

ASX ANNOUNCEMENT

Chinese NMPA Accepts New Drug Application for Illuccix for Prostate Cancer Imaging

Melbourne (Australia) and Indianapolis, IN (U.S.) – 20 January 2026. Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, “Telix”) today announces that the Chinese National Medical Products Administration (NMPA) Center for Drug Evaluation (CDE) has accepted the filing of a New Drug Application (NDA) for TLX591-Px (Illuccix®, Kit for the preparation of ⁶⁸Ga-PSMA-11), Telix’s lead prostate cancer imaging agent.

The NDA was submitted with Telix’s strategic partner for the Greater China region, Grand Pharmaceutical Group Limited (00512.HK, Grand Pharma). Seeking a broad label that reflects clinical utility at multiple stages of prostate cancer care, the submission includes data from the Illuccix China Pivotal Phase 3 Registration study¹, which reported positive top-line results in December 2025².

The Illuccix China study met its primary endpoint, with an overall patient-level positive predictive value (PPV) of 94.8% for the detection of tumors in patients with biochemical recurrence (BCR) of prostate cancer with TLX591-Px^{2,3}. This confirmed that the clinical experience of TLX591-Px PSMA-PET⁴ imaging in Chinese patients is comparable to studies in non-Chinese patients. The high PPV was demonstrated even in patients with very low PSA⁵ values, and across differing metastatic locations. More than two-thirds (67.2%) of patients experienced a change in their treatment plan as a consequence of TLX591-Px PSMA-PET imaging compared with the initial plan at baseline³, demonstrating a major impact on clinical decision-making in Chinese patients.

Kevin Richardson, Chief Executive Officer, Precision Medicine, Telix, commented, “Submitting this New Drug Application for TLX591-Px, the first for any of our products in China, is a major milestone for Telix and our partner Grand Pharma. Geographic expansion is core to the growth strategy for our precision medicine business, and China represents a strategically important market for Telix. We look forward to progressing regulatory approvals together with Grand Pharma and subject to NMPA approval, bringing our lead commercial imaging product to market in China to serve the needs of men living with prostate cancer.”

About Prostate Cancer in China

In China, more than 134,000 men were diagnosed with prostate cancer in 2022⁶, increasing by approximately 6% each year⁷. In line with government policy supporting wider geographic access to nuclear medicine, the number of PET/CT cameras installed in China is expected to have surpassed 1,600 at the end of 2025⁸, compared with 133 in 2010⁹.

¹ ClinicalTrials.gov ID: [NCT05847348](https://clinicaltrials.gov/ct2/show/study/NCT05847348).

² Telix ASX disclosure 22 December 2025.

³ Telix data on file. Illuccix China Clinical Study Report, December 2025.

⁴ Imaging of prostate-specific membrane antigen with positron emission tomography.

⁵ Prostate-specific antigen.

⁶ Global Cancer Statistics 2022: GLOBOCAN survey. Published August 2024.

⁷ Ye Dingwei et al. *Lancet Oncology*, 2022.

⁸ Yang et al. *J Nuc. Med.* 2024.

⁹ Goetz Partners research 2020.

About Illuccix

Telix's lead prostate imaging product, gallium-68 (⁶⁸Ga) gozetotide injection (also known as ⁶⁸Ga PSMA-11 and marketed under the brand name Illuccix®), has been approved by the U.S. Food and Drug Administration (FDA)¹⁰, by the Australian Therapeutic Goods Administration (TGA)¹¹, by Health Canada¹², by the Brazilian Health Regulatory Agency (ANVISA)¹³, by the United Kingdom (UK) Medicines and Healthcare Products Regulatory Agency (MHRA)¹⁴ and in 19 countries within the European Economic Area (EEA).

PSMA-PET imaging represents a significant advance in prostate cancer management, largely replacing conventional imaging methods such as bone scans and computed tomography (CT) scans as the standard of care after initial diagnosis and biochemical recurrence (BCR) in the United States. Global guidelines recognize its superior accuracy in staging primary disease and assessing BCR¹⁵.

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 (⁶⁸Ga) gozetotide injection), Telix's first generation PSMA-PET imaging agent, has been approved in multiple markets globally.

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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¹⁰ Telix ASX disclosure 20 December 2021.

¹¹ Telix ASX disclosure 2 November 2021.

¹² Telix ASX disclosure 14 October 2022.

¹³ Telix ASX disclosure 18 March 2025.

¹⁴ Telix ASX disclosure 13 February 2025.

¹⁵ NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.3.2026; EAU Guidelines. Edn. presented at the EAU Annual Congress Madrid 2025. ISBN 978-94-92671-29-5:

<https://uroweb.org/guidelines/prostate-cancer>; Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. 2023: <https://www.esmo.org/guidelines/guidelines-by-topic/esmo-clinical-practice-guidelines-genitourinary-cancers/clinical-practice-guidelines-prostate-cancer/eupdate-prostate-cancer-treatment-recommendations>

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

Legal Notices

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You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the Australian Securities Exchange (ASX), U.S. Securities and Exchange Commission (SEC), including our Annual Report on Form 20-F filed with the SEC, or on our website.

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