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ASX ANNOUNCEMENT

Telix Completes Enrollment in Phase 3 BiPASS Study, Aligns with FDA on NDA Pathway

- The Phase 3 BiPASS™ study of Illuccix® and Gozellix® for prostate cancer imaging in the pre-biopsy setting has completed enrollment of 350 patients.
- Telix has positively engaged with the FDA on a New Drug Application (NDA) pathway in the U.S. that would support new product reimbursement and broaden access to ^{68}Ga-PSMA-PET imaging across a significantly larger patient population.
- BiPASS is designed to evaluate the diagnostic performance of ^{68}Ga-PSMA-11 PET combined with MRI for the detection of prostate cancer prior to biopsy.

Melbourne (Australia) and Indianapolis, IN (U.S.) – September 2, 2026. Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today announced completion of patient enrollment in the Phase 3 BiPASS™ study of its commercial PSMA-PET[1] imaging agents, Illuccix® (kit for the preparation of gallium Ga68 gozetotide injection) and Gozellix® (kit for the preparation of gallium Ga68 gozetotide injection) for prostate cancer imaging in the pre-biopsy setting. Telix has also aligned with the United States (U.S.) Food and Drug Administration (FDA) on a New Drug Application (NDA) pathway for BiPASS that, if approved, would support reimbursement as a new product and broaden patient access.

BiPASS (**Bi**opsy of the **P**rostate **A**voidance **S**tratification **S**tudy[2]) is the first registrational study of ^{68}Ga-PSMA-PET imaging in the pre-biopsy setting. The study aims to evaluate whether the combination of MRI[3] and PSMA-PET/CT[4] with Telix's proprietary ^{68}Ga-PSMA-PET agents can further improve diagnostic accuracy, reduce unnecessary biopsies, or improve targeting of biopsy compared with current standard practice. A total of 350 patients were enrolled in the U.S. and Australia in this prospective, open-label Phase 3 trial.

Globally, more than three million prostate biopsies are performed each year[5], yet up to 75% are found to be negative[6]. Patient compliance remains a significant clinical challenge with approximately one in four patients declining a physician recommendation to undergo biopsy[7]. Biopsy is often stressful and painful, may lead to complications, and delivers no real diagnostic benefit for many patients[8].

BiPASS builds on the clinical foundation established by the landmark PRIMARY[9] and PRIMARY2[10] studies, which demonstrated that combining ^{68}Ga-PSMA-PET imaging with MRI can significantly improve the detection of clinically significant prostate cancer while reducing unnecessary biopsies by almost 50 percent. If BiPASS meets its primary objectives, the data, alongside evidence from PRIMARY and PRIMARY2, have the potential to shift ^{68}Ga-PSMA-PET beyond its current use in initial staging and secondary re-staging at disease recurrence and establish precision imaging as a

[1] Imaging of prostate-specific membrane antigen with positron emission tomography.
[2] ClinicalTrials.gov ID: NCT07052214.
[3] Magnetic resonance imaging.
[4] Imaging of prostate-specific membrane antigen with positron emission tomography/computed tomography.
[5] Hu et al. *JAMA Oncol.* 2024.
[6] Vickers et al. *J Clin Oncol.* 2010.
[7] Schaufler C et al. *Urologic Oncology: Seminars and Original Investigations*. 2022.
[8] Durkan G et al. *Prostate Cancer Prostatic Dis.* 2000.
[9] Emmett et al., *Eur Urol.* 2021.
[10] Buteau et al. *Lancet Oncol.* 2026. ClinicalTrials.gov ID: NCT05154162.

critical step in initial diagnosis. Earlier and more accurate identification of clinically significant disease could improve patient selection and treatment decisions, reduce unnecessary biopsies, and potentially decrease the long-term patient burden and healthcare cost of prostate cancer recurrence. Successful implementation of BiPASS could broaden access to ^{68}Ga-PSMA-PET imaging across a substantially larger patient population.

Professor Louise Emmett, Director of Theranostics and Nuclear Medicine, St Vincent's Hospital and BiPASS Investigator, said, "Completing patient enrollment in BiPASS is an important milestone for men with suspected prostate cancer, particularly those with equivocal MRI findings. The PRIMARY and PRIMARY2 studies demonstrated that ^{68}Ga-PSMA-PET, when used alongside MRI, can safely halve the number of biopsies required without missing clinically significant prostate cancer. BiPASS now has the potential to fundamentally change the current standard of care, streamlining the diagnostic pathway, accelerating treatment decision-making and helping to ensure that men receive the most appropriate therapy earlier in their treatment journey."

Dr. Brian Mazzarella, Vice President of Research for Urology America and BiPASS Investigator added, "PSMA-PET imaging with tracers such as Illuccix and Gozellix has already changed how we stage and manage prostate cancer. By combining the functional information from PSMA-PET with the detailed anatomic information provided by MRI, we have an unprecedented opportunity to improve the detection of clinically significant prostate cancer and guide more informed diagnostic decisions. For patients, this approach has the potential to reduce unnecessary procedures, lower procedural risk, ease anxiety, and ultimately enable more precise, individualized treatment decision-making."

Dr. David N. Cade, Telix Group Chief Medical Officer, commented, "Recruitment of BiPASS was completed rapidly, reflecting strong enthusiasm from clinicians and patients for a more accurate, non-invasive approach to diagnosis. We believe BiPASS may represent a transformative event in the management of prostate cancer, alongside the compelling data from the PRIMARY studies. Instead of asking how best to stage prostate cancer, clinicians may increasingly use advanced imaging to determine which men need to undergo biopsy in the first place. Telix is uniquely positioned to define and lead this patient-first approach that, if approved, would represent a new clinical application with a reimbursement pathway that facilitates much broader patient access to gallium-based PSMA-PET."

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®, commercially available in 22 countries including the U.S. and Gozellix®, approved by the FDA. 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 (^{131}I-iodofalan) in recurrent glioblastoma, and TLX250-Tx (lutetium (^{177}Lu) girentuximab tetraxetan) in kidney cancer, additionally complemented by a deep pipeline of next generation candidates.

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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