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## ASX ANNOUNCEMENT

### **Telix Resubmits NDA to U.S. FDA for TLX101-Px (Pixclara®) Brain Cancer Imaging Candidate**

Melbourne (Australia) and Indianapolis, IN (U.S.) – March 16, 2026. Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, “Telix”) today announces the resubmission of a New Drug Application (NDA) to the United States (U.S.) Food and Drug Administration (FDA) for TLX101-Px, (Pixclara®<sup>1</sup>, Floretyrosine F 18 or <sup>18</sup>F-FET), an investigational PET<sup>2</sup> imaging agent for the characterization of recurrent or progressive glioma (brain cancer) from treatment related changes in both adult and pediatric patients.

Telix has resubmitted the NDA with the additional data requested by the FDA. The Company believes, based on the Type A meeting and ongoing consultation with the FDA, that the additional data and statistical analysis, along with the primary data set provided in the original submission, appropriately addresses the Complete Response Letter<sup>3</sup>.

Given the potential to address significant unmet medical need, TLX101-Px has been granted Orphan Drug<sup>4</sup> and Fast Track<sup>5</sup> designations by the FDA. PET imaging with <sup>18</sup>F-FET is already included in international clinical practice guidelines for the imaging of gliomas<sup>6</sup>, however there is currently no FDA-approved targeted amino acid PET agent for adult and pediatric brain cancer imaging commercially available in the U.S.

Dr. David N. Cade, Telix Group Chief Medical Officer, said, “We appreciate the FDA’s recognition of the critical unmet need to improve the diagnosis and management of glioma, particularly in the post-treatment setting. Our resubmission is supported by an extensive and compelling data set – particularly so for an orphan indication. We are grateful to our global clinical collaborators, who share our commitment to ensuring patients in the U.S. can benefit from this important patient management tool.”

Maggie Haynes, Executive Director, Head for the Cure Foundation, added: “Our community is encouraged by the FDA’s ongoing engagement and guidance to the sponsor and support for the Expanded Access Program for TLX101-Px. We are hopeful of an expedited review, so this important and proven imaging option can become available to those who urgently need it.”

#### **About TLX101-Px**

TLX101-Px is a PET imaging agent, which has been granted fast track and orphan drug designations by the FDA as an imaging agent for the characterization of recurrent or progressive glioma from treatment related changes. TLX101-Px targets membrane transport proteins known as LAT1 and

<sup>1</sup> Brand name subject to final regulatory approval.

<sup>2</sup> Positron emission tomography.

<sup>3</sup> Telix ASX disclosure April 28, 2025.

<sup>4</sup> Telix ASX disclosure October 6, 2020.

<sup>5</sup> Telix ASX disclosure April 16, 2024. Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. More: <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track>

<sup>6</sup> Galldiks et al. *Lancet Oncol.* 2025 (Joint guidelines from the European Association of Nuclear Medicine (EANM), European Association of Neuro-Oncology (EANO), Society of Nuclear Medicine and Molecular Imaging (SNMMI), Response Assessment in Neuro-Oncology (RANO), The European Society for Pediatric Oncology and The Response Assessment in Pediatric Neuro-Oncology for the characterization of recurrence in glioma patients); National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Central Nervous System Cancers V1.2025.

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LAT2<sup>7</sup>. This enables TLX101-Px to be potentially utilized as a companion diagnostic agent to TLX101-Tx (iodofalan <sup>131</sup>I), Telix's LAT1-targeting glioblastoma (GBM) therapy candidate, currently under investigation in the pivotal IPAX-BriGHT study<sup>8</sup>.

### About gliomas in the U.S.

Gliomas are very diffusely infiltrative tumors that affect the surrounding brain tissue. They are the most common form of central nervous system (CNS) neoplasm that originates from glial cells, accounting for approximately 30% of all brain and CNS tumors and 80% of all malignant brain tumors<sup>9</sup>. In the U.S., there are six cases of gliomas diagnosed per 100,000 people every year<sup>10</sup>. GBM is a high-grade glioma and the most common and aggressive form of primary brain cancer, with approximately 22,000 new cases diagnosed annually in the U.S.<sup>11</sup>. The mainstay of treatment for GBM comprises surgical resection, followed by combined radiotherapy and chemotherapy. Despite such treatment, recurrence occurs in almost all patients<sup>12</sup>, with an expected survival duration of 12-15 months from diagnosis<sup>13</sup>.

### About Telix Pharmaceuticals Limited

Telix is a global biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals and associated medical technologies, with the goal to address significant unmet medical needs in oncology and rare diseases. With international operations in the United States, United Kingdom, Brazil, Canada, Europe (Belgium and Switzerland), and Japan, Telix is headquartered in Melbourne, Australia. 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 (<sup>68</sup>Ga) 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 (<sup>68</sup>Ga) gozetotide injection) has been approved by the U.S. FDA<sup>14</sup>. TLX101-Px and TLX101-Tx have not received marketing authorizations in any jurisdiction.

Visit [www.telixpharma.com](http://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.*

<sup>7</sup> L-type amino acid transporters 1 and 2.

<sup>8</sup> ClinicalTrials.gov ID: [NCT07100730](https://clinicaltrials.gov/ct2/show/study/NCT07100730).

<sup>9</sup> Goodenberger et al. *Cancer Genet.* 2012.

<sup>10</sup> Mesfin et al. *StatPearls.* 2024.

<sup>11</sup> Ostrom 2022, CBTRUS (Central Brain Tumor Registry of the United States) Statistical Report.

<sup>12</sup> Park et al. *Journal of Clinical Oncology.* 2010.

<sup>13</sup> Ostrom et al. *Neuro Oncol.* 2018.

<sup>14</sup> Telix ASX disclosure March 21, 2025.

*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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