

ASX RELEASE**ProstACT Update: TARGET Study Ethics Approval**

Melbourne (Australia) – 12 April 2022. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces its ProstACT TARGET Phase II clinical trial of the Company's prostate cancer antibody therapy candidate TLX591 (¹⁷⁷Lu-DOTA-rosopatamab), in patients experiencing a first recurrence of prostate-specific antigen (PSA) after initial therapy for prostate cancer, has been granted Human Research Ethics Committee (HREC) approval.

Telix's primary goal with the ProstACT study series is to complete the pivotal Phase III ProstACT GLOBAL study in a second-line setting in patients with metastatic castration-resistant prostate cancer (mCRPC) progressing on first-line novel androgen agents. The inclusion of the TARGET study, will generate data on the use of TLX591 in patients at an earlier stage in their prostate cancer, supporting potential future indication expansion. This is in line with Telix's vision to benefit men along the full spectrum of their prostate cancer journey, creating multiple opportunities to deliver insights into the clinical performance of TLX591 throughout the program duration.¹ As an antibody-based radiopharmaceutical, TLX591 is given as just two doses, two-weeks apart, and requires much less lutetium to deliver long-lasting radiation to the tumour with potential to reduce costs and off-target side effects such as salivary gland toxicity.

ProstACT TARGET is a Phase II single arm study in Australia in 50 patients with prostate-specific membrane antigen (PSMA) -avid² biochemically recurrent oligometastatic (five or less metastases) prostate cancer, in combination with external beam radiation therapy (EBRT). The clinical objectives are delaying disease recurrence and thus deferring the commencement of androgen deprivation therapy (ADT) with the primary endpoint biological progression-free survival (PFS BIO). The study is a collaboration with Telix's strategic partner, GenesisCare.

Telix Group CEO and Managing Director, Dr. Christian Behrenbruch stated, "We are delighted to have been granted approval to commence the Phase II ProstACT TARGET study for TLX591, a key milestone in the ProstACT family of trials. TARGET is part of the Company's long-term clinical and commercial strategy to develop TLX591 across multiple points from men with early, localised disease all the way through to advanced metastatic disease, integrating molecularly targeted radiation (MTR) with standard of care at each stage in the patient journey. Alongside the ProstACT SELECT study, this program will add value and clinical insight to the platform, with opportunity for near-term data readouts."

GenesisCare Global Chief Medical Officer, Wally Curran MD, added, "It is a privilege to partner with Telix on the Phase II ProstACT TARGET study, a trial which brings hope to thousands of men living with prostate cancer in Australia and worldwide. Leveraging our global network of treatment centres, we look forward to commencing patient enrolment and helping Telix develop and rapidly scale a bold new approach to prostate cancer therapy."

About ProstACT

ProstACT is a series of studies of the investigational product TLX591, the Company's antibody-based, PSMA targeted prostate cancer therapy candidate TLX591 (¹⁷⁷Lu-DOTA-rosopatamab).

¹ ASX disclosure 19 August 2021.

² Defined by PSMA PET imaging.

The three studies running concurrently in the program include:

- ProstACT GLOBAL – A phase III 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 ⁶⁸Ga-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).
- ProstACT SELECT, a Phase I radiogenomics study with the goal of comparing ⁶⁸Ga-PSMA (gallium) and ¹⁷⁷Lu-PSMA (lutetium), specifically exploring the biodistribution differences between small molecule and antibody-based targeting. The study is designed to inform optimal patient selection for Telix's antibody-based ¹⁷⁷Lu therapy, with the goal of enabling indication expansion for Telix's PSMA therapeutic portfolio. ProstACT SELECT is a multi-centre study and will enrol up to 50 patients, with a first patient dosed in January 2022.³
- ProstACT TARGET, a Phase II study to evaluate TLX591 in combination with external beam radiation therapy (EBRT) in patients with oligometastatic PSMA-expressing disease, providing data in early prostate cancer relapse. The study, which targets enrolment of 50 patients across multiple Australian sites, is a collaboration with Telix's strategic partner, GenesisCare, and is being conducted within its network. GenesisCare is co-funding the study alongside Telix.

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic products using Molecularly Targeted Radiation (MTR). Telix is headquartered in Melbourne, Australia with international operations in Belgium, Japan, Switzerland, and the United States. Telix is developing a portfolio of clinical-stage products that address significant unmet medical need in 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](https://twitter.com/TelixPharma) (@TelixPharma) and [LinkedIn](https://www.linkedin.com/company/telix-pharmaceuticals).

Telix's lead product, Illuccix® (kit for preparation of gallium-68 (⁶⁸Ga) gozetotide (also known as ⁶⁸Ga PSMA-11) injection) for prostate cancer imaging, has been approved by the U.S. Food and Drug Administration (FDA),⁴ and by the Australian Therapeutic Goods Administration (TGA).⁵ Telix is also progressing marketing authorisation applications for this investigational candidate in Europe⁶ and Canada.⁷

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³ ASX disclosure 27 January 2022.

⁴ ASX disclosure 20 December 2021.

⁵ ASX disclosure 2 November 2021.

⁶ ASX disclosure 10 December 2021.

⁷ ASX disclosure 16 December 2020.

This announcement has been authorised for release by Dr. Christian Behrenbruch, Managing Director and Group Chief Executive Officer.

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