

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

Melbourne (Australia) and Indianapolis, IN (U.S.) – 22 December 2025. Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, “Telix”) today provides a precision medicine portfolio update in relation to:

- **TLX591-CDx (Illuccix® in approved jurisdictions, <sup>68</sup>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®<sup>1</sup>, <sup>18</sup>F-floretirosine), 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®<sup>1</sup>, <sup>89</sup>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 <sup>68</sup>Ga-PSMA-11) for prostate cancer imaging in Chinese patients. The Illuccix China<sup>2</sup> 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<sup>3</sup> 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%)

<sup>1</sup> Brand name subject to final regulatory approval.

<sup>2</sup> ClinicalTrials.gov ID: [NCT05847348](https://clinicaltrials.gov/ct2/show/NCT05847348).

<sup>3</sup> Imaging of prostate-specific membrane antigen with positron emission tomography.

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<sup>4</sup>, increasing by approximately 6% each year<sup>5</sup>. 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<sup>6</sup>, compared with 133 in 2010<sup>7</sup>.

### FDA Resubmission Update: TLX101-CDx

Telix advises that its New Drug Application (NDA) resubmission for TLX101-CDx, (Pixclara<sup>®</sup><sup>1</sup>, <sup>18</sup>F-floretynosine) 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)<sup>8</sup>, 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)<sup>9</sup> 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)<sup>10</sup> for TLX250-CDx (Zircaix<sup>®</sup><sup>1</sup>, <sup>89</sup>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<sup>11</sup> 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)<sup>12</sup> remains active for TLX250-CDx, reflective of Telix's commitment to serving patients.

<sup>4</sup> Global Cancer Statistics 2022: GLOBOCAN survey. Published August 2024.

<sup>5</sup> Ye Dingwei et al. *Lancet Oncology*, 2022.

<sup>6</sup> Yang et al. *J Nuc. Med.* 2024.

<sup>7</sup> Goetz Partners research 2020.

<sup>8</sup> Telix ASX disclosure 28 April 2025.

<sup>9</sup> ClinicalTrials.gov ID: [NCT06743100](https://clinicaltrials.gov/ct2/show/NCT06743100).

<sup>10</sup> Telix ASX disclosure 28 August 2025.

<sup>11</sup> ClinicalTrials.gov ID: [NCT03849118](https://clinicaltrials.gov/ct2/show/NCT03849118).

<sup>12</sup> ClinicalTrials.gov ID: [NCT06090331](https://clinicaltrials.gov/ct2/show/NCT06090331).

## 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 (<sup>68</sup>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 (<sup>68</sup>Ga) gozetotide injection) has been approved by the U.S. FDA<sup>13</sup>.

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](http://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](#).

### Telix Investor Relations (Global)

Ms. Kyahn Williamson  
Telix Pharmaceuticals Limited  
SVP Investor Relations and Corporate Communications  
Email: [kyahn.williamson@telixpharma.com](mailto:kyahn.williamson@telixpharma.com)

### Telix Investor Relations (U.S.)

Annie Kasparian  
Telix Pharmaceuticals Limited  
Director Investor Relations and Corporate Communications  
Email: [annie.kasparian@telixpharma.com](mailto:annie.kasparian@telixpharma.com)

### Media Contact

Eliza Schleifstein  
917.763.8106 (Mobile)  
[Eliza@schleifsteinpr.com](mailto:Eliza@schleifsteinpr.com)

*This announcement has been authorized for release by the Telix Pharmaceuticals Limited Disclosure Committee on behalf of the Board.*

### Legal Notices

#### *Cautionary Statement Regarding Forward-Looking Statements.*

*You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the Australian Securities Exchange (ASX), U.S. Securities and Exchange Commission (SEC), including our Annual Report on Form 20-F filed with the SEC, or on our website.*

*The information contained in this announcement is not intended to be an offer for subscription, invitation or recommendation with respect to securities of Telix Pharmaceuticals Limited (Telix) in any jurisdiction, including the United*

<sup>13</sup> Telix ASX disclosure 21 March 2025.

States. The information and opinions contained in this announcement are subject to change without notification. To the maximum extent permitted by law, Telix disclaims any obligation or undertaking to update or revise any information or opinions contained in this announcement, including any forward-looking statements (as referred to below), whether as a result of new information, future developments, a change in expectations or assumptions, or otherwise. No representation or warranty, express or implied, is made in relation to the accuracy or completeness of the information contained or opinions expressed in the course of this announcement.

This announcement may contain forward-looking statements, including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that relate to anticipated future events, financial performance, plans, strategies or business developments. Forward-looking statements can generally be identified by the use of words such as "may", "expect", "intend", "plan", "estimate", "anticipate", "believe", "outlook", "forecast" and "guidance", or the negative of these words or other similar terms or expressions. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements are based on Telix's good-faith assumptions as to the financial, market, regulatory and other risks and considerations that exist and affect Telix's business and operations in the future and there can be no assurance that any of the assumptions will prove to be correct. In the context of Telix's business, forward-looking statements may include, but are not limited to, statements about: the initiation, timing, progress, completion and results of Telix's preclinical and clinical trials, and Telix's research and development programs; Telix's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; the timing or likelihood of regulatory filings and approvals for Telix's product candidates, including the planned NDA resubmission for TLX101-CDx and the planned BLA resubmission for TLX250-CDx, manufacturing activities and product marketing activities; Telix's sales, marketing and distribution and manufacturing capabilities and strategies; the commercialization of Telix's product candidates, if or when they have been approved; Telix's ability to obtain an adequate supply of raw materials at reasonable costs for its products and product candidates; estimates of Telix's expenses, future revenues and capital requirements; Telix's financial performance; developments relating to Telix's competitors and industry; the anticipated impact of U.S. and foreign tariffs and other macroeconomic conditions on Telix's business; and the pricing and reimbursement of Telix's product candidates, if and after they have been approved. Telix's actual results, performance or achievements may be materially different from those which may be expressed or implied by such statements, and the differences may be adverse. Accordingly, you should not place undue reliance on these forward-looking statements.

**Trademarks and Trade Names.** All trademarks and trade names referenced in this press release are the property of Telix Pharmaceuticals Limited (Telix) or, where applicable, the property of their respective owners. For convenience, trademarks and trade names may appear without the ® or ™ symbols. Such omissions are not intended to indicate any waiver of rights by Telix or the respective owners. Trademark registration status may vary from country to country. Telix does not intend the use or display of any third-party trademarks or trade names to imply any affiliation with, endorsement by, or sponsorship from those third parties.

©2025 Telix Pharmaceuticals Limited. All rights reserved.