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ASX ANNOUNCEMENT

FDA Accepts New Drug Application and Grants Priority Review for TLX101-CDx (Pixclara®) Brain Cancer Imaging Agent

Melbourne (Australia) – 24 October 2024. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that the United States (U.S.) Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for TLX101-CDx (Pixclara®[1]), an agent for the imaging of glioma. The application has been granted priority review and designated a PDUFA[2] goal date of 26 April 2025, paving the way for a U.S. commercial launch in 2025[3].

Pixclara (^{18}F-floretyrosine or ^{18}F-FET) is a PET agent for the characterisation of progressive or recurrent glioma from treatment related changes in both adult and pediatric patients. FET PET is already included in international clinical practice guidelines for the imaging of gliomas[4], 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. Given its potential to address significant unmet medical need, Pixclara has been designated as an orphan drug[5] and granted fast track designation[6] by the FDA.

There is a critical unmet need to improve the diagnosis and management of gliomas, which are the most common primary brain tumours of the central nervous system, particularly in the post-treatment setting. Conventional MRI[7] imaging techniques have several limitations, including a lack of biological specificity, dependency on blood-brain barrier disruption, and an inherent inability to differentiate between tumour progression or treatment-related causes. This can yield inconclusive results and delay time-sensitive treatment decisions[8].

With low survival rates and the need to make rapid decisions, precision imaging is paramount. Subject to regulatory approval, Pixclara has the potential to address this need, enabling patients in the U.S. to receive greater clarity in their diagnosis and treatment decision making. Telix is also reviewing the potential use of Pixclara as a "companion" diagnostic agent for TLX101-Tx, the investigational neuro-oncology drug currently in development, which targets the same amino acid transporter mechanism with therapeutic targeted radiation.

Kevin Richardson, Chief Executive Officer, Telix Precision Medicine, said, "Telix believes that the FDA approval of Pixclara will drive a step-change for brain cancer imaging in the U.S., and bring it into line with a more advanced standard of care currently used in other markets. There is currently a critical need for better imaging in brain cancer, and Telix is dedicated to delivering precision medicine solutions that address patient needs and enhance both cancer imaging and treatment outcomes."

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[1] Brand name subject to final regulatory approval.
[2] Prescription User Drug Fee Act.
[3] Subject to FDA marketing authorsation approval.
[4] 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.
[5] Telix ASX disclosure 6 October 2020.
[6] Telix ASX disclosure 16 April 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
[7] Magnetic resonance imaging.
[8] Smith NJ et al. *J Nucl Med.* 2023.

About TLX101-CDx

TLX101-CDx (Pixclara) is a PET imaging agent, which has been granted fast track and orphan drug designations by the FDA as an imaging agent for the characterisation of glioma. TLX101-CDx targets membrane transport proteins known as LAT and LAT2[9]. This enables Pixclara to be potentially utilised as a companion diagnostic agent to TLX101 (^{131}I-iodofalan, or ^{131}I-IPA), Telix's LAT1-targeting investigational glioblastoma (GBM) therapy, currently under investigation in the Telix's IPAX-2[10] and IPAX-Linz[11] 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[12]. 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.[13]. The mainstay of treatment for GBM comprises surgical resection, followed by combined radiotherapy and chemotherapy. Despite such treatment, recurrence occurs in almost all patients[14], with an expected survival duration of 12-15 months from diagnosis[15].

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 U.S. Food and Drug Administration (FDA)[16], by the Australian Therapeutic Goods Administration (TGA)[17], and by Health Canada[18]. 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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[9] Large amino acid transporters 1 and 2.
[10] Telix media release 8 August 2023. ClinicalTrials.gov ID: NCT05450744.
[11] Telix media release 22 November 2022.
[12] Goodenberger et al. *Cancer Genet.* 2012.
[13] Ostrom 2022, CBTRUS (Central Brain Tumor Registry of the United States) Statistical Report.
[14] Park et al. *Journal of Clinical Oncology.* 2010.
[15] Ostrom et al. *Neuro Oncol.* 2018.
[16] Telix ASX disclosure 20 December 2021.
[17] Telix ASX disclosure 2 November 2021.
[18] Telix ASX disclosure 14 October 2022.

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

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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) or on our website.

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