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## ASX ANNOUNCEMENT

### **Telix Submits European Marketing Authorization Application for TLX101-Px for Brain Cancer Imaging**

Melbourne (Australia) and Indianapolis, IN (U.S.) – 18 February 2026. Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, “Telix”) today announces that it has submitted a marketing authorization application (MAA) in Europe for TLX101-Px (O-(2-[<sup>18</sup>F]fluoroethyl)-L-tyrosine, <sup>18</sup>F-FET), its glioma (brain cancer) imaging candidate.

Telix has been preparing the European and U.S. regulatory packages for TLX101-Px concurrently, bringing forward the European submission to meet an agreed filing date while aligning with aspects of the U.S. Food and Drug Administration (FDA) package to support the additional application. The submission covers major European markets<sup>1</sup>. Telix is seeking to expand patient access to advanced brain imaging through a broad clinical label, reflective of current clinical practice guidelines<sup>2</sup>. Submission of the U.S. New Drug Application (NDA) will follow.

In Europe, positron emission tomography (PET) imaging of glioma with <sup>18</sup>F-FET (FET-PET) is currently performed under physician-supervised use through hospital-based production at a limited number of sites. However, there is currently no generally available commercial product in Europe that ensures consistent quality and access for glioma imaging, an acute and immediate need<sup>3</sup>. Telix aims to expand patient access to advanced imaging that can distinguish progressive or recurrent glioma from treatment-related changes in both adults and children, with potential for additional future indications. TLX101-Px is also being developed as a patient selection and response assessment tool for Telix’s glioblastoma therapy candidate TLX101-Tx (iodofalan <sup>131</sup>I), which has been granted orphan drug designation in Europe and the U.S. and is the subject of the Phase 3 IPAX-BriGHT trial in patients with recurrent glioblastoma, launching in multiple European countries<sup>4</sup>.

Philipp Lohmann, Group Leader Digital Translational Neuroimaging at Forschungszentrum Jülich research center in Germany, commented, “FET-PET imaging is already used in clinical practice in Europe for the evaluation of gliomas, and plays a critical role in treatment decision making. This applies particularly in the post-therapy setting, where conventional MRI<sup>5</sup> alone can be limited in its ability to distinguish tumor progression from treatment-related changes. Having widespread access to TLX101-Px has potential to provide clinicians with greater biological insight, supporting more confident and timely management of patients with brain tumors.”

Kevin Richardson, Chief Executive Officer, Telix Precision Medicine, added, “We see a compelling opportunity in Europe to broaden access to authorized targeted radiopharmaceuticals for brain cancer imaging and therapy, and as such this submission is an important milestone for Telix. The

<sup>1</sup> The French National Agency for Medicines and Health Products Safety (ANSM), in its capacity as Reference Member State, is responsible for coordinating and leading the scientific evaluation of the dossier, in collaboration with the concerned Member States, nominated by Telix and representing the major European markets for Telix’s brain cancer imaging product.

<sup>2</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.

<sup>3</sup> Albert et al. *Lancet Oncol.* 2024.

<sup>4</sup> ClinicalTrials.gov ID: [NCT07100730](https://clinicaltrials.gov/ct2/show/study/NCT07100730).

<sup>5</sup> Magnetic Resonance Imaging.

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strategic value of this submission is particularly relevant to establishing widespread glioma imaging as part of our corresponding therapeutic development program. We have been able to utilize aspects of our FDA package to expedite the European filing, which has been submitted in accordance with a pre-defined date agreed with the regulator, with the U.S. resubmission to follow.”

### **About glioma in Europe**

In Europe, approximately 67,500 brain and central nervous system tumors are diagnosed every year<sup>6</sup>, with gliomas accounting for approximately 30% of these, and up to 80% of all malignant brain tumors<sup>7</sup>. There is a critical unmet need to improve the diagnosis and management of gliomas, which are the most common primary brain tumors of the central nervous system, particularly in the post-treatment setting<sup>5</sup>. Conventional MRI imaging techniques have several limitations, including a lack of biological specificity, dependency on blood-brain barrier disruption, and an inherent inability to differentiate between tumor progression or treatment-related causes. This can yield inconclusive results and delay time-sensitive treatment decisions<sup>8</sup>. With low survival rates and the need to make rapid decisions, precision imaging is paramount<sup>5</sup>. Subject to regulatory approval, TLX101-Px has the potential to address this need, enabling patients in Europe to receive greater clarity in their diagnosis and treatment decision making.

### **About TLX101-Px**

TLX101-Px (O-(2-[<sup>18</sup>F]fluoroethyl)-L-tyrosine) is Telix’s PET imaging candidate for the characterization of glioma. TLX101-Px targets membrane transport proteins known as L-type amino acid transporters 1 and 2 (LAT1 and LAT2). This enables TLX101-Px to be potentially utilized as a complementary diagnostic agent to TLX101-Tx (iodofalan <sup>131</sup>I), Telix’s LAT1-targeting investigational glioblastoma (GBM) therapy, currently under investigation in Telix’s IPAX-2<sup>9</sup> and IPAX-BrIGHT<sup>6</sup> studies. TLX101-Px and TLX101-Tx have not received a marketing authorization in any jurisdiction. In relevant European markets, the proposed brand name for TLX101-Px is “Pixlumi®”. Brand name and commercial launch are subject to final 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 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](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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<sup>6</sup> Frosina et al. *Sci Rep.* 2024.

<sup>7</sup> Goodenberger et al. *Cancer Genetics.* 2012.

<sup>8</sup> Smith et al. *J Nucl Med.* 2023.

<sup>9</sup> ClinicalTrials.gov ID: [NCT05450744](https://clinicaltrials.gov/ct2/show/study/NCT05450744).

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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

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*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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