

ASX ANNOUNCEMENT

ProstACT Global Phase 3 Update: First Patient Dosed in Randomized Treatment Expansion, Part 1 Readout Plans Confirmed

Melbourne (Australia) and Indianapolis, IN (U.S.) – 8 December 2025. Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, “Telix”) today announces that the first patient has been dosed in Part 2 (randomized treatment expansion) of its ProstACT Global Phase 3 study evaluating its lead prostate cancer therapy candidate TLX591 (lutetium (¹⁷⁷Lu) rosopitamab tetraxetan) in patients with metastatic castration resistant prostate cancer (mCRPC). The patient was dosed at the Australian Prostate Centre (APC) in Melbourne, Australia.

ProstACT Global is the first Phase 3 trial to combine a PSMA¹-targeted radio antibody-drug conjugate (rADC) therapy administered together with Standard of Care (SOC; abiraterone, enzalutamide or docetaxel) versus SOC alone. Part 2 of ProstACT Global will enroll approximately 490 patients and is currently recruiting patients in Australia, New Zealand and Canada.

As previously agreed with FDA and disclosed to the market, Telix will submit Part 1 data to the United States (U.S.) Food and Drug Administration (FDA) to enable clearance to expand Part 2 of the trial to U.S. sites. A public disclosure of preliminary results from Part 1 of the study will be aligned to engagement with the FDA.

The study is also approved to commence in China, Japan², Singapore, South Korea, Türkiye and the United Kingdom. As part of the further global expansion of the trial, Telix will file a clinical trial application (CTA) with the European Medicines Agency (EMA) to enable expansion into EU sites.

Dr. David N. Cade, Group Chief Medical Officer, Telix, commented, “Dosing the first patient into Part 2 of the randomized treatment expansion of ProstACT Global trial is a significant milestone for Telix’s late-stage prostate cancer therapeutics pipeline. We look forward to presenting the preliminary data from Part 1 of the study to the FDA and EMA in the coming months³.”

About ProstACT Global

ProstACT Global (ClinicalTrials.gov ID: [NCT06520345](https://clinicaltrials.gov/ct2/show/study/NCT06520345)) is an international, multicenter trial in two parts: Part 1, safety and dosimetry lead-in with 30 patients (target enrollment complete); and Part 2, 2:1 randomized global expansion with an overall target enrollment of approximately 490 patients. Eligible patients must have confirmed progressive mCRPC assessed with a ⁶⁸Ga-PSMA-11 PET⁴ imaging agent (such as Illucix® or Gozellix®, kits for the preparation of gallium-68 (⁶⁸Ga) gozetotide injection) following prior treatment with an androgen receptor pathway inhibitor (ARPI).

The antibody approach demonstrates different targeting and pharmacology to that observed in other PSMA-targeted small peptide radioligand therapies (RLT). In contrast to these therapies⁵, collective long-term follow-up of patients administered with TLX591 has not observed significant acute or delayed kidney toxicity, as the agent is cleared through the liver, instead of the kidneys⁶. Due to its

¹ Prostate-specific membrane antigen.

² Japanese regulator Pharmaceuticals and Medical Devices Agency (PMDA) has granted approval for a Japan-specific Part 1 in nine patients, prior to commencing Part 2.

³ Collation of available published data. Not from head-to-head studies, cross trial or product data should be interpreted with caution.

⁴ Positron emission tomography.

⁵ Tagawa et al. *Curr Oncol Rep.* 2021; Steinhelfer et al. *JNM.* 2024.

⁶ Tagawa et al. *Cancer.* 2019.

large molecular weight, TLX591 also demonstrates minimal salivary and lacrimal gland uptake, reducing dry mouth and dry eyes, common adverse effects of existing PSMA-targeted RLTs⁷.

Additional information on the Phase 3 ProstACT Global study can be found at:

<https://telixpharma.com/prostact/>

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals and associated medical technologies. Telix is headquartered in Melbourne, Australia, with international operations in the United States, United Kingdom, Brazil, Canada, 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) and the Nasdaq Global Select Market (NASDAQ: TLX).

Illuccix® (kit for the preparation of gallium-68 (⁶⁸Ga) gozetotide injection), Telix's first generation PSMA-PET imaging agent, has been approved in multiple markets globally. Gozellix® (kit for the preparation of gallium-68 (⁶⁸Ga) gozetotide injection) has been approved by the U.S. FDA⁸. TLX591 has not received a marketing authorization in any jurisdiction.

Visit www.telixpharma.com for further information about Telix, including details of the latest share price, ASX and U.S. Securities and Exchange Commission (SEC) filings, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on [LinkedIn](#), [X](#) and [Facebook](#).

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

⁷ Pepin et al. *Pract Radiat Oncol*. 2025.

⁸ Telix ASX disclosure 21 March 2025.

Cautionary Statement Regarding Forward-Looking Statements.

You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the Australian Securities Exchange (ASX), U.S. Securities and Exchange Commission (SEC), including our Annual Report on Form 20-F filed with the SEC, or on our website.

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