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ASX ANNOUNCEMENT

Telix Files TLX250-CDx (Zircaix®) BLA for Kidney Cancer Imaging

Melbourne (Australia) and Indianapolis, IN (U.S.A.) – 30 December 2024. Telix Pharmaceuticals Limited (ASX: TLX; Nasdaq: TLX, Telix, the Company) today announces that it has submitted its Biologics License Application (BLA) to the United States (U.S.) Food and Drug Administration (FDA) for TLX250-CDx (Zircaix®[1], ^{89}Zr- girentuximab) kidney cancer imaging[2].

TLX250-CDx is an investigational PET[3] drug product for the non-invasive diagnosis and characterisation of clear cell renal cell carcinoma (ccRCC), the most common and aggressive form of kidney cancer. If approved, TLX250-CDx will be the first and only targeted PET agent specifically for kidney cancer to be commercially available in the U.S., further building on Telix's successful urology imaging franchise.

The FDA is expected to advise the PDUFA[4] goal date following the 60-day administrative review of the application.

Kevin Richardson, Chief Executive Officer, Precision Medicine at Telix, stated, "We are pleased to be progressing the BLA for TLX250-CDx, which has been granted Breakthrough designation, and may therefore be eligible for priority review. Telix continues to target a full U.S. commercial launch in 2025 addressing a major unmet medical need for patients with suspected ccRCC."

About TLX250-CDx

TLX250-CDx (Zircaix®[1]) is an investigational PET agent that is under development for the diagnosis and characterisation of ccRCC. Telix's pivotal Phase III ZIRCON trial (ClinicalTrials.gov ID: NCT03849118) 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 for ccRCC across three independent 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 characterising ccRCC. Confidence intervals exceeded expectations amongst all three readers, showing evidence of high accuracy and consistency of interpretation.

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic radiopharmaceuticals and associated medical technologies. Telix is headquartered in Melbourne, Australia, with international operations in the United States, 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).

[1] Brand name subject to final regulatory approval.
[2] Telix ASX disclosure 31 July 2024. The FDA requested additional data demonstrating adequate sterility assurance during dispensing of TLX250-CDx in the radiopharmacy production environment.
[3] Positron emission tomography.
[4] Prescription Drug User Fee Act.
[5] Shuch et al. *Lancet Oncol.* 2024. Telix ASX disclosures 7 November 2022.

Telix's lead imaging product, gallium-68 (^{68}Ga) gozetotide injection (also known as ^{68}Ga PSMA-11 and marketed under the brand name Illuccix®), has been approved by the U.S. Food and Drug Administration (FDA)[6], by the Australian Therapeutic Goods Administration (TGA) [7], and by Health Canada[8]. No other Telix product has received a marketing authorisation in any jurisdiction.

Visit www.telixpharma.com for further information about Telix, including details of the latest share price, announcements made to the ASX, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on X and LinkedIn.

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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 registration statement on Form 20-F filed with the SEC, or on our website.

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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 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.

[6] Telix ASX disclosure 20 December 2021.
[7] Telix ASX disclosure 2 November 2021.
[8] Telix ASX disclosure 14 October 2022.