

## **ASX ANNOUNCEMENT**

### **FDA Alignment to Advance ProstACT Global Phase 3 Trial**

- *FDA and Telix align on advancement into Part 2 of the ProstACT Global Phase 3 study in the United States.*
- *FDA agrees with the clinical protocol and proposed statistical framework across three standard-of-care combination cohorts.*
- *Part 2 (randomized cohort) continues to recruit in jurisdictions where the study has regulatory approval.*

MELBOURNE, Australia and INDIANAPOLIS, July 2, 2026 -- Telix Pharmaceuticals (ASX: TLX, NASDAQ: TLX, "Telix") today announced the successful outcome of a Type B meeting with the United States (U.S.) Food and Drug Administration (FDA) to review the Part 1 safety and dosimetry data and Part 2 protocol design of the ProstACT Global Phase 3 trial of its therapeutic candidate TLX591-Tx (lutetium-177 (<sup>177</sup>Lu) rosopitamab tetraxetan) in metastatic castration resistant prostate cancer.

The FDA has confirmed that the safety data from Part 1 of the study is sufficient to enable progression of Part 2 of ProstACT Global into the U.S. in which TLX591-Tx is administered in two doses, 14 days apart, in combination with one of three randomized standard of care (SOC) therapies: abiraterone, enzalutamide or docetaxel. The FDA and Telix also achieved alignment on the Part 2 clinical trial protocol, statistical analysis plan, and ongoing safety monitoring plan. The result is a consistent framework for study execution as enrollment continues internationally and expands into the U.S.

David N. Cade, MD, Group Chief Medical Officer, Telix, said, "This is an excellent outcome that enables submission of our IND amendment for initiation of Part 2 of ProstACT Global in the U.S. Part 2 continues to enroll strongly in regions where recruitment is open."

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, "TLX591-Tx has the potential to redefine how radiopharmaceutical therapy is integrated into clinical practice. Because the complete treatment course is delivered over approximately two weeks, physicians can layer it into an existing regimen with minimal interruption, providing greater flexibility to sequence therapies while preserving future treatment options in patients with metastatic prostate cancer."

Initiation of Part 2 in the U.S. remains subject to the FDA's review of an Investigational New Drug (IND) amendment. The IND amendment will also be aligned with a pending regulatory submission to initiate the ProstACT Global study in Europe. The trial continues to enroll patients in regions where Part 2 is approved<sup>1</sup>.

#### **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

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<sup>1</sup> 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.

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global expansion with an overall target enrollment of approximately 490 patients. Eligible patients must have confirmed progressive mCRPC assessed with a <sup>68</sup>Ga-PSMA-11 PET<sup>2</sup> imaging agent (such as Illuccix®, kit for the preparation of gallium-68 (<sup>68</sup>Ga) gozetotide injection, or Gozellix®, kit for the preparation of gallium-68 (<sup>68</sup>Ga) gozetotide injection) following prior treatment with one ARPI.

The antibody-based approach demonstrates differentiated targeting and pharmacology to other PSMA-targeted small molecule radioligand therapies (RLT). In contrast to these therapies<sup>3</sup>, collective long-term follow-up of patients administered with TLX591-Tx has not observed significant acute or delayed kidney toxicity, as the agent is hepatically (liver) excreted, a comparatively radioresistant organ<sup>4</sup>. TLX591-Tx also demonstrates minimal salivary and lacrimal gland uptake, reducing the prevalence of xerostomia (dry mouth) and dry eye, which are typical adverse effects of existing PSMA-targeted RLTs<sup>5</sup>. Additional information on the Phase 3 ProstACT Global study can be found at: <https://telixpharma.com/prostact/>

## 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®, 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 in prostate cancer, TLX101-Tx in recurrent glioblastoma, TLX250-Tx 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](http://www.telixpharma.com) or follow Telix on LinkedIn, X and Facebook.

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

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<sup>2</sup> Positron emission tomography.

<sup>3</sup> Tagawa et al. *Curr Oncol Rep.* 2021; Steinhelfer et al. *J Nucl Med.* 2024.

<sup>4</sup> Tagawa et al. *Cancer.* 2019.

<sup>5</sup> Pepin et al. *Pract Radiat Oncol.* 2025.

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