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ASX ANNOUNCEMENT

Telix Provides Regulatory Update on TLX250-CDx

Melbourne (Australia) and Indianapolis, IN (U.S.) – 28 August 2025. Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today announces that it has received a Complete Response Letter (CRL) from the United States (U.S.) Food and Drug Administration (FDA) for the Biologics License Application (BLA) for TLX250-CDx (Zircaix®[1], ^{89}Zr-DFO-girentuximab), an investigational PET[2] agent for the diagnosis and characterization of renal masses as clear cell renal cell carcinoma (ccRCC).

The CRL identifies deficiencies relating to the Chemistry, Manufacturing, and Controls (CMC) package. The FDA has requested additional data to establish comparability between the drug product used in the ZIRCON Phase 3 clinical trial and the scaled-up manufacturing process intended for commercial use. Additionally, the FDA has documented notices of deficiency (Form 483) issued to two third-party manufacturing and supply chain partners that will require remediation prior to resubmission.

Telix believes these concerns are readily addressable and submission remediation will begin immediately. The Company will request a Type A meeting with the FDA as soon as practicable to address the deficiencies and determine an appropriate timeframe for resubmission. TLX250-CDx has a Breakthrough Therapy designation and Priority Review status, acknowledging its importance in addressing a significant unmet medical need and clinically demonstrating benefit over available diagnostics.

Dr. Christian Behrenbruch, Managing Director and Group CEO, said, "TLX250-CDx breaks new ground as a highly novel biologic-based PET imaging agent using a first-in-class isotope. Like many radiopharmaceuticals, it has a complex supply chain, and as the field advances this creates new challenges around the regulatory framework applied to these products. We believe the outstanding matters are resolvable and that we can address the remaining FDA requests within a reasonable time frame."

The CRL does not impact Telix's stated revenue guidance for 2025[3], as guidance excludes revenue forecasts from unapproved products. The Company intends to continue to provide patient access to TLX250-CDx through the FDA-approved expanded access program (EAP), subject to consultation with the FDA.

Investor Conference Call

An investor conference call will be held on: **Thursday 28 August at 10.30am AEST / Wednesday 27 August at 8.30pm ET**. Participants can register and receive dial in details for the conference call via this link: https://s1.c-conf.com/diamondpass/10049865-f765s4.html

[1] Brand name subject to final regulatory approval.
[2] Positron emission tomography.
[3] Telix ASX disclosure 20 February 2025.

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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).

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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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.

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