***Telix Pharmaceuticals Limited***
*ACN 616 620 369*
*55 Flemington Road*
*North Melbourne*
*Victoria, 3051*
*Australia*

**ASX ANNOUNCEMENT**

# FDA Accepts BLA for TLX250-CDx (Zircaix®) for Kidney Cancer Imaging, Grants Priority Review

*Melbourne (Australia) and Indianapolis, IN (U.S.A.) – 26 February 2025*. Telix Pharmaceuticals Limited (ASX: TLX, Nasdaq: TLX, Telix, the Company) today announces that the United States (U.S.) Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) for its breakthrough investigational kidney cancer PET[1] imaging agent TLX250-CDx (Zircaix®[2], $^{89}$Zr-DFO-girentuximab), granted a Priority Review and provided a PDUFA[3] date of 27 August 2025, paving the way for a U.S. commercial launch in 2025.

If approved, TLX250-CDx will become the first commercially available imaging agent to accurately and non-invasively diagnose and characterize clear cell renal cell carcinoma (ccRCC), the most common and one of the most aggressive sub-types of kidney cancer. It works by specifically binding to carbonic anhydrase IX (CAIX), a validated target protein expressed on 95% of ccRCC cells to produce images with high tumor-to-background ratio and high intra- and inter-reader consistency.

The BLA is based on Telix's successful global Phase 3 ZIRCON[4] study, which demonstrated 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[5]. The results of this study were published in *The Lancet Oncology* in September 2024, in a peer-reviewed manuscript by Professor Brian Shuch (University of California, Los Angeles, UCLA) and colleagues[6]. The paper outlines the critical unmet need for a new, non-invasive technique that can accurately detect and differentiate ccRCC from other renal masses in patients and concluded that TLX250-CDx meets this need and 'has the potential to be practice changing.'

Kevin Richardson, Chief Executive Officer, Precision Medicine, said, "We are delighted that the FDA has accepted this BLA as it moves us one step closer to bringing our breakthrough product to patients. We are aiming to revolutionize the management of kidney cancer, just as PSMA-PET/CT[7] scanning has changed the management of prostate cancer. By providing a more definitive clinical diagnosis for renal masses, we believe that Zircaix[2] will help physicians make more timely and confident patient management decisions and more quickly provide patients with a clear understanding of their disease and treatment options. Building further on Telix's successful urology franchise, we are preparing to bring this powerful precision medicine product to market in 2025[8]."

## About TLX250-CDx

TLX250-CDx (Zircaix®[2]) 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

[1] Positron emission tomography.
[2] Brand name subject to final regulatory approval.
[3] Prescription Drug User Fee Act.
[4] Zirconium in Renal Cancer Oncology, ClinicalTrials.gov ID: NCT03849118.
[5] Telix ASX disclosures 7 November 2022.
[6] Shuch et al. *Lancet Oncology.* 2024.
[7] Imaging of prostate-specific membrane antigen with positron emission tomography/computed tomography.
[8] Subject to regulatory approval.

radiology readers[5]. 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. Confidence intervals exceeded expectations amongst all three readers, showing evidence of high accuracy and consistency of interpretation.

As part of Telix's commitment to access to medicine, the Company operates an expanded access program (EAP) in the U.S.[9], named patient programs (NPPs) in Europe, and a special access scheme (SAS) in Australia to allow continued access to TLX250-CDx outside of a clinical trial, to patients for whom there are no comparable or satisfactory alternate options. TLX250-CDx has not received a marketing authorization in any jurisdiction and is for investigational use only.

**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, 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. ARTMS, IsoTherapeutics, Lightpoint, Optimal Tracers and RLS are Telix Group companies. 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 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**

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

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

Legal Notices

*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 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*

[9] ClinicalTrials.gov ID: NCT06090331.

*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 and results of Telix's preclinical and clinical trials, and Telix's research and development programs; Telix's ability to advance product candidates into, enrol and successfully complete, clinical studies, including multi-national clinical trials; the timing or likelihood of regulatory filings and approvals for Telix's product candidates, manufacturing activities and product marketing activities; Telix's sales, marketing and distribution and manufacturing capabilities and strategies; the commercialisation 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; 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.*