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ASX ANNOUNCEMENT

Telix Submits NDA for New Prostate Cancer Imaging Agent

Melbourne (Australia) – 27 May 2024. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces it has submitted a New Drug Application (NDA) to the United States (U.S.) Food and Drug Administration (FDA) for TLX007-CDx, a new and proprietary cold kit (“Kit”) for the preparation of PSMA-PET imaging¹ for prostate cancer.

Subject to regulatory approval, this Kit will enable use of a PSMA imaging product with a considerably extended distribution profile compared to currently approved gallium-68 (⁶⁸Ga) PSMA-PET imaging agents. The Kit’s innovative properties are designed to facilitate more flexible production, including with ⁶⁸Ga sourced from both newer high activity generators and cyclotrons powered by the ARTMS® QUANTM Irradiation System™² and GE FASTlab™³ solid and liquid target production system. The Company believes this will further expand the availability, distribution and scheduling flexibility of PSMA-PET imaging.

Despite the commercial availability of PSMA-PET imaging agents in the U.S., access is still severely limited for underserved patient demographics in many regions. This most notably impacts African Americans⁴ and Veterans⁵, who already experience much higher incidence rates of prostate cancer, including late-stage presentation, than the general population.

Telix’s new investigational prostate cancer imaging product is intended to address the unmet needs of patients, referrers and health care professionals, and expand patient reach using Telix’s established nuclear pharmacy distribution partnerships and industry-leading on-time reliability.

PSMA-PET imaging represents a major advancement in prostate cancer management and in the U.S. has replaced conventional imaging methods (bone scan, CT scan) as the standard of care after initial diagnosis and biochemical recurrence⁶. Despite this major medical advancement, only a relatively small fraction of the 3.4 million men living with prostate cancer in America have undergone a PSMA-PET imaging scan^{7,8}.

Mike Crosby, Founder and CEO Veterans Prostate Cancer Awareness (VPCa) stated, “Even in some of the most populous U.S. states, access to PSMA-PET imaging can be highly variable. Patients in rural areas of the country often bear the extra burden of long-distance travel, extended time off work, and increased out of pocket costs to access medical services. All of these factors contribute to ‘financial toxicity’ as well as challenges in accessing proper care commonly associated with cancer treatment. If approved by the FDA, this new product will have a significant impact on prostate cancer patients, physicians, and their caregivers by helping to eliminate the inequity of access to PSMA-PET agents, and increase the ability to accurately diagnose cancer early, reducing the cost of care, and increasing the probability of patients’ survival.”

Dr Christian Behrenbruch, Managing Director and Group CEO of Telix stated, “The scheduling flexibility and accessibility, along with the excellent clinical performance of ⁶⁸Ga-based PSMA-PET

¹ Imaging of prostate-specific membrane antigen with positron emission tomography.

² Telix ASX disclosure 11 April 2024. For further information visit: <https://www.artms.ca/>

³ FASTlab is a trademark of GE Healthcare and its affiliates.

⁴ Hinata N et al. *World J Mens Health*. 2022.

⁵ Zhu K et al. *Cancer Epidemiol Biomarkers Prev*. 2009.

⁶ NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.4.2024.

⁷ NIH Common Cancer Sites — [Cancer Stat Facts](#). Accessed May 2024.

⁸ Company analysis based on proprietary and public domain data.

imaging, has enabled Telix to drive rapid geographic expansion of PSMA-PET imaging with our first product Illuccix®. A core value of our Company is the commitment to improving access to medicine and delivering clinical utility that will benefit patients, very much reflected in the development of this exciting new product. We believe this is particularly important as demand for PSMA-PET imaging is forecast to grow significantly over the coming decade.”

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic radiopharmaceuticals and associated medical devices. 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 and commercial stage products that aims to address significant unmet medical needs in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX).

Telix’s lead imaging product, gallium-68 (⁶⁸Ga) gozetotide injection (also known as ⁶⁸Ga PSMA-11 and marketed under the brand name Illuccix®), has been approved by the U.S. Food and Drug Administration (FDA)⁹, by the Australian Therapeutic Goods Administration (TGA)¹⁰, and by Health Canada¹¹. No other Telix product has received a marketing authorisation in any jurisdiction.

Visit 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 [X](#) and [LinkedIn](#).

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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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⁹ Telix ASX disclosure 20 December 2021.

¹⁰ Telix ASX disclosure 2 November 2021.

¹¹ Telix ASX disclosure 14 October 2022.

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. You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the ASX or on our website.

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