

ASX ANNOUNCEMENT

ProstACT Global Study: Status

Melbourne (Australia) and Indianapolis, IN (U.S.) – 17 December 2025. Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, “Telix”) today provides an update to confirm the current status of the ProstACT Global Phase 3 study of its lead prostate cancer therapy candidate TLX591 (lutetium (¹⁷⁷Lu) rosopatamab tetraxetan) in patients with metastatic castration resistant prostate cancer (mCRPC). This announcement is provided in response to inaccurate information in market circulation.

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. Telix confirms that it has completed patient enrolment into Part 1 of the study, a safety and dosimetry lead-in, in accordance with the study protocol.

Preparation is now underway to complete data lock and read-out. This includes data from each of the three cohorts in Part 1, including the docetaxel cohort which was the final cohort to complete enrolment. As previously disclosed², data from Part 1 will be presented to the United States (U.S) Food and Drug Administration (FDA) to ascertain eligibility for U.S. patients to participate in the Part 2 (randomized treatment expansion) portion of the study. Preliminary results from Part 1 of the study will be publicly disclosed at the time of readout and engagement with the FDA.

In accordance with the study protocol, an Independent Data Monitoring Committee (IDMC) has reviewed the available data in Part 1 of the study and, per the IDMC charter, has recommended that the study proceed to Part 2. Accordingly, Telix has advanced the study into Part 2, in jurisdictions where it has obtained approval from health authorities. Part 2 has been initiated on the basis that Part 1 indicates no unexpected safety or clinical characteristics that differ from prior experience.

Part 2 of ProstACT Global has dosed its first patients, and is approved and open for enrolment in Australia, New Zealand and Canada. The study has also received regulatory approval to commence in China, Singapore, Türkiye, the United Kingdom, South Korea and Japan³. As part of the further global expansion of the trial, Telix intends to file a clinical trial application (CTA) with the European Medicines Agency (EMA) to enable expansion into EU sites.

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 enrolment complete); and Part 2, 2:1 randomized global expansion with an overall target enrolment of approximately 490 patients. Eligible patients must have confirmed progressive mCRPC assessed with a ⁶⁸Ga-PSMA-11 PET⁴ imaging agent (such as Illucix®, kit for the preparation of gallium-68 (⁶⁸Ga) gozetotide injection or Gozellix®, kit for the preparation of gallium-68 (⁶⁸Ga) gozetotide injection) following prior treatment with an androgen receptor pathway inhibitor (ARPI).

¹ Prostate-specific membrane antigen.

² Telix ASX disclosure 8 December 2025.

³ 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.

⁴ Positron emission tomography.

The antibody approach demonstrates different targeting and pharmacology to that observed in other PSMA-targeted small peptide radioligand therapies (RLTs). 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. TLX591 also demonstrates limited 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®, 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 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.

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

⁶ Tagawa et al. *Cancer.* 2019.

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

⁸ Telix ASX disclosure 21 March 2025.

Legal Notices

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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