

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 (^{68}Ga) gozetotide injection (also known as ^{68}Ga 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 (^{68}Ga) 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](#).

Telix Investor Relations (Global)

Ms. Kyahn Williamson
Telix Pharmaceuticals Limited
SVP Investor Relations and Corporate Communications
Email: kyahn.williamson@telixpharma.com

Telix Investor Relations (U.S.)

Annie Kasparian
Telix Pharmaceuticals Limited
Director Investor Relations and Corporate Communications
Email: annie.kasparian@telixpharma.com

Media Contact

Eliza Schleifstein
917.763.8106 (Mobile)
Eliza@schleifsteinpr.com

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

Cautionary Statement Regarding Forward-Looking Statements.

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.

The information contained in this announcement is not intended to be an offer for subscription, invitation or recommendation with respect to securities of Telix Pharmaceuticals Limited (Telix) in any jurisdiction, including the United States. The information and opinions contained in this announcement are subject to change without notification. To the maximum extent permitted by law, Telix disclaims any obligation or undertaking to update or revise any information or opinions contained in this announcement, including any forward-looking statements (as referred to below), whether as a result of new information, future developments, a change in expectations or assumptions, or otherwise. No representation or warranty, express or implied, is made in relation to the accuracy or completeness of the information contained or opinions expressed in the course of this announcement.

This announcement may contain forward-looking statements, including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that relate to anticipated future events, financial performance, plans, strategies or business developments. Forward-looking statements can generally be identified by the use of words such as “may”, “expect”, “intend”, “plan”, “estimate”, “anticipate”, “believe”, “outlook”, “forecast” and “guidance”, or the negative of these words or other similar terms or expressions. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements are based on Telix’s good-faith assumptions as to the financial, market, regulatory and other risks and considerations that exist and affect Telix’s business and operations in the future and there can be no assurance that any of the assumptions will prove to be correct. In the context of Telix’s business, forward-looking statements may include, but are not limited to, statements about: the initiation, timing, progress, completion and results of Telix’s preclinical and clinical trials, and Telix’s research and development programs; Telix’s ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; the timing or likelihood of regulatory filings and approvals for Telix’s product candidates, including the planned NDA resubmission for TLX101-Px and the planned BLA resubmission for TLX250-Px, manufacturing activities and product marketing activities; Telix’s sales, marketing and distribution and manufacturing capabilities and strategies; the commercialization of Telix’s product candidates, if or when they have been approved; Telix’s ability to obtain an adequate supply of raw materials at reasonable costs for its products and product candidates; estimates of Telix’s expenses, future revenues and capital requirements; Telix’s financial performance; developments relating to Telix’s competitors and industry; the anticipated impact of U.S. and foreign tariffs and other macroeconomic conditions on Telix’s business; and the pricing and reimbursement of Telix’s product candidates, if and after they have been approved. Telix’s actual results, performance or achievements may be materially different from those which may be expressed or implied by such statements, and the differences may be adverse. Accordingly, you should not place undue reliance on these forward-looking statements.

Trademarks and Trade Names. All trademarks and trade names referenced in this press release are the property of Telix Pharmaceuticals Limited (Telix) or, where applicable, the property of their respective owners. For convenience, trademarks and trade names may appear without the ® or ™ symbols. Such omissions are not intended to indicate any waiver of rights by Telix or the respective owners. Trademark registration status may vary from country to country. Telix does not intend the use or display of any third-party trademarks or trade names to imply any affiliation with, endorsement by, or sponsorship from those third parties.

©2026 Telix Pharmaceuticals Limited. All rights reserved.