

**ASX RELEASE**

## **Chinese NMPA Approves Study of Telix Kidney Cancer Imaging Candidate**

*Melbourne (Australia) – 28 September 2022.* Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that the Chinese National Medical Products Administration (NMPA) Center for Drug Evaluation (CDE) has approved a pivotal Phase III registration study that will bridge to Telix's global Phase III 'ZIRCON' trial of TLX250-CDx (<sup>89</sup>Zr-girentuximab), for the imaging of clear cell renal cell carcinoma (ccRCC) with position emission tomography (PET).

The investigational new drug (IND) application was submitted by Telix's partner in the Greater China region, Grand Pharmaceutical Group Limited (Grand Pharma). The bridging study is required to provide "supplementary" data obtained in a Chinese population to establish that the diagnostic efficacy of this investigational product is equivalent in Chinese and Western populations. A dosimetry study enrolling 10 patients will precede the multi-centre Phase III bridging study, which is expected to enrol 100 patients.

A successful outcome from Telix's global ZIRCON trial combined with positive data from this Phase III bridging study will support a future marketing authorisation application for TLX250-CDx in China.

Dr David N Cade, CEO Telix Asia Pacific, said "This IND is a significant milestone for Telix and our partner Grand Pharma, enabling us to proceed with a pivotal registration study and ultimately bring new options to the 73,000 people newly diagnosed with renal cell carcinoma in China each year where there is currently critical unmet medical need."

### **About TLX250-CDx**

TLX250-CDx (<sup>89</sup>Zr-girentuximab) is an investigational product being developed by Telix for the purpose of non-invasive detection of clear cell renal cancer in patients with "indeterminate renal masses" (IDRMs), typically identified based on computed tomography (CT) or magnetic resonance imaging (MRI) imaging and are an increasing medical dilemma as more scans are performed and more IDRMs are identified.

Girentuximab is a monoclonal antibody that targets carbonic anhydrase IX (CAIX), a cell surface target that is highly expressed in several human cancers including renal, lung and oesophageal cancers. In July 2020, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy (BT) designation for TLX250-CDx,<sup>1</sup> reflecting the significant unmet clinical need to improve the diagnosis and staging of clear cell renal cell carcinoma (ccRCC), the most common and aggressive form of kidney cancer.

### **About the ZIRCON Study**

ZIRCON (Zirconium Imaging in Renal Cancer Oncology, [NCT03849118](https://clinicaltrials.gov/ct2/show/study/NCT03849118)) is a confirmatory, prospective, open-label, multi-centre phase III study to evaluate sensitivity and specificity of <sup>89</sup>Zr-TLX250-CDx PET/CT imaging to non-invasively detect clear cell renal cell cancer (ccRCC) in adult patients with "indeterminate renal masses" (IDRMs), scheduled for partial or total nephrectomy. The study completed enrolment in July 2022 and Telix expects to report study outcomes in 2H, 2022.<sup>2</sup>

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<sup>1</sup> ASX disclosure 1 July 2020.

<sup>2</sup> ASX disclosure 11 July 2022.

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## 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). For more information visit [www.telixpharma.com](http://www.telixpharma.com) and follow Telix on [Twitter](https://twitter.com/TelixPharma) (@TelixPharma) and [LinkedIn](https://www.linkedin.com/company/telix-pharmaceuticals).

Telix's lead product, gallium-68 (<sup>68</sup>Ga) gozetotide (also known as <sup>68</sup>Ga PSMA-11) injection, has been approved by the U.S. Food and Drug Administration (FDA),<sup>3</sup> and by the Australian Therapeutic Goods Administration (TGA).<sup>4</sup> Telix is also progressing marketing authorisation applications for this investigational candidate in Europe<sup>5</sup> and Canada.<sup>6</sup>

## Telix Investor Relations

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*This announcement has been authorised for release by the disclosure committee of Telix Pharmaceuticals Limited.*

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

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

<sup>5</sup> ASX disclosure 10 December 2021.

<sup>6</sup> ASX disclosure 16 December 2020.