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ASX ANNOUNCEMENT

BLA Filing Update for Renal Cancer Imaging Agent TLX250-CDx

Melbourne (Australia) – 31 July 2024. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) announces that following completion [1] of its Biologics License Application (BLA) submission and the subsequent administrative review period, it has been notified that the United States (U.S.) Food and Drug Administration (FDA) has not accepted the BLA filing for TLX250-CDx (^{89}Zr-DFO-girentuximab), its investigational imaging agent for clear cell renal cell carcinoma (ccRCC).

During the 60-day administrative review, the FDA has identified a filing issue in the Chemistry, Manufacturing and Controls (CMC) package. The specific filing concern relates to demonstrating adequate sterility assurance during dispensing of TLX250-CDx in the radiopharmacy production environment. Telix can confirm that despite this concern raised by the FDA, all Process Performance Qualification (PPQ) batches submitted as part of the BLA application passed the sterility requirements of product release.

The FDA has indicated that this issue will require remediation in order for the application to advance to full review. The FDA has not indicated any deficiencies in the clinical or nonclinical data relating to the safety or efficacy of TLX250-CDx[2].

Based on current information, Telix expects to be able to complete remedial actions within approximately 90 days and resubmit the BLA. Per FDA regulations, Telix is entitled to request a meeting with the FDA within 30 days to discuss the decision outcomes. Telix intends to engage with the FDA during this period to agree on the requisite submission amendments. The Company will provide a further update when the package is resubmitted and continues to target a full U.S. commercial launch of TLX250-CDx in 2025.

Dr Christian Behrenbruch, Managing Director and Group Chief Executive Officer at Telix, stated, “TLX250-CDx is a breakthrough product and, if approved, would be the first targeted imaging agent for the non-invasive detection of renal cancer. We have been working closely with the FDA through the BLA rolling review due to the novel nature of this product candidate and value the FDA’s constructive feedback at this early stage in the process. We expect to be able to satisfy its requirements within a minimal time frame and continue to see a clear path to product commercialisation in 2025.”

The Company confirms that this is a non-material delay and there is no impact on revenue forecasts or research and development (R&D) expenditure for 2024. Telix can confirm that the previously issued revenue guidance of US$490M to US$510M (AU$745M to AU$776M at current exchange rates) for FY24 and previously advised guidance for R&D expenditure remains unchanged.[2]

About TLX250-CDx

TLX250-CDx (^{89}Zr-DFO-girentuximab, Zircaix®[3]) is a PET diagnostic imaging agent that is under development to characterise indeterminate renal masses as ccRCC or non-ccRCC in a non-invasive manner. Telix’s pivotal Phase III ZIRCON trial (ClinicalTrials.gov ID: NCT03849118) evaluating TLX250-CDx in 300 patients, of which 284 were evaluable, was completed in 2022 and met all primary and secondary endpoints, including showing 86% sensitivity and 87% specificity and a 93%

[1] Telix ASX disclosure 3 June 2024.
[2] Telix ASX disclosures 18 July 2024 and 22 February 2024.
[3] Brand name subject to final regulatory approval.

positive-predictive value for ccRCC across three independent readers [4]. We believe this demonstrated the ability of TLX250-CDx to reliably detect the clear cell phenotype and provide an accurate, non-invasive method for diagnosing ccRCC. Confidence intervals exceeded expectations in all three readers, showing evidence of high accuracy and consistency of interpretation.

As part of Telix's commitment to access to medicine, the Company continues to run an expanded access program (EAP) in the U.S.[5], 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.

Telix's Policy on Offering Compassionate Use to Investigational Medicines can be downloaded at the following link.

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic radiopharmaceuticals and associated medical devices. 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).

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.

[4] Telix ASX disclosures 7 November 2022.
[5] ClinicalTrials.gov ID: NCT06090331.
[6] Telix ASX disclosure 20 December 2021.
[7] Telix ASX disclosure 2 November 2021.
[8] Telix ASX disclosure 14 October 2022.

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 the Company's good-faith assumptions as to the financial, market, regulatory and other risks and considerations that exist and affect the Company'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 studies, 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, manufacturing activities and product marketing activities; the commercialisation of Telix's product candidates, if or when they have been approved; 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. You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the ASX or on our website.

To the maximum extent permitted by law, Telix disclaims any obligation or undertaking to publicly update or revise any forward-looking statements contained in this announcement, whether as a result of new information, future developments or a change in expectations or assumptions.