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ASX ANNOUNCEMENT

Telix Submits NDA for TLX101-CDx (Pixclara®) Brain Cancer Imaging Agent

Melbourne (Australia) – 28 August 2024. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces it has submitted a New Drug Application (NDA) to the United States (U.S.) Food and Drug Administration (FDA) for TLX101-CDx, (Pixclara®[1], ^{18}F-floretyrosine or ^{18}F-FET), an investigational PET[2] agent for the characterisation of progressive or recurrent glioma (brain cancer) from treatment related changes in both adult and pediatric patients.

Given the potential to address significant unmet medical need, Pixclara®[1] has been granted Orphan Drug[3] and Fast Track[4] designation by the FDA, which facilitates expedited review and closer consultation with the agency during the review process. FET PET (Pixclara®[1]) is already included in international clinical practice guidelines for the imaging of gliomas[5], 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.

There is a critical unmet need to improve the diagnosis and management of glioma, particularly in the post-treatment setting. With low survival rates and the need to make rapid decisions, precision imaging is paramount. Subject to regulatory approval, Pixclara®[1] has the potential to address this need, enabling patients to receive greater clarity in their diagnosis and treatment decision making. Pixclara®[1] is also being developed as the "companion" theranostic imaging agent for TLX101, Telix's investigational neuro-oncology drug candidate, which targets the same amino acid transporter mechanism with therapeutic targeted radiation.

Kevin Richardson, Chief Executive Officer, Telix Precision Medicine, stated, "Gliomas are the most common primary brain tumours of the central nervous system. Conventional imaging with MRI[6] often yields inconclusive results in characterising recurrent disease and therefore delays time-sensitive decision making[4]. Limitations of conventional imaging techniques include the lack of biological specificity, dependency on blood-brain barrier disruption, and an inherent inability to differentiate between tumour progression or treatment-related causes[7]. Telix's filing of this NDA for Pixclara®[1] is an important milestone, reflecting our commitment to improved and accessible neuro-oncology imaging in the U.S., and taking us one step closer to commercial availability in 2025, subject to FDA approval."

About TLX101-CDx

TLX101-CDx (Pixclara®[1]) 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 LAT1 and LAT2[8]. This enables TLX101-CDx to be potentially utilised as a companion diagnostic agent to TLX101 (4-L-[^{131}I] iodo-phenylalanine, or ^{131}I-

[1] Brand name subject to final regulatory approval.
[2] Positron emission tomography.
[3] Telix ASX disclosure 6 October 2020.
[4] 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
[5] 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.
[6] Magnetic resonance imaging.
[7] Smith NJ et al. *J Nucl Med.* 2023.
[8] Large amino acid transporters 1 and 2.

IPA), Telix's LAT1-targeting investigational glioblastoma (GBM) therapy, currently under investigation in the IPAX-2[9] and IPAX-Linz[10] 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[11]. 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.[12]. The mainstay of treatment for GBM comprises surgical resection, followed by combined radiotherapy and chemotherapy. Despite such treatment, recurrence occurs in almost all patients[13], with an expected survival duration of 12-15 months from diagnosis[14].

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)[15], by the Australian Therapeutic Goods Administration (TGA)[16], and by Health Canada[17]. 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.

Legal Notices

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.

[9] Telix media release 8 August 2023. ClinicalTrials.gov ID: NCT05450744.
[10] Telix media release 22 November 2022.
[11] Goodenberger et al. *Cancer Genet.* 2012.
[12] Ostrom 2022, CBTRUS (Central Brain Tumor Registry of the United States) Statistical Report.
[13] Park et al. *Journal of Clinical Oncology.* 2010.
[14] Ostrom et al. *Neuro Oncol.* 2018.
[15] Telix ASX disclosure 20 December 2021.
[16] Telix ASX disclosure 2 November 2021.
[17] Telix ASX disclosure 14 October 2022.

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This announcement may contain forward-looking statements 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 and results of Telix's preclinical and clinical trials, and Telix's research and development programs; Telix's ability to advance product candidates into, enrol 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; Telix's sales, marketing and distribution and manufacturing capabilities and strategies; the commercialisation 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; 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.