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**ASX RELEASE**

## **ZIRCON Phase III Kidney Cancer Imaging Study Presented at AUA: New Data Confirms Efficacy in Masses 2cm or Smaller**

Melbourne (Australia) – 1 May 2023. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces additional positive results from its completed pivotal Phase III ZIRCON study of TLX250-CDx (<sup>89</sup>Zr-DFO-girentuximab) in clear cell renal cell carcinoma (ccRCC) (ClinicalTrials.gov Identifier: [NCT03849118](https://clinicaltrials.gov/ct2/show/study/NCT03849118)).

The results were featured in a late-breaking oral presentation delivered on Sunday, 30 April 2023 (CST) by Associate Professor Brian Shuch, MD, Director, Kidney Cancer Program, UCLA Institute of Urologic Oncology (Los Angeles, California) and a principal investigator in the Phase III ZIRCON study, at the American Urological Association's (AUA) Annual Meeting in Chicago.

New data presented demonstrates the high value of TLX250-CDx PET/CT imaging in detecting ccRCC, with secondary analysis confirming utility and effectiveness in very small renal masses, which are prevalent and present a significant diagnostic challenge.

In very small renal lesions ( $\leq 2$ cm, a secondary endpoint), sensitivity was 84% for all three readers, with specificity 92.3% to 100%. This reinforces the accuracy of this investigational diagnostic imaging agent across all analyses, with previously presented data showing an overall sensitivity and specificity of 86% and 87%, respectively.<sup>1,2</sup>

Dr Colin Hayward, Chief Medical Officer at Telix stated, "The excellent sensitivity and specificity for small lesions considerably expands the clinical utility and potentially the commercial opportunity for TLX250-CDx. We expect that the ability to diagnose even very small lesions as ccRCC will be an important factor in driving market adoption, subject to product approval."

Associate Professor Brian Shuch, MD commented, "It is a great pleasure to be showcasing new data from Telix's Phase III ZIRCON study at AUA, the largest gathering of urologists in the world. We now have analyses on the outcome for very small renal masses, where the data set still shows outstanding sensitivity and specificity, far exceeding confirmatory trial success targets. This data is meaningful for surgeons to help them improve management by aiding risk stratification, selecting appropriate patients for treatment or in those where further imaging/biopsy could be indicated."

Telix is in the process of implementing an expanded access program in the United States and establishing named patient programs for TLX250-CDx in Europe.

### **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

<sup>1</sup> Top line data released to ASX on 7 November 2022.

<sup>2</sup> Telix media release 20 February 2023.

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details and other publications that may be of interest. You can also follow Telix on [Twitter](#) (@TelixPharma) and [LinkedIn](#).

TLX250-CDx has not received a marketing authorisation in any jurisdiction. 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> and by Health Canada.<sup>5</sup> Telix is also progressing a marketing authorisation application for this investigational candidate in the United Kingdom.<sup>6</sup>

## 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.*

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

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

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

<sup>6</sup> Telix ASX disclosure 3 April 2023.