



**Telix Pharmaceuticals Limited**

ACN 616 620 369  
55 Flemington Road  
North Melbourne  
Victoria, 3051  
Australia

**ASX RELEASE**

## **Update: European Marketing Authorisation Applications for Illuccix®**

*Melbourne (Australia) and Liège (Belgium) – 3 April 2023.* Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces the filing of a Marketing Authorisation Application (MAA) with the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA) for its finished product Illuccix® 25 micrograms kit for radiopharmaceutical preparation for positron emission tomography (PET) imaging of prostate cancer.

The review period for the UK MAA follows a 150-day national application procedure.<sup>1</sup> The Company is also in the process of filing a separate decentralised MAA application for the European Union (EU) and will advise on the review timetable upon final acceptance of the dossier by the reference Competent Authority (CA).

Raphaël Ortiz, Telix EMEA CEO said, “Telix is committed to ensuring widespread access to commercially available gallium-based PSMA-PET imaging across the EU and UK. We are therefore pleased to report that the revised MAAs for the region are progressing satisfactorily, in line with the Company’s commitment to serving patients globally.”

In 2020, prostate cancer was the most common cancer in men in the UK, with approximately 57,000 new cases being diagnosed, exhibiting a significantly higher incidence than either lung cancer (27,000 new cases) or bowel cancer (29,000 new cases). Prostate cancer was also a leading cause of cancer death in men, with 13,000 men dying from the disease in the UK in 2020. 236,000 British men were estimated to be living with prostate cancer in 2020.<sup>2</sup>

### **About Telix Pharmaceuticals Limited**

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic radiopharmaceuticals. Telix is headquartered in Melbourne, Australia with international operations in the United States, Europe (Belgium and Switzerland), and Japan. Telix is developing a portfolio of clinical-stage products that aims to address significant unmet medical need in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX).

Visit [www.telixpharma.com](http://www.telixpharma.com) for further information about Telix, including details of the latest share price, announcements made to the ASX, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on [Twitter](https://twitter.com/TelixPharma) (@TelixPharma) and [LinkedIn](https://www.linkedin.com/company/telix-pharmaceuticals).

Illuccix®, kit for the preparation of gallium Ga 68 gozetotide injection (also known as <sup>68</sup>Ga PSMA-11), has been approved by the U.S. Food and Drug Administration (FDA),<sup>3</sup> the Australian Therapeutic Goods Administration (TGA),<sup>4</sup> and Health Canada.<sup>5</sup>

---

<sup>1</sup> With a period of up to 60 days during the review for the applicant to reply to requests for additional information.

<sup>2</sup> Globocan 2020.

<sup>3</sup> ASX disclosure 20 December 2021.

<sup>4</sup> ASX disclosure 2 November 2021.

<sup>5</sup> ASX disclosure 14 October 2022.

---

## Telix Investor Relations

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

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

### Legal Notices

*This announcement is not intended as promotion or advertising directed to any healthcare professional or other audience in any country worldwide (including Australia, United States and the United Kingdom). This announcement may include forward-looking statements 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”, “outlook”, “forecast” and “guidance”, or other similar words. 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 the Company’s good-faith assumptions as to the financial, market, regulatory and other risks and considerations that exist and affect the Company’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 studies, 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, manufacturing activities and product marketing activities; the commercialisation of Telix’s product candidates, if or when they have been approved; 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.*

*Except as required by applicable laws or regulations, Telix does not undertake to publicly update or review any forward-looking statements. Past performance cannot be relied on as a guide to future performance. Readers should read this announcement together with our material risks, as disclosed in our most recently filed reports with the ASX and on our website.*

*©2023 Telix Pharmaceuticals Limited. The Telix Pharmaceuticals and Illuccix name and logo are trademarks of Telix Pharmaceuticals Limited and its affiliates (all rights reserved).*