis to guide optimal, individualized treatment planning for patients."

Kevin Richardson, Chief Executive Officer, Precision Medicine, Telix, added, "The inclusion of TLX250-CDx PET imaging for the first time in SNMMI/EANM/ACNM guidelines is an important development for Telix and will help raise awareness of this breakthrough precision diagnostic. Subject to regulatory approval, endorsement by this expert global multidisciplinary panel will help to drive adoption and implementation into clinical workflows, supporting clinical utility and enhancing decision-making to improve patient outcomes."

SNMMI, EANM and ACNM periodically define new procedure standards/guidelines to help advance the science of nuclear medicine and to improve the quality of service to patients. Each standard/guideline, representing a policy statement by these groups undergoes a thorough consensus process in which it has been subjected to extensive review.

About TLX250-CDx

TLX250-CDx is an investigational PET agent that is under development for the diagnosis and characterization of ccRCC. 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% PPV for ccRCC across three independent radiology readers. 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).

Illuccix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection), Telix's first generation PSMA-PET imaging agent, has been approved in multiple markets globally. Gozellix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection) has been approved by the U.S. FDA[10].

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] Positron emission tomography.

[2] Brand name subject to final regulatory approval.

[3] https://snmmi.org/common/Uploaded%20files/Web/Clinical%20Practice/Procedure%20Standards/2025/SNMMI_EANM_ACNM_Renal_Masses-Final%20JNM%20sumbission.pdf

[4] 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

[5] Steven P. Rowe, Brian M. Shuch, Mark W. Ball, Axel Bex, Mehrbod S. Javadi, Alan Klitzke, Karolien Goffin, Peter Mulders, Neeta Pandit-Taskar, Ashwin Singh Parihar, Benjamin L. Viglianti, Michael A. Gorin, and Ken Herrmann.

[6] Clear cell renal cell carcinoma, the most common and one of the most aggressive subtypes of kidney cancer.

[7] ClinicalTrials.gov ID: NCT03849118.

[8] Telix ASX disclosures 7 November 2022. Shuch et al. *Lancet Oncology.* 2024.

[9] Stillebroer et al. *Eur Urol*. 2010.

[10] Telix ASX disclosure 21 March 2025.