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**ASX ANNOUNCEMENT**

# Telix Granted FDA Fast Track Designation for BiPASS Pre-Biopsy Prostate Cancer Imaging

- FDA Fast Track designation granted for Telix's BiPASS® program, which is evaluating $^{68}$Ga-PSMA-PET imaging alongside MRI in the pre-biopsy prostate cancer setting.
- The designation recognizes the program's potential to address an important unmet need by enabling an imaging-first approach to initial prostate cancer diagnosis.
- Fast Track facilitates more frequent engagement with the FDA and may enable expedited review of the planned NDA.

*Melbourne (Australia) and Indianapolis, IN (U.S.) – September 30, 2026*. Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today announces that the United States (U.S.) Food and Drug Administration (FDA) has granted Fast Track designation for the Company's BiPASS® program.

BiPASS (**Bi**opsy of the **P**rostate **A**voidance **S**tratification **S**tudy[1]) is evaluating gallium-68 ($^{68}$Ga) PSMA-PET imaging[2] in combination with MRI[3] for the detection of prostate cancer prior to biopsy.

Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need[4], potentially accelerating patient access if approved. More than three million prostate biopsies are performed globally each year[5], yet up to 75% produce a negative result[6]. Biopsy can be stressful and painful for patients and may provide no meaningful diagnostic benefit[7], highlighting the importance of improved diagnostic tools earlier in the patient journey.

Telix recently completed enrollment in the Phase 3 BiPASS study of its proprietary $^{68}$Ga-PSMA-PET agents, Illuccix® and Gozellix®[8] for pre-biopsy prostate cancer diagnosis. The Company has positively engaged with the FDA on a new drug application (NDA) pathway and is planning its submission. The NDA pathway supports registration as a new product which, if approved, would broaden access to $^{68}$Ga-PSMA-PET imaging for a substantially larger patient population.

BiPASS builds on the clinical foundation established by the PRIMARY[9] and PRIMARY2[10] studies. These studies demonstrated that combining $^{68}$Ga-PSMA-PET imaging with MRI can significantly improve detection of clinically significant prostate cancer while reducing unnecessary biopsies by almost 50 percent. BiPASS is not intended to replace biopsy when it benefits the patient but rather aims to improve the diagnostic pathway by helping clinicians determine which patients would benefit from biopsy and where biopsy should be targeted.

Dr. David N. Cade, Group Chief Medical Officer at Telix, said, "Fast Track designation reflects the FDA's recognition of the potential for BiPASS to address an important unmet need in the prostate

[1] ClinicalTrials.gov ID: NCT07052214.
[2] Imaging of prostate-specific membrane antigen with positron emission tomography.
[3] Magnetic resonance imaging.
[4] Visit: https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.
[5] Hu et al. *JAMA Oncol.* 2024.
[6] Vickers et al. *J Clin Oncol.* 2010.
[7] Durkan G et al. *Prostate Cancer Prostatic Dis.* 2000.
[8] Illuccix® (kit for the preparation of gallium Ga68 gozetotide injection) and Gozellix® (kit for the preparation of gallium Ga68 gozetotide injection).
[9] Emmett et al., *Eur Urol.* 2021.
[10] Buteau et al. *Lancet Oncol.* 2026. ClinicalTrials.gov ID: NCT05154162.

cancer diagnostic pathway. We believe gallium-68 PSMA-PET, used alongside MRI, could help physicians make more informed decisions before biopsy, improve diagnostic confidence and potentially reduce unnecessary invasive procedures for patients. This designation supports continued close engagement with the FDA as we advance BiPASS toward an NDA submission."

Illuccix and Gozellix are approved for PET imaging of PSMA-positive lesions in patients with prostate cancer with suspected metastasis who are candidates for initial definitive therapy, and in patients with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level. Illuccix is also approved for the selection of patients indicated for PSMA-directed therapy. The use of Illuccix and Gozellix in the pre-biopsy setting remains investigational and has not been approved by the FDA or any other regulatory authority.

**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 precision diagnostics 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), approved by the U.S. Food and Drug Administration (FDA) for prostate imaging, and Pixclara® (floretyrosine F18) approved by the FDA for glioma imaging. The Company's late-stage therapeutic pipeline includes three investigational assets in pivotal-stage trials: TLX591-Tx (lutetium-177 ($^{177}$Lu) rosopatamab tetraxetan) in prostate cancer, TLX101-Tx (iodofalan $^{131}$I) in recurrent glioblastoma, and TLX250-Tx (lutetium ($^{177}$Lu) girentuximab tetraxetan) in kidney cancer, additionally complemented by a deep pipeline of next generation candidates. TLX591-Tx, TLX101-Tx and TLX250-Tx have not received marketing authorizations in any jurisdiction.

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

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