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ASX ANNOUNCEMENT

Illuccix® Receives European Approval

Melbourne (Australia) and Liège (Belgium) – 17 January 2025. Telix Pharmaceuticals Limited (ASX: TLX, Nasdaq: TLX, Telix, the Company) today announces that it has received a positive decision on the Marketing Authorization Application (MAA) for its prostate cancer PET[1] imaging agent Illuccix® (kit for the preparation of gallium-68 gozetotide injection), which was submitted in Europe via a decentralized procedure (DCP).

This significant milestone follows the issuance of the Final Assessment Report from the German Competent Authority BfArM[2] as Reference Member State (RMS). Through the DCP, the RMS and all 18 European Economic Area (EEA) Concerned Member States (CMS)[3] agree that Illuccix should receive marketing authorization. The DCP regulatory process will now transition into an administrative national phase to implement authorizations to facilitate commercial launch in each country[4].

Kevin Richardson, Chief Executive Officer, Telix Precision Medicine commented, "We are delighted by this positive outcome, setting the stage for a European commercial launch of Illuccix. This clinically important prostate cancer imaging modality is currently recommended in international clinical practice guidelines including European Association of Urology (EAU) and European Society for Medical Oncology (ESMO)."

PSMA-PET imaging[5] represents a major advancement in prostate cancer management, largely replacing conventional imaging methods (bone scan, CT[6] scan) as the standard of care after initial diagnosis and biochemical recurrence (BCR). European guidelines highlight the superior accuracy of PSMA-PET for the staging of primary disease[7] and evaluation of BCR/biochemical persistence (BCP)[8].

About Illuccix®

Telix's lead 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)[9], by the Australian Therapeutic Goods Administration (TGA) [10], and by Health Canada[11].

[1] Positron emission tomography.
[2] The German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte).
[3] Germany serves as the Reference Member State in the Decentralised Procedure. The other 18 Concerned Member States are Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, and Sweden.
[4] Regulatory approval timeframe from EEA CMSs may vary considerably.
[5] Imaging of prostate-specific membrane antigen with positron emission tomography.
[6] Computed tomography.
[7] EAU, ESMO.
[8] EAU.
[9] Telix ASX disclosure 20 December 2021.
[10] Telix ASX disclosure 2 November 2021.
[11] Telix ASX disclosure 14 October 2022.

In Europe, Illuccix, after radiolabelling with gallium-68, will be indicated for detection of PSMA-positive lesions with PET in adults with prostate cancer (PCa) in the following clinical settings:

- Primary staging of patients with high-risk PCa prior to primary curative therapy
- Suspected recurrent PCa in patients with increasing levels of serum prostate-specific antigen (PSA) after primary curative therapy
- Identification of patients with PSMA-positive progressive metastatic castration-resistant prostate cancer (mCRPC) for whom PSMA-targeted therapy is indicated.

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. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (Nasdaq: TLX).

Visit www.telixpharma.com 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 X and LinkedIn.

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

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.