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Telix Commences Phase III Clinical Trial of Prostate Cancer Therapy

Melbourne (Australia) – 10 May 2021. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces it has been granted Human Research Ethics Committee (HREC) approval and received Clinical Trial Notification (CTN) clearance by the Australian Therapeutic Goods Administration (TGA) to commence a Phase III clinical trial of the Company's PSMA[1] targeted prostate cancer therapy candidate TLX591 (^{177}Lu-DOTA-rosopatamab), in patients with advanced metastatic castrate-resistant prostate cancer (mCRPC).

The Phase III "ProstACT" trial is an international, multi-centre, randomised controlled trial (RCT) in patients with PSMA-expressing mCRPC, experiencing disease progression following prior treatment with a novel androgen axis drug (NAAD). The ProstACT trial will enrol approximately 390 patients and incorporates patient selection using ^{68}Ga-PSMA imaging with TLX591-CDx (Illuccix®). The trial will compare standard of care therapy alone versus standard of care therapy plus TLX591, with a primary endpoint of radiographic progression-free survival (rPFS). Trial secondary endpoints will include overall survival and quality-of-life assessment. Telix has commenced the initiation of Australian ProstACT trial sites and will add global sites progressively during the second half of 2021, subject to the requisite approvals.

Telix Chief Executive Officer Dr. Christian Behrenbruch stated, "The commencement of the ProstACT Phase III study for TLX591 marks a major corporate milestone for Telix that brings the Company a step closer to delivering on a major unmet medical need for treatment options in this patient population. ProstACT builds on a significant body of clinical data for TLX591[2], which to date has been studied in over 200 patients with advanced prostate cancer, across five previous studies. TLX591 has demonstrated promising and competitive clinical potential that we believe warrants further confirmation in this second-line disease setting. It is also noteworthy that Telix's differentiated approach to integrating molecular imaging with PET alongside therapy, enables a comparatively streamlined study that we believe will support efficient patient enrolment and study execution."

About Prostate Cancer

Prostate cancer is the second most common cancer in men after skin cancer and worldwide 1.4 million men were diagnosed with prostate cancer in 2020. Despite advances in treatment, prostate cancer still accounts for a large number of deaths and in 2020 more than 375,000 men died from their disease. Rates of diagnosis are increasing, and the highest incidences of prostate cancer are found in the United States, Europe, Australia and New Zealand.[3]

About TLX591

TLX591 (^{177}Lu-DOTA-rosopatamab) is an antibody-based radioimmunoconjugate (molecularly-targeted radiotherapy or "MTR") targeting PSMA, a cancer target highly expressed in men with metastatic prostate cancer.

About Telix Pharmaceuticals Limited

Telix is a clinical-stage biopharmaceutical company focused on the development of diagnostic and therapeutic products using Molecularly Targeted Radiation (MTR). Telix is headquartered in Melbourne, Australia with international operations in Belgium, Japan, and the United States. Telix is developing a portfolio of clinical-stage products that address significant unmet medical needs in

[1] Prostate-Specific Membrane Antigen (PSMA)
[2] Tagawa S et al. Cancer 2019.
[3] GLOBOCAN 2020.

oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com and follow Telix on Twitter (@TelixPharma) and LinkedIn.

Telix's lead investigational product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been accepted for filing by the U.S. FDA,[4] and is under priority evaluation by the Australian Therapeutic Goods Administration (TGA).[5] Telix is also progressing marketing authorisation applications for Illuccix® in the European Union[6] and Canada.[7] None of Telix's products, including TLX591 and TLX591-CDx, have received a marketing authorisation in any jurisdiction.

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[4] ASX disclosure 24/11/20.
[5] ASX disclosure 14/04/21.
[6] ASX disclosure 1/05/20.
[7] ASX disclosure 16/12/20.