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ASX ANNOUNCEMENT

Telix Provides Regulatory Update on TLX101-CDx

Melbourne (Australia) and Indianapolis, IN (U.S.) – 28 April 2025. Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, Telix, the Company) today announces that it has received a Complete Response Letter (CRL) from the United States (U.S.) Food and Drug Administration (FDA) for its New Drug Application (NDA) for TLX101-CDx (Floretyrosine F18 or ^{18}F-FET, Pixclara®[1]), an investigational agent for the imaging of glioma, a rare and life-threatening brain cancer.

The CRL states that the FDA has completed its review of the application and has ruled that the NDA cannot be approved in its current form. The FDA stated additional confirmatory clinical evidence is required to progress the application, despite a robust consultation process prior to submission and during review of the NDA. The FDA has not raised any concerns regarding product safety. The Company will be requesting a hearing with the FDA to review the basis for the decision and is assessing clinical strategies available to augment the package in the near term.

This is a disappointing outcome for American glioma patients. FET-PET is recommended medical best practice in relevant international oncology practice guidelines[2] and is used extensively in other parts of the world. The FDA has granted TLX101-CDx Orphan Drug and Fast Track designation, a tacit acknowledgement of the drug candidate's importance in addressing a significant unmet medical need and clinically demonstrating benefit over existing medical solutions.

Telix Managing Director and Group CEO, Dr. Christian Behrenbruch, said, “We are committed to commercializing TLX101-CDx and fulfilling the unmet need to improve imaging to enable timelier and more accurate decisions for the clinical management of glioma. We have multiple go-forward pathways available to us, such as providing additional confirmatory data through several active clinical programs, including Company-led studies. Our immediate focus is understanding the FDA’s feedback and augmenting our submission with additional data to satisfy the Agency as soon as possible.”

The CRL does not impact Telix’s stated financial guidance for 2025[3], as guidance excludes revenue forecasts from unapproved products. The Company remains committed to providing patient access to TLX101-CDx through the FDA-approved expanded access program (EAP)[4].

Investor Conference Call

An investor conference call will be held on:

Monday 28th April at 9.30am AEST / Sunday 27th April at 7.30pm ET

Participants can register and receive dial in details via this link:
https://s1.c-conf.com/diamondpass/10047004-td1o9y.html

About Telix Pharmaceuticals Limited

[1]Provisional brand name, subject to final regulatory approval.
[2] Albert et al. *Lancet Oncol.* 2024.
[3] Telix ASX disclosure 20 February 2025.
[4] ClinicalTrials.gov ID: NCT06743100.

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, 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. 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.

TLX101-CDx has not received a marketing authorization in any jurisdiction.

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

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.