

ASX ANNOUNCEMENT

ProstACT Global Phase 3 Study (Part 1) Achieves Primary Objectives

- Webcast and conference call to be held today, Tuesday March 10 at 9:30 a.m. AEDT (Monday March 9 at 6:30 p.m. EDT). Investors can register at the following link: <https://s1.c-conf.com/diamondpass/10053620-ju7y6t.html>

Melbourne (Australia) and Indianapolis, IN (U.S.) – March 10, 2026. Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, “Telix”) today announces that Part 1 of the ProstACT Global Phase 3 study, the safety and dosimetry lead-in for its therapeutic candidate – TLX591-Tx (lutetium-177 (¹⁷⁷Lu) rosopatomab tetraxetan) – has achieved its primary objectives, demonstrating an acceptable safety and tolerability profile with no new safety signals observed.

Key findings include:

- Tolerability profile supported by dosimetry and low-grade non-hematologic events.
- Lesion dosimetry indicates no difference in absorbed dose profile across cohorts.
- No adverse drug-drug interactions observed in TLX591-Tx combinations.
- Hematologic events are in line with expectations and transient and manageable, with similar rates of recovery across all patient cohorts.
- The results from Part 1 are consistent with prior clinical studies of this first-in-class lutetium radio antibody-drug conjugate (rADC) therapy.

Part 1 of the study confirmed the safety profile, biodistribution and dosimetry of TLX591-Tx administered in two doses, 14 days apart, in combination with one of three standard of care (SOC) therapies: abiraterone, enzalutamide or docetaxel. The patient population comprised prostate-specific membrane antigen (PSMA) positive metastatic castration resistant prostate cancer (mCRPC) patients previously treated with one androgen receptor pathway inhibitor (ARPI).

ProstACT Global is a differentiated Phase 3 trial comparing PSMA-targeted ¹⁷⁷Lu-rADC therapy administered with SOC versus SOC alone, a trial design intended to reflect current global clinical practice¹. Telix has already advanced the study into Part 2 – a 2:1 randomized treatment expansion – in jurisdictions where the clinical trial has obtained approval from health authorities². Part 1 data will be presented to the United States (U.S.) Food and Drug Administration (FDA) to seek an Investigational New Drug (IND) amendment to progress Part 2 in the U.S.

Neeraj Agarwal, MD, Professor of Medicine and Presidential Endowed Chair of Cancer Research at Huntsman Cancer Institute, Salt Lake City, and ProstACT Global Principal Investigator and Steering Committee member, commented, “These results reinforce the feasibility of integrating TLX591-Tx with current standard of care therapies for mCRPC, including ARPIs such as enzalutamide or abiraterone, or docetaxel. Hematologic events align with those typically seen in this patient population and therapeutic class, and these cases resolved quickly. The dosimetry profile, along with the low-grade nature of non-hematologic adverse events, further supports the tolerability profile of this investigational therapy.”

¹ National Comprehensive Cancer Network® Clinical Practice Guidelines in Oncology for Prostate Cancer V3.2026; Narayan et al. *Clin Genitourin Cancer*. 2024.

² Part 2 is enrolling in Australia, New Zealand, and Canada, and has also received regulatory approval to commence in China, Singapore, South Korea, Türkiye, and the United Kingdom.

David N. Cade, MD, Group Chief Medical Officer, Telix added, “Despite advances in clinical practice, men with advanced prostate cancer still need improved first and second line treatment options. These results build on prior findings and highlight the potential for TLX591-Tx in combination with contemporary standard of care, to become a new first-line option for patients facing this aggressive disease. We are encouraged by the data and look forward to engaging with the FDA at the earliest opportunity, while continuing to advance enrollment in Part 2 in regions where clinical trial initiation has already been approved.”

Summary results

ProstACT Global Part 1 dosed 36 patients, allocated across 3 cohorts:

- Cohort 1 (11 patients): TLX591-Tx + enzalutamide.
- Cohort 2 (11 patients): TLX591-Tx + abiraterone.
- Cohort 3 (14 patients): TLX591-Tx followed by docetaxel.

Safety and tolerability

- An acceptable safety profile was observed across combination cohorts and tolerability of TLX591-Tx was consistent with prior studies.
- All 36 patients received both doses of TLX591-Tx per protocol, no new safety signals were observed.
- Almost all treatment-emergent non-hematologic events were Grade 1 or Grade 2. The most prevalent were fatigue (53%), nausea (28%) and dry mouth (25%).
- Hematologic events were transient and manageable.
- Grade 3 thrombocytopenia (14%) and neutropenia (22%), and Grade 4 thrombocytopenia (31%) and neutropenia (25%) events were in line with the profile expected for this class of therapy and extent of disease.

Dosimetry and biodistribution

- Radiation exposure to key organs was well below established safety limits³.
- Limited dose to salivary glands and kidneys.
- Lesion dosimetry demonstrated uptake across tumor sites and across all cohorts.
- Pharmacokinetics demonstrated sustained activity at 15 days, corroborated by imaging which demonstrated prolonged tumor retention.
- No evidence of drug-drug interactions impacting TLX591-Tx targeting, distribution or clearance.

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 36 patients (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 Illuccix®, 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 one ARPI.

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

³ Wahl et al. *J Nucl Med.* 2021; Emami et al. *Int J Radiat Oncol Biol Phys.* 1991.

⁴ Positron emission tomography.

⁵ Tagawa et al. *Curr Oncol Rep.* 2021; Steinhelfer et al. *J Nucl Med.* 2024.

radioresistant organ, instead of the kidneys⁶. Due to its large molecular weight, TLX591-Tx 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 global biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals and associated medical technologies, with the goal to address significant unmet medical needs in oncology and rare diseases. With international operations in the United States, United Kingdom, Brazil, Canada, Europe (Belgium and Switzerland), and Japan, Telix is headquartered in Melbourne, Australia. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (NASDAQ: TLX).

Telix's Precision Medicine franchise includes Illuccix®, approved in multiple markets globally, and Gozellix®, approved by the U.S. FDA⁸. TLX591-Tx 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.

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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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⁶ Tagawa et al. *Cancer*. 2019.

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

⁸ Telix ASX disclosure March 21, 2025.

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