

ASX ANNOUNCEMENT

**Telix and FDA Agree on Resubmission Pathway for TLX101-CDx
(Pixclara®) U.S. NDA**

Melbourne (Australia) and Indianapolis, IN (U.S.) – 9 September 2025. Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, “Telix”) today announces that it has reached agreement with the United States (U.S.) Food and Drug Administration (FDA) regarding resubmission of its New Drug Application (NDA) for TLX101-CDx (Floretyrosine F18 or ¹⁸F-FET, Pixclara®¹), an investigational agent for the imaging of glioma, a rare and life-threatening brain cancer. As previously advised, the Company confirms its plan to resubmit the NDA during Q4 2025².

Following engagement with the FDA, including a successful Type A meeting, Telix has received detailed feedback regarding a resubmission package which will include an additional confirmatory efficacy study analysis of existing data. Based on this feedback, Telix believes the study will meet the FDA’s request for additional confirmatory evidence to supplement the NDA and address the review matters cited in the Complete Response Letter (CRL).

Dr. David N. Cade, Telix Group Chief Medical Officer, said, “As previously advised, Telix had multiple options for delivering additional data requested by the FDA in the CRL response³. This flexibility has enabled us to work with relative speed to reach a mutually agreed path forward for resubmission of the NDA. We remain steadfastly focused on our goal of bringing this important imaging agent to patients in the U.S. to support improved diagnosis and management of glioma”.

The FDA will advise of a new PDUFA⁴ goal date following a successful resubmission. The agency has acknowledged the unmet medical need and has indicated that an expedited review is likely to be granted on this basis, subject to submission review.

TLX101-CDx is not included in Telix’s stated revenue guidance for 2025, as guidance excludes revenue forecasts from unapproved products⁵. The Company remains committed to providing ongoing patient access to TLX101-CDx through the FDA-approved expanded access program (EAP)⁶ up until U.S. regulatory approval.

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

¹ Provisional brand name, subject to final regulatory approval.

² Telix ASX disclosure 21 August 2025, noted resubmission planned in approximately three months

³ Telix ASX disclosure 28 April 2025.

⁴ Prescription Drug User Fee Act.

⁵ Telix ASX disclosure 20 February 2025.

⁶ ClinicalTrials.gov ID: [NCT06743100](https://clinicaltrials.gov/ct2/show/study/NCT06743100).

needs in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (NASDAQ: TLX).

Illuccix® (kit for the preparation of gallium-68 (⁶⁸Ga) gozetotide injection), Telix's first generation PSMA-PET imaging agent, has been approved in multiple markets globally. Gozellix® (kit for the preparation of gallium-68 (⁶⁸Ga) gozetotide injection) has been approved by the U.S. FDA⁷. TLX101-CDx has not received a marketing authorization in any jurisdiction.

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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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, completion and results of Telix's preclinical

⁷ Telix ASX disclosure 21 March 2025.

and clinical trials, and Telix's research and development programs; Telix's ability to advance product candidates into, enroll 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, including Telix's planned resubmission of the New Drug Application (NDA) for TLX101-CDx in 2025, which is subject to FDA acceptance of the NDA for review, as well as the FDA's timeline for review of the NDA, if accepted; Telix's sales, marketing and distribution and manufacturing capabilities and strategies; the commercialization 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; the anticipated impact of U.S. and foreign tariffs and other macroeconomic conditions on Telix's business; 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.

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