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ASX ANNOUNCEMENT

CMS Grants Transitional Pass-Through Status for Gozellix

Melbourne (Australia) and Indianapolis, IN (U.S.) – 23 September 2025. Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today announces that the United States (U.S.) Centers for Medicare & Medicaid Services (CMS) has granted Transitional Pass-Through (TPT) payment status for Gozellix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection), Telix's next-generation PSMA-PET[1] imaging agent for prostate cancer.

This designation enables separate reimbursement for Gozellix® under the Hospital Outpatient Prospective Payment System (HOPPS), effective 1 October 2025, and marks a significant milestone in Telix's U.S. commercial strategy. Gozellix® has already been assigned a permanent Healthcare Common Procedure Coding System (HCPCS) Level II code A9616 to be recognized by CMS and commercial health insurers, effective 1 October 2025[2]. Additionally, patients are not subject to the 20% patient coinsurance under TPT.

After radiolabelling with ^{68}Ga, Gozellix® is indicated for PET scanning of PSMA positive lesions in men with prostate cancer who have suspected metastasis and are candidates for initial definitive therapy, and those with suspected biochemical recurrence (BCR) based on elevated serum prostate-specific antigen (PSA) level[3].

Gozellix® is a novel imaging agent offering a longer shelf life of up to six hours and an extended distribution radius compared to existing gallium-based products, helping to overcome many of the logistical barriers that have historically limited access to PSMA-PET imaging[4]. Its innovative formulation enables scalable production, with preparation possible via gallium generators (50mCi and 100mCi) or cyclotron-based methods. This flexibility has the potential to significantly improve efficiency, scheduling flexibility, and throughput for scanning clinics[5]. Cyclotron production of Gozellix® is supported by the GE FASTlab™[6] solid and liquid target production system and Telix's ARTMS QUANTM Irradiation System® (QIS®), the market-leading cyclotron solid target technology, enabling large-scale production across both commercial networks and academic centers.

Kevin Richardson, Chief Executive Officer, Precision Medicine, Telix, said, "Granting TPT status for Gozellix is a strong endorsement of the clinical value of our next-generation imaging agent. Gozellix is already available nationally, and this reimbursement milestone will reduce the out-of-pocket burden for patients, enhance patient access to advanced prostate cancer imaging and simplify payment for providers. As the only provider with two FDA-approved and reimbursed products in this class, we are pleased to make PSMA-PET/CT imaging accessible to more patients and providers across the U.S."

[1] Imaging of prostate-specific membrane antigen with positron emission tomography.
[2] Telix ASX disclosure 9 July 2025.
[3] Gozellix® prescribing information.
[4] Data on file.
[5] Gozellix® prescribing information. Data on file.
[6] FASTlab is a trademark of GE Healthcare and its affiliates.

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals and associated medical technologies. 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 developing a portfolio of clinical and commercial stage products that aims to address significant unmet medical needs in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (NASDAQ: TLX).

Illuccix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection), Telix's first generation PSMA-PET imaging agent, has been approved in multiple markets globally. Gozellix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection) has been approved by the U.S. FDA[7].

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

[7] Telix ASX disclosure 21 March 2025.

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