Telix Pharmaceuticals Limited
ACN 616 620 369
55 Flemington Road
North Melbourne
Victoria, 3051
Australia

ASX ANNOUNCEMENT

Telix Announces Positive rPFS Data from ProstACT SELECT Trial of TLX591 rADC Therapy Candidate in Prostate Cancer

- TLX591 is an investigational anti-PSMA[1] radio-antibody-drug conjugate (rADC) therapy being developed for the treatment of mCRPC, differentiated by a short two-week dosing regimen.
- Reported median radiographic progression-free survival (rPFS) is 8.8 months.
- Builds on prior data from the ProstACT SELECT[2] trial, demonstrating favourable safety profile and biodistribution[3].

Melbourne (Australia) – 31 May 2024. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces additional positive data from the ProstACT SELECT trial ("SELECT") of TLX591 (^{177}Lu rosopatamab tetraxetan), a lutetium-labelled rADC therapy for the treatment of adult patients with PSMA-positive metastatic castrate-resistant prostate cancer (mCRPC). SELECT is a radiogenomics study intended to evaluate lesion concordance between ^{68}Ga (gallium)-based PSMA-PET[4] imaging and TLX591 dosimetry for the purpose of validating PET imaging for patient selection for rADC therapy. The Company has previously reported final safety data from this study[3].

The study has reported a median rPFS of 8.8 months, representing an encouraging signal of the potential efficacy of TLX591 in this patient population. The evaluable sample size for rPFS comprised 23 patients with previously treated, progressive mCRPC and who received two 76 mCi intravenous (IV) infusions of TLX591, 14 days apart[5]. The SELECT trial included a heterogeneous population of low, medium and high disease burden patients to facilitate imaging cross-comparison, with the majority having undergone two prior lines of therapy.

Nat Lenzo, MD, Nuclear Oncologist and General Internal Medicine Physician and lead recruiter onto the SELECT trial, commented, "We are encouraged by this rPFS result, which compares favourably to small molecule radioligand therapy (RLT) Phase I and II studies at similar stages of development[6]. This is a compelling signal of the potential efficacy of TLX591 in this heavily pre-treated population. The results further support the development of this candidate in an earlier mCRPC patient population which is the focus of the ProstACT GLOBAL[7] Phase III trial and where there remains significant unmet need for effective treatment."

Dr David N. Cade, MD, Group Chief Medical Officer at Telix, stated, "TLX591 is a radio-ADC with significant potential advantages compared to small molecule radiopharmaceuticals in treating prostate cancer. TLX591 is differentiated by a patient-friendly dosing regimen with far lower cumulative radiation exposure compared to small molecule radioligand therapies[8]. This positive signal of efficacy from SELECT builds on prior studies that demonstrated the potential for TLX591 to deliver improved quality of life and durable tumour control in this advanced patient population[9]."

[1] Prostate-specific membrane antigen.
[2] ProstACT SELECT ClinicalTrials.gov ID: NCT04786847.
[3] Telix ASX disclosure 19 October 2023.
[4] Imaging of prostate-specific membrane antigen with positron emission tomography.
[5] The study recruited 30 patients, with 5 patients completing low-dose dosimetry. Two patients did not complete a second dose and therefore were excluded from the rPFS calculation.
[6] Hofman et al. *Lancet Oncol* 2018; Violet et al. *Journal of Nuc Med* 2019; Calais et al. *Journal of Nuc Med* 2021.
[7] ProstACT GLOBAL ClinicalTrials.gov ID: NCT04876651.
[8] 152 mCi cumulative radiation exposure with TLX591 compared with up to 1200 mCi with current approved RLT, based on prescribing information.
[9] Bander et al. *J Clin Oncol.* 2005; Tagawa et al. *Clin Cancer Res.* 2013; Tagawa et al. *Cancer.* 2019; Batra et al. *Urol Oncol.* 2020; Niaz et al. *Oncologist.* 2020.

TLX591 is being further evaluated in the Phase III ProstACT GLOBAL trial in first and second line mCRPC, which is now preparing to enrol patients at its first U.S. sites. This innovative trial design allows physicians a choice of androgen receptor inhibition or docetaxel chemotherapy, thus integrating with real-world standard of care, reflective of Telix's continued innovation in prostate cancer care and commitment to patient outcomes.

About TLX591

TLX591 (INN: lutetium Lu 177 rosopatamab tetraxetan) is Telix's lead investigational radio antibody-drug conjugate (rADC) for the treatment of mCRPC, composed of a high-specificity PSMA-targeting antibody, chelator linker, and cytotoxic lutetium (^{177}Lu) payload. TLX591 is administered intravenously under a two-dose fractionated regimen, potentially enabling the delivery of a highly targeted and potent dose with improved off-target organ radiation exposure. The mAb-based approach may offer distinct advantages in selectivity, internalisation, and retention time over small molecule RLTs for the treatment of mCRPC.

A total of 242 patients have been treated with TLX591 across eight Phase I and Phase II trials[9] including a previously published Phase II (open-label, single-arm) trial, which reported a 42.3 month OS in 17 patients with advanced mCRPC when TLX591 was delivered under a fractionated dosing regimen[10].

About ProstACT SELECT

The purpose of the ProstACT SELECT trial is to evaluate the utility of PSMA-PET imaging with Illuccix® to select patients for TLX591 rADC therapy. The primary objectives are to determine whole body biodistribution and organ radiation dosimetry, and assess the safety and tolerability of TLX591 in patients with advanced mCRPC. Radiographic progression-free survival (rPFS) is a secondary study objective.

Previously reported data from the SELECT trial includes[3]:

- Confirmation of biodistribution and safety profile with a low rate of off-target side effects.
- Confirmation of internalisation and long retention, delivering a payload to the tumour, potentially maximising cell killing effect.
- Lower rates of haematologic toxicity than prior, later-line studies of TLX591.

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)[11], by the Australian Therapeutic Goods Administration (TGA)[12], and by Health Canada[13]. 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.

[10] Tagawa et al. *Cancer.* 2019.
[11] Telix ASX disclosure 20 December 2021.
[12] Telix ASX disclosure 2 November 2021.
[13] Telix ASX disclosure 14 October 2022.

Telix Investor Relations

Ms. Kyahn Williamson
Telix Pharmaceuticals Limited
SVP Investor Relations and Corporate Communications
Email: kyahn.williamson@telixpharma.com

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

Legal Notices

The information contained in this announcement is not intended to be an offer for subscription, invitation or recommendation with respect to shares of Telix Pharmaceuticals Limited (Telix) in any jurisdiction, including the United States. No representation or warranty, express or implied, is made in relation to the accuracy or completeness of the information contained or opinions expressed in the course of this announcement. The information contained in this announcement is subject to change without notification.

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", "outlook", "forecast" and "guidance", or other similar words. 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 the Company's good-faith assumptions as to the financial, market, regulatory and other risks and considerations that exist and affect the Company'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 studies, 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, manufacturing activities and product marketing activities; the commercialisation of Telix's product candidates, if or when they have been approved; 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. You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the ASX or on our website.

To the maximum extent permitted by law, Telix disclaims any obligation or undertaking to publicly update or revise any forward-looking statements contained in this announcement, whether as a result of new information, future developments or a change in expectations or assumptions.