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**ASX RELEASE** 

# <u>First Patient Dosed in Pivotal Phase III Study of TLX591-CDx (Illuccix®)</u> <u>for Prostate Cancer Imaging in Chinese Patients</u>

*Melbourne (Australia) – 11 August 2023.* Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that a first patient has been dosed in China in the pivotal Phase III registration study of TLX591-CDx (Illuccix<sup>®</sup>, Kit for the preparation of <sup>68</sup>Ga-PSMA-11), <sup>1</sup> for the imaging of prostate cancer using positron emission tomography (PET).

The Phase III Illuccix China study (ClinicalTrials.gov ID: NCT05847348) is a prospective, open-label, single-arm, multicenter study in Chinese patients with biochemically recurrent (BCR) prostate cancer that is intended to bridge to the marketing authorisation granted to Illuccix by the United States Food and Drug Administration (FDA). The study – a collaboration with Telix's strategic partner for the Greater China region, Grand Pharmaceutical Group Limited (Grand Pharma) – is required to establish that the diagnostic utility of TLX591-CDx is equivalent in Chinese and Western populations. This study will enrol up to 110 patients with BCR prostate cancer, and data will support a future marketing authorisation application for TLX591-CDx in China.

Dr Shams UL Arifeen, Regional Medical Director, Telix Asia Pacific said, "We are pleased to have commenced this study, which brings advanced PSMA-PET imaging<sup>2</sup> one step closer for Chinese men with prostate cancer. With our strategic collaborator in the region, Grand Pharma, we would like to express our gratitude to Dr Yong He, principal investigator at Zhongnan Hospital of Wuhan University as well as his clinical research team, and the patients who will contribute to this important study."

## **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>3</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 1,240 by the end of 2023, compared with 133 in 2010.<sup>4</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).

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<sup>&</sup>lt;sup>1</sup> For regulatory reasons, Telix refers to its <sup>68</sup>Ga-PSMA-11 kit as Illuccix in markets where it has received regulatory approval, and TLX591-CDx when referring to its use in both approved and unapproved markets. Registrations vary country to country. Always refer to local labelling.

<sup>&</sup>lt;sup>2</sup> Imaging of prostate-specific membrane antigen with positron emission tomography.

<sup>&</sup>lt;sup>3</sup> Ye Dingwei et al. Lancet Oncology, 2022.

<sup>&</sup>lt;sup>4</sup> Goetz Partners research 2020.

Visit <a href="www.telixpharma.com">www.telixpharma.com</a> 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 <a href="www.telixpharma">Twitter</a> (@TelixPharma) and <a href="www.telixpharma">LinkedIn</a>.

Telix's lead product, Illuccix<sup>®</sup> (TLX591-CDx), has been approved by the U.S. FDA,<sup>5</sup> by the Australian Therapeutic Goods Administration,<sup>6</sup> and by Health Canada.<sup>7</sup> Telix is also progressing marketing authorisation applications for this investigational candidate in the United Kingdom and the European Union.<sup>8</sup>

## **About Grand Pharmaceutical Group Limited**

Grand Pharma is an international pharmaceutical company of technological innovation. Its core businesses cover three major areas, namely pharmaceutical technology, nuclear medicine antitumour diagnosis and treatment and cerebro-cardiovascular precision interventional diagnosis and treatment technology and biotechnology. Based on the pharmaceutical and biological industries, Grand Pharma focuses on the needs of patients, and take technological innovation as the driving force. In response to the unmet clinical needs, Grand Pharma will increase its investment in global innovative products and advanced technologies, enrich and improve its product pipelines, consolidate and strengthen its industrial chain layout, and fully leverage Grand Pharma's industrial strengths and R&D capabilities to provide more advanced and diverse treatment solutions to patients worldwide.

#### **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>&</sup>lt;sup>5</sup> Telix ASX disclosure 20 December 2021.

<sup>&</sup>lt;sup>6</sup> Telix ASX disclosure 2 November 2021.

<sup>&</sup>lt;sup>7</sup> Telix ASX disclosure 14 October 2022.

<sup>&</sup>lt;sup>8</sup> Telix ASX disclosure 3 April 2023.

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