

### ASX ANNOUNCEMENT

# Illuccix® Approved in the United Kingdom

*Melbourne (Australia) – 13 February 2025.* Telix Pharmaceuticals Limited (ASX: TLX, Nasdaq: TLX, Telix, the Company) today announces that the United Kingdom (UK) Medicines and Healthcare Products Regulatory Agency (MHRA) has approved the Marketing Authorization Application (MAA) for its prostate cancer PET<sup>1</sup> imaging agent Illuccix® (kit for the preparation of gallium-68 gozetotide injection).

Illuccix is indicated in the UK for the detection and localization of prostate-specific membrane antigen (PSMA)-positive lesions in adults with prostate cancer, using PET. PSMA-PET imaging<sup>2</sup> represents a major advancement in prostate cancer management, largely replacing conventional imaging methods (bone scan, CT<sup>3</sup> scan) as the standard of care after initial diagnosis and biochemical recurrence (BCR). Global guidelines highlight the superior accuracy of PSMA-PET for the staging of primary disease and evaluation of BCR/biochemical persistence (BCP)<sup>4</sup>.

Gary Cook, MD, Professor of Molecular Imaging at Kings College London School of Biomedical Engineering & Imaging Sciences, commented, "PSMA-PET supply shortages in the UK and Europe have escalated over the past 12 months as demand increases, which has led to delays for men in urgent need of a scan to direct clinical management. It is great news that Telix can now help address this unmet need and improve equity of access in the UK through their Illuccix imaging agent and network distribution model."

Raphaël Ortiz, Chief Executive Officer, Telix International added, "PSMA-PET imaging is one of the most important developments in prostate cancer detection in recent years and we are delighted that we can now bring Illuccix to physicians and their patients across the UK. A key advantage of Illuccix is that the radioisotope (gallium-68) can be produced using a generator locally, taking just a few minutes with minimal equipment. Reliable service delivery combined with greater scheduling flexibility, including in non-metropolitan locations, will benefit patients, physicians and clinical sites in the UK."

Illuccix will be made available in the UK through Telix's exclusive distribution partner, Xiel Limited, a specialist distributor of nuclear medicine, radiotherapy and diagnostic radiology technologies across the UK and Ireland. To order or enquire about Illuccix availability, UK healthcare professionals can email: <a href="mailto:radiopharm@xiel.co.uk">radiopharm@xiel.co.uk</a> or call +44 (0)1749 372217.

# About Illuccix®

Telix's prostate imaging product, gallium-68 (<sup>68</sup>Ga) gozetotide injection (also known as <sup>68</sup>Ga PSMA-11 and marketed under the brand name Illuccix®), has been approved by the U.S. Food and Drug Administration (FDA)<sup>5</sup>, by the Australian Therapeutic Goods Administration (TGA)<sup>6</sup>, by Health

<sup>&</sup>lt;sup>1</sup> Positron emission tomography.

<sup>&</sup>lt;sup>2</sup> Imaging of prostate-specific membrane antigen with positron emission tomography.

<sup>&</sup>lt;sup>3</sup> Computed tomography.

<sup>&</sup>lt;sup>4</sup> EAU Guidelines. Edn. presented at the EAU Annual Congress Paris 2024. ISBN 978-94-92671-23-3.: <u>https://uroweb.org/guidelines/prostate-cancer</u>; Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. 2023: <u>https://www.esmo.org/guidelines/guidelines-by-topic/esmo-clinical-practice-guidelines-genitourinary-cancers/clinical-practice-guidelines-prostate-cancer/eupdate-prostate-cancer-treatment-recommendations</u>

<sup>&</sup>lt;sup>5</sup> Telix ASX disclosure 20 December 2021. <sup>6</sup> Telix ASX disclosure 2 November 2021.

Canada<sup>7</sup>, by the Danish Medicines Agency<sup>8</sup>, and by the UK MHRA. Illuccix is currently in national approval review in 19 European countries following a positive decentralized procedure (DCP) opinion by BfArM<sup>9</sup>.

# 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, 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. ARTMS, IsoTherapeutics, Lightpoint, Optimal Tracers and RLS are Telix Group companies. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (Nasdaq: TLX).

Telix's osteomyelitis (bone infection) imaging agent, technetium-99m (<sup>99m</sup>Tc) besilesomab, marketed under the brand name Scintimun®, is approved in 32 European countries and Mexico. Telix's miniaturized surgical gamma probe, SENSEI®, for minimally invasive and robotic-assisted surgery, is registered with the FDA for use in the U.S. and has attained a Conformité Européenne (CE) Mark for use in the European Economic Area. No other Telix product has received a marketing authorization in any jurisdiction.

Visit <u>www.telixpharma.com</u> for further information about Telix, including details of the latest share price, ASX and SEC filings, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on <u>LinkedIn</u>, <u>X</u> and <u>Facebook</u>.

# **Telix Investor Relations**

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

#### Legal Notices

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 registration statement on Form 20-F filed with the SEC, or on our website.

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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",

<sup>&</sup>lt;sup>7</sup> Telix ASX disclosure 14 October 2022.

<sup>&</sup>lt;sup>8</sup> Telix media release 11 February 2025.

<sup>&</sup>lt;sup>9</sup> The German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte).

Telix ASX disclosure 17 January 2025.

"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 and results of Telix's preclinical and clinical trials, and Telix's research and development programs; Telix's ability to advance product candidates into, enrol and successfully complete, clinical studies, including multi-national clinical trials; the timing or likelihood of regulatory filings and approvals for Telix's product candidates, manufacturing activities and product marketing activities; Telix's sales, marketing and distribution and manufacturing capabilities and strategies; the commercialisation 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; 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.

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