# Precision Medicine Portfolio Update: Illuccix China Phase 3 Study, TLX101-CDx and TLX250-CDx FDA Resubmissions

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MELBOURNE, Australia and INDIANAPOLIS, Dec. 22, 2025 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today provides a precision medicine portfolio update in relation to:

- **TLX591-CDx (Illuccix® in approved jurisdictions, $^{68}$Ga-PSMA-11):** Positive data from Phase 3 study in Chinese patients provides the basis for near-term NDA submission in China.
- **TLX101-CDx (Pixclara®[1], $^{18}$F-floretyrosine), PET imaging candidate for glioma:** Following collaborative interactions with the FDA, finalizing NDA resubmission and expect to provide a further near-term update on FDA acceptance of the file.
- **TLX250-CDx (Zircaix®[1], $^{89}$Zr-DFO-girentuximab), PET imaging candidate for ccRCC:** Positive Type A meeting held with the FDA to align on remediation of CMC deficiencies identified in the CRL.

Further details on each of these updates is provided below.

**Illuccix China Phase 3 Registration Study**

Telix is pleased to announce positive top-line results from its Phase 3 registration study of TLX591-CDx (Illuccix®, Kit for the preparation of $^{68}$Ga-PSMA-11) for prostate cancer imaging in Chinese patients. The Illuccix China[2] trial met its primary endpoint of patient-level positive predictive value (PPV) for the detection of tumors in patients with biochemical recurrence (BCR) of prostate cancer following prior radical prostatectomy or radiation therapy. The study confirms that the clinical experience of TLX591-CDx PSMA-PET[3] imaging in Chinese patients is comparable to that observed in patients studied elsewhere.

Illuccix China is a Phase 3 prospective, open-label, single-arm, multicenter study conducted in collaboration with Telix's strategic commercial partner for the Greater China region, Grand Pharmaceutical Group Limited (Grand Pharma). The study in 140 patients delivered a strong result for the primary endpoint, with an overall patient-level PPV of 94.8% for the detection of tumors with TLX591-CDx (95% confidence interval [CI]: 85.9%, 98.2%), with the lower bound of the 95% CI (85.9%). The region-level PPV was 100.0% in the prostate bed and in the extra-pelvic soft tissue, lymph nodes, and organ metastases (non-bone); 94.7% in the pelvic region outside of the prostate bed, including lymph nodes; and 87.0% in bone metastases.

In the study, patients with suspected BCR were stratified into groups according to their baseline prostate specific antigen (PSA) levels. TLX591-CDx PSMA-PET imaging demonstrated high PPV in all patient groups, including at very low baseline PSA levels.

| Baseline PSA | PPV (95% CI) |
|---|---|
| ≥ 5.0 ng/mL | 100.0% (78.5%, 100.0%) |
| < 5.0 to 2.0 ng/mL | 100.0% (67.6%, 100.0%) |
| < 2.0 to 1.0 ng/mL | 90.9% (62.3%, 98.4%) |
| < 1.0 to 0.5 ng/mL | 90.0% (59.6%, 98.2%) |
| < 0.5 to 0.2 ng/mL | 93.3% (70.2%, 98.8%) |

More than two-thirds (67.2%) of patients experienced a change in their treatment plan as a consequence of TLX591-CDx PSMA-PET imaging compared with the initial plan at baseline. This outcome confirms that PSMA-PET imaging with TLX591-CDx had a meaningful impact on clinical decision-making in Chinese patients, potentially leading to improved treatment strategies for participants with BCR. Final data from the study will be submitted for peer-reviewed publication.

Dr. David N. Cade, Group Chief Medical Officer, Telix, commented, "This is an outstanding result. The primary endpoint of the study was met decisively, with the positive predictive value significantly exceeding the performance threshold agreed with the Chinese regulator. Importantly, the high PPV was consistent even in patients with very low PSA values, and across differing metastatic locations, demonstrating broad clinical applicability. These compelling data will enable Telix and our partner Grand Pharma to submit a New Drug Application for Illuccix in China, a strategically important market."

In China, more than 134,000 men were diagnosed with prostate cancer in 2022[4], increasing by approximately 6% each year[5]. In line with government policy supporting wider geographic access to nuclear medicine, the number of PET/CT cameras installed in China is expected to surpass 1,600 by the end of 2025[6], compared with 133 in 2010[7].

**FDA Resubmission Update: TLX101-CDx**

Telix advises that its New Drug Application (NDA) resubmission for TLX101-CDx, (Pixclara®[1], $^{18}$F-floretyrosine) to the United States (U.S.) Food and Drug Administration (FDA), is progressing well. The Company has had collaborative interactions with the FDA around providing additional clinical data and a revised statistical analysis plan.

Following a productive Type A meeting to review the basis of the Complete Response Letter (CRL)[8], Telix is currently finalizing its package for resubmission. The Company will provide a further near-term update when the resubmission has been filed and accepted by the FDA. The approved Expanded Access Program (EAP)[9] remains active for TLX101-CDx, reflective of Telix's commitment to serving patients.

**FDA Resubmission Update: TLX250-CDx**

Telix has recently participated in a Type A meeting to discuss the CRL it received following review of the Biologics License Application (BLA)[10] for TLX250-CDx (Zircaix®[1], $^{89}$Zr-DFO-girentuximab). Telix believes it has reached alignment with the FDA on the remediation of identified deficiencies regarding the product's chemistry, manufacturing, and controls (CMC) package, which formed the substantive basis of the CRL.

The FDA has collaboratively granted Telix an additional meeting in January to review Telix's plan for the additional data requested to establish comparability between the drug product used in the ZIRCON Phase 3 clinical trial[11] and the scaled-up manufacturing process intended for commercial use. Telix will provide a further update following receipt of the official FDA meeting minutes of both Type A meetings. The approved Expanded Access Program (EAP)[12] remains active for TLX250-CDx, reflective of Telix's commitment to serving patients.

**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[13].

TLX101-CDx is Telix's PET imaging candidate for glioma, a rare and life-threatening brain cancer. TLX250-CDx is Telix's PET imaging candidate for the diagnosis and characterization of clear cell renal cell carcinoma, the most common kidney cancer subtype. TLX101-CDx and TLX250-CDx have not received a marketing authorization in any jurisdiction.

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] ClinicalTrials.gov ID: NCT05847348.

[3] Imaging of prostate-specific membrane antigen with positron emission tomography.

[4] Global Cancer Statistics 2022: GLOBOCAN survey. Published August 2024.

[5] Ye Dingwei et al. *Lancet Oncology*, 2022.

[6] Yang et al. *J Nuc. Med.* 2024.

[7] Goetz Partners research 2020.

[8] Telix ASX disclosure 28 April 2025.

[9] ClinicalTrials.gov ID: NCT06743100.

[10] Telix ASX disclosure 28 August 2025.

[11] ClinicalTrials.gov ID: NCT03849118.

[12] ClinicalTrials.gov ID: NCT06090331.

[13] Telix ASX disclosure 21 March 2025.