First Patients Dosed in OPTIMAL-e Trial for Earlier Stage Prostate Cancer

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- First patients dosed in OPTIMAL-e[1] Phase 2 study evaluating TLX597-Tx for metastatic hormone-sensitive prostate cancer at St Vincent's Hospital Sydney.
- OPTIMAL-e will evaluate TLX597-Tx in earlier prostate cancer treatment setting, building on the OPTIMAL-PSMA[2] study which recently completed patient enrollment.
- TLX597-Tx is Telix's next generation PSMA [3]-targeting small molecule radioligand therapy candidate designed to improve efficacy and quality of life in earlier-stage prostate cancer.

MELBOURNE, Australia and INDIANAPOLIS, July 16, 2026 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") and St Vincent's Hospital today announced that the first patients have been dosed with TLX597-Tx (^{177}Lu-DOTA-HYNIC-panPSMA) in the OPTIMAL-e trial, led by Professor Louise Emmett for patients with metastatic hormone-sensitive prostate cancer (mHSPC) at St Vincent's Hospital in Sydney, Australia.

OPTIMAL-e is a single-arm, open-label trial, evaluating adaptive-dosed TLX597-Tx in combination with androgen deprivation therapy (ADT) and an androgen receptor pathway inhibitor (ARPI) in men with mHSPC. The study will evaluate the impact of TLX597-Tx on PSA[4] response rate in an earlier treatment setting, assessing its potential to improve both the depth and durability of PSA response, while further evaluating the safety of dose intensification.

TLX597-Tx is a highly-targeted next generation small molecule RLT[5] designed to improve efficacy and quality of life in earlier-stage metastatic prostate cancer. It has demonstrated a favorable biodistribution and dosimetry profile in prior studies including OPTIMAL-PSMA[6], suggesting low exposure to salivary glands and the kidneys, the healthy organs of concern with PSMA RLT, and high uptake in PSMA-expressing tumors.

Louise Emmett, MD, Director of Theranostics and Nuclear Medicine, St. Vincent's Hospital, and Lead Investigator of the OPTIMAL-e study, said, "I am excited to lead the OPTIMAL-e trial, which is evaluating an adaptive treatment approach designed to tailor therapy to each patient's response. By using PSMA-PET[7] imaging and PSA measurements to monitor disease burden, treatment can be continued when the PSMA target persists, and paused when there is a significant reduction in tumor burden. This individualized strategy aims to maintain disease control while minimizing unnecessary treatment exposure, with the potential to keep patients in a low-volume disease state for longer and support quality of life. The findings from OPTIMAL-e may help shape future treatment strategies and advance precision medicine for men living with prostate cancer."

David N. Cade, MD, Group Chief Medical Officer, Telix, said, "The initiation of OPTIMAL-e marks an important evolution of PSMA-targeted radioligand therapy for earlier metastatic prostate cancer, where maintaining quality of life is paramount. While the currently approved radioligand therapy has demonstrated a modest improvement in overall survival in advanced-stage disease, we believe earlier intervention may offer the potential to further improve outcomes and prolong quality of life for patients."

TLX597-Tx has not received marketing authorization in any jurisdiction.

About OPTIMAL-e

OPTIMAL-e is a Phase 2, non-randomized pilot study evaluating adaptive-dosed TLX597-Tx (^{177}Lu-DOTA-HYNIC-panPSMA) in combination with ADT and an ARPI in patients with metastatic hormone-sensitive prostate cancer (mHSPC). Adaptive dosing of ^{177}-Lu-PSMA is the concept of only treating if the PSMA target is persistent, while pausing treatment if there is a marked reduction in the tumor target, with re-treatment at first confirmed PSA rise (once the target has returned). The study is investigating whether intensified, response-adapted PSMA-targeted radioligand therapy can deepen responses, improve disease control and enable treatment pauses for selected patients based on PSMA-PET imaging and PSA outcomes.

TLX597-Tx is being developed alongside TLX591-Tx (lutetium-177 (^{177}Lu) rosopatamab tetraxetan), Telix's lead antibody-based prostate cancer therapy candidate, currently the subject of the Phase 3 ProstACT Global[8] trial in mCRPC[9], which is actively dosing patients in jurisdictions with regulatory approval. TLX591-Tx and TLX597-Tx exhibit complementary modes-of-action, suggesting the potential for distinct applications in mCRPC and mHSPC settings as part of Telix's portfolio approach to treating prostate cancer.

About Telix Pharmaceuticals Limited

Telix Pharmaceuticals (ASX: TLX, NASDAQ: TLX) is a commercial-stage global radiopharmaceutical company, advancing targeted theranostics to improve outcomes for people with cancer across the patient journey. Theranostics pairs a precision diagnostic with a targeted therapy to both diagnose and treat disease.

Telix's commercial franchise is anchored by its prostate cancer imaging portfolio: Illuccix® (kit for the preparation of gallium-68 gozetotide injection), commercially available in 22 countries including the U.S. and Gozellix® (kit for the preparation of gallium-68 gozetotide injection), Telix's next-generation PSMA-PET imaging agent approved by the U.S. FDA. The Company's late-stage therapeutic pipeline includes three assets in pivotal-stage trials - TLX591-Tx (lutetium-177 (^{177}Lu) rosopatamab tetraxetan) in prostate cancer, TLX101-Tx (^{131}I-iodofalan) in recurrent glioblastoma, TLX250-Tx (^{177}Lu-girentuximab) in kidney cancer, complemented by a deep pipeline of next generation assets.

Telix is headquartered in Melbourne, Australia, with operations across North America, Europe, Latin America and Asia-Pacific. For more information, visit www.telixpharma.com or follow Telix on LinkedIn, X and Facebook.

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[1] Australian New Zealand Clinical Trials Registry ID: ACTRN12626000034336.

[2] Australian New Zealand Clinical Trials Registry ID: ACTRN12625000971437.

[3] Prostate-specific membrane antigen.

[4] Prostate-specific antigen.

[5] Radioligand therapy.

[6] Telix media release April 30, 2026.

[7] Imaging of prostate-specific membrane antigen with positron emission tomography.

[8] ClinicalTrials.gov ID: NCT06520345.

[9] Metastatic castration-resistant prostate cancer.