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**ASX RELEASE**

## **Chinese NMPA Approves Pivotal Phase III Study of TLX591-CDx for Prostate Cancer Imaging**

Melbourne (Australia) – 17 October 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 an investigational new drug (IND) application to commence a pivotal Phase III registration study of TLX591-CDx (Kit for the preparation of <sup>68</sup>Ga-PSMA-11), for the imaging of prostate cancer using Positron Emission Tomography (PET) that will bridge to the marketing authorisation granted to Illuccix® by the United States Food and Drug Administration (FDA).

The IND application was submitted in partnership with Grand Pharmaceutical Group Limited (Grand Pharma), Telix's partner in the Greater China region. The bridging study is required to provide data obtained in a Chinese population to establish that the diagnostic efficacy of TLX591-CDx is equivalent in Chinese and Western populations. This study will enrol up to 110 patients with suspected recurrent prostate cancer and is anticipated to commence in Q1 2023. Positive data from this Phase III bridging study will support a future marketing authorisation application for TLX591-CDx (Illuccix) in China.

Dr David N Cade, CEO Telix Asia Pacific, said "Each year 115,000 Chinese men will be diagnosed with prostate cancer, which makes it the most rapidly rising cancer in terms of incidence and mortality in China. PSMA PET imaging has the potential to profoundly impact the management of this disease, enabling clinicians to detect prostate cancer right throughout the body. This new imaging modality is already recognised in leading clinical practice guidelines, and is being adopted as a standard of care in many parts of the world. We look forward to working closely with our partner Grand Pharma to bring this important product to market in China, where there is currently unmet medical need."

### **About Prostate Cancer in China**

The Asia Pacific region comprises approximately one third of the world's male population and includes many nations whose populations are ageing or increasingly adopting a more affluent, "Western-style" lifestyle, the two main demographic trends driving increasing cancer incidence rates. Consequently, the incidence of prostate cancer is increasing in many parts of the region.

In China, 115,000 men are diagnosed with prostate cancer each year, increasing by approximately 6% each year.<sup>1</sup>

In line with government policy supporting wider geographic access to nuclear medicine, the number of PET/CT cameras installed in China is forecast to reach 1,110 by the end of 2022, compared with 133 in 2010.<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

<sup>1</sup> Ye Dingwei et al. *Lancet Oncology*, 2022.

<sup>2</sup> Goetz Partners research 2020.

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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-pharma).

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 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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*To the maximum extent permitted by law, Telix disclaims any obligation or undertaking to publicly update or revise any forward-looking statements contained in this announcement, whether as a result of new information, future developments or a change in expectations or assumptions.*

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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 14 October 2022.