ProstACT Global Phase 3 (Part 1) Data Presented in Late-Breaking Oral Session at ASCO 2026

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- *Telix's first-in-class lutetium radio antibody-drug conjugate (rADC) candidate, TLX591-Tx, demonstrates acceptable tolerability across all standard-of-care (SoC) combination cohorts, with no new safety signals.*
- *Findings support feasibility of TLX591-Tx in combination with contemporary SoC in post-ARPI metastatic castration-resistant prostate cancer (mCRPC).*
- *Part 2 (randomized treatment expansion) is actively dosing patients in jurisdictions where health authority approval has been granted[1].*

MELBOURNE, Australia and INDIANAPOLIS, June 02, 2026 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") announces the oral presentation of Part 1 safety, dosimetry and pharmacokinetics data from the ProstACT Global Phase 3 Study of TLX591-Tx (lutetium-177 (^{177}Lu) rosopatamab tetraxetan), in metastatic castration-resistant prostate cancer (mCRPC). The late-breaking data were presented today at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois by study Principal Investigator Pedro C. Barata, MD, Medical Oncologist, University Hospitals Seidman Cancer Center and Associate Professor of Medicine, Case Western Reserve University of School of Medicine, Cleveland, Ohio.

Results demonstrated that TLX591-Tx, Telix's lead prostate-specific membrane antigen (PSMA) targeted lutetium rADC therapy candidate, has an acceptable safety and tolerability profile when administered with standard of care (SoC) therapies in mCRPC, with no new safety signals observed.

ProstACT Global is an international, multi-center, randomized Phase 3 trial comparing TLX591-Tx, administered as two doses, 14 days apart with SoC (abiraterone, enzalutamide or docetaxel) versus SoC alone. The study is designed to reflect real-world clinical practice[2] and enrolls PSMA-positive mCRPC patients previously treated with one androgen receptor pathway inhibitor (ARPI).

Patients were monitored for treatment-emergent adverse events and underwent serial SPECT/CT[3] imaging after TLX591-Tx administration for dosimetry and blood sampling for pharmacokinetics. The primary endpoint was safety and tolerability of TLX591-Tx + SoC. Key secondary endpoints were pharmacokinetics and radiation dosimetry.

Results: Data from 36 patients (baseline median PSA[4]: 18.18 ng/mL) who received any study treatment were included: Cohort 1 (11 patients), TLX591-Tx + abiraterone; Cohort 2 (11 patients), TLX591-Tx + enzalutamide; Cohort 3 (14 patients), TLX591-Tx followed by docetaxel.

Safety and tolerability

- Acceptable safety profile observed across all combination cohorts, tolerability of TLX591-Tx consistent with prior studies.
- All 36 patients received both doses of TLX591-Tx per protocol.
- No new safety signals identified.
- Almost all treatment-emergent non-hematologic events were Grade 1–2, primarily 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 pharmacokinetics

- Radiation exposure to key organs was well below established safety limits[5].
- Highest absorbed dose observed in liver (range, 1.62-5.08 mGy/MBq), with lower doses received by kidneys (0.336-0.961 mGy/MBq) and salivary glands (0.001-0.104 mGy/MBq).

- Lesion dosimetry confirmed uptake across tumor sites and across all cohorts.
- Pharmacokinetics demonstrated sustained activity at Day 15, corroborated by imaging which demonstrated prolonged tumor retention.
- No evidence of drug-drug interactions impacting TLX591-Tx targeting, distribution or clearance.

Telix has initiated Part 2, a 2:1 randomized treatment expansion, in jurisdictions where regulatory approvals have been obtained. Engagement is underway with the United States (U.S.) Food and Drug Administration (FDA) to discuss Part 1 data and seek an Investigational New Drug (IND) amendment to progress Part 2 in the U.S.

Pedro C. Barata, MD, stated, "These results support the feasibility of administering TLX591-Tx alongside current standard-of-care therapies for mCRPC, including ARPIs. Imaging demonstrated sustained tumor retention through day 15, while dosimetry analyses showed radiation exposure below established safety thresholds and limited dose to key organs. Hematologic adverse events were generally consistent with those expected in this patient population and therapeutic class and were transient in most cases. Overall, the safety, dosimetry, and tumor-targeting findings, together with the high treatment compliance observed in this study, support further evaluation of this approach, in the randomized phase of the trial."

David N. Cade, MD, Group Chief Medical Officer, Telix added, "Despite meaningful advances in clinical practice, mCRPC remains a disease where patients urgently need additional first and second-line options. These Part 1 results, presented today at ASCO, build on prior clinical findings and further support our view that TLX591-Tx in combination with contemporary standard of care has the potential to become a new treatment option for this aggressive disease."

The ASCO presentation abstract can be found here.

About ProstACT Global

ProstACT Global (ClinicalTrials.gov ID: 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 ^{68}Ga-PSMA-11 PET[6] imaging agent (such as Illuccix®, kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection, or Gozellix®, kit for the preparation of gallium-68 (^{68}Ga) 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 therapies[7], 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 radioresistant organ, instead of the kidneys[8]. 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 RLTs[9].

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 radiopharmaceuticals with the goal of addressing significant unmet medical need in oncology and rare diseases. 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 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. FDA [10]. 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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[1] Part 2 is enrolling in Australia, New Zealand, Canada, Türkiye, and the United Kingdom, and has also received regulatory approval to commence in China, Singapore and South Korea.

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

[3] Single-photon emission computed tomography.

[4] Prostate-specific antigen.

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

[6] Positron emission tomography.

[7] Tagawa et al. *Curr Oncol Rep.* 2021; Steinhelfer et al. *J Nucl Med.* 2024.

[8] Tagawa et al. *Cancer.* 2019.

[9] Pepin et al. *Pract Radiat Oncol.* 2025.

[10] Telix ASX disclosure March 21, 2025.