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ASX RELEASE

TLX101-CDx (Pixclara™) Granted FDA Fast Track Designation

- *FDA Fast Track designation granted for TLX101-CDx for glioma (brain cancer) imaging*
- *Collaboration agreement announced for joint development and commercialisation with UCSF*
- *PharmaLogic announced as commercial manufacturing and pharmacy distribution partner*

Melbourne (Australia) – 16 April 2024. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that the United States (U.S.) Food and Drug Administration (FDA) has granted Fast Track designation[1] for the Company's investigational glioma imaging product, TLX101-CDx (Pixclara™[2], ^{18}F-floretyrosine or ^{18}F-FET).

The granted Fast Track designation is for the characterisation of progressive or recurrent glioma using positron emission tomography (PET). Concurrently, Telix is in the final stages of preparing its U.S. New Drug Application (NDA) for TLX101-CDx in this initial indication, in both adult and paediatric patients. This designation enables expedited review and closer consultation with the FDA during the review process.

Amino acid PET is currently included in U.S. and European guidelines for the imaging of gliomas[3], however there is no FDA-approved targeted PET agent for brain cancer imaging in the U.S. Telix's goal is to make this product commercially available in the U.S., significantly increasing patient access to this important imaging agent.

Collaboration with the University of California, San Francisco

Telix has an exclusive research collaboration and data license agreement with the University of California, San Francisco (UCSF). UCSF is one of the leading academic centres conducting clinical research into the use of FET PET[4] in a variety of neurological malignancies. This academic-industrial collaboration supporting joint development and commercialisation will enable Telix to offer TLX101-CDx access as a commercial product in the U.S., subject to regulatory approval.

Thomas A. Hope, MD, Professor of Radiology at UCSF, said, "There is critical unmet need to improve the diagnosis and management of glioma, particularly in the post-treatment setting, and we are excited to leverage the clinical experience at UCSF to help make this investigational agent more widely available. ^{18}F-FET has the potential to help determine if a glioma is truly progressing or undergoing a treatment-induced change, known as pseudo-progression, where MRI[5] – the standard of care – can often be inconclusive."

David N. Cade, MD, Group Chief Medical Officer at Telix, stated, "This unique collaboration between Dr. Hope's team at UCSF and Telix will enable us to utilise our collective clinical data and expertise to facilitate nationwide access to FET PET in the United States while fostering ongoing research and development with the objective of expanding the clinical utility of this advanced imaging agent for

[1] 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.
[2] Brand name subject to final regulatory approval.
[3] Joint European Association of Nuclear Medicine//European Association of Neurooncology/Response Assessment in Neurooncology practice guidelines/Society for Nuclear Medicine and Molecular Imaging procedure standards for the clinical use of PET imaging in gliomas.
[4] Positron emission tomography with ^{18}F-floretyrosine.
[5] Magnetic resonance imaging.

the benefit of patients."

Commercial Partnership: PharmaLogic Holdings Corp

Telix has selected PharmaLogic Holdings Corp (PharmaLogic) as its commercial manufacturing and pharmacy distribution partner, to supply finished unit doses of TLX101-CDx to the U.S. market.

Steven Chilinski, President and CEO at Pharmalogic, added, "Telix has quickly grown into a global theranostics leader with an impressive product pipeline. Through this partnership, we're delighted to bring this imaging agent to glioma patients in the U.S. upon regulatory approval."

Richard Valeix, Group Chief Commercial Officer at Telix, continued, "These milestones represent significant progress as we bring this investigational product closer to market in the U.S. and commercial launch. PharmaLogic has rapidly developed an excellent reputation for manufacturing radiopharmaceuticals to rigorous quality standards and will deliver a key component of Telix's supply chain strategy for TLX101-CDx in the U.S., subject to regulatory approval."

About TLX101-CDx

TLX101-CDx (Pixclara™[2]) is a PET imaging agent, which has been previously granted orphan drug designation (ODD) in the U.S. as an imaging agent for the management of glioma[6]. TLX101-CDx targets membrane transport proteins known as LAT1 and LAT2[7]. This enables TLX101-CDx to be potentially utilised as a companion diagnostic agent to TLX101 (4-L-[^{131}I] iodo-phenylalanine, or ^{131}I-IPA), Telix's LAT1-targeting investigational glioblastoma (GBM) therapy, currently under investigation in the and IPAX-2[8] and IPAX-Linz[9] studies.

About gliomas in the U.S.

Gliomas are very diffusely infiltrative tumours 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 tumours and 80% of all malignant brain tumours[10]. In the U.S., there are six cases of gliomas diagnosed per 100,000 people every year. 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.[11]. The mainstay of treatment for GBM comprises surgical resection, followed by combined radiotherapy and chemotherapy. Despite such treatment, recurrence occurs in almost all patients[12], with an expected survival duration of 12-15 months from diagnosis[13].

About PharmaLogic

PharmaLogic is a world-class contract development and manufacturing organisation specialising in novel diagnostic imaging and therapeutic radiopharmaceuticals for the treatment of cancers and other malignancies. In addition to an established and reliable network of radiopharmacies, PharmaLogic has decades of expertise in drug development from discovery, through manufacturing and commercialisation. The Company seeks to take the lead in the advancement of radiopharmaceutical technology for the benefit of patients worldwide. For more information, visit: www.radiopharmacy.com.

[6] Telix ASX disclosure 6 October 2020.
[7] Large amino acid transporters 1 and 2.
[8] Telix media release 8 August 2023. ClinicalTrials.gov ID: NCT05450744.
[9] Telix media release 22 November 2022.
[10] Goodenberger et al. *Cancer Genet.* 2012.
[11] Ostrom 2022, CBTRUS (Central Brain Tumor Registry of the United States) Statistical Report.
[12] Park et al. *Journal of Clinical Oncology.* 2010.
[13] Ostrom et al. *Neuro Oncol.* 2018.

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic radiopharmaceuticals and associated medical devices. Telix is headquartered in Melbourne, Australia, with international operations in the United States, 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).

Telix's lead imaging product, gallium-68 (^{68}Ga) gozetotide injection (also known as ^{68}Ga PSMA-11 and marketed under the brand name Illuccix®), has been approved by the FDA[14], by the Australian Therapeutic Goods Administration (TGA)[15], and by Health Canada[16]. No other Telix product has received a marketing authorisation in any jurisdiction.

Visit www.telixpharma.com for further information about Telix, including details of the latest share price, announcements made to the ASX, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on X and LinkedIn.

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

[14] Telix ASX disclosure 20 December 2021.
[15] Telix ASX disclosure 2 November 2021.
[16] Telix ASX disclosure 14 October 2022.