Telix Pharmaceuticals Limited
ACN 616 620 369
55 Flemington Road
North Melbourne
Victoria, 3051
Australia

ASX ANNOUNCEMENT

FDA Accepts Telix NDA for New Prostate Cancer Imaging Agent

Melbourne (Australia) – 24 July 2024. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that the United States (U.S.) Food and Drug Administration (FDA) has accepted the filing of its New Drug Application (NDA) for TLX007-CDx, a new and proprietary cold kit ("Kit") for the preparation of PSMA-PET imaging[1] for prostate cancer. The PDUFA[2] goal date is March 24, 2025.

If approved, the new Kit will enable use of a PSMA imaging product with a considerably extended geographic distribution radius from a nuclear pharmacy compared to currently approved gallium-68 (^{68}Ga) based agents. Its innovative properties are designed to facilitate more flexible production, including with higher activity ^{68}Ga sourced from both newer high activity generators and cyclotrons powered by the ARTMS® QUANTM Irradiation System™[3] and GE FASTlab™[4] solid and liquid target production system. Through this NDA, Telix's objective is to further enhance patient access to PSMA-PET imaging and the clinical benefits of ^{68}Ga imaging to underserved populations across the U.S., 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 recurrence[5]. 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[6,7].

Dr Christian Behrenbruch, Managing Director and Group CEO of Telix stated, "We have seen rapid adoption and geographic expansion of PSMA-PET imaging with our first commercial product Illuccix®. This filing acceptance is an important step towards further improving equity of access and reinforcing our commitment to innovation in prostate cancer to continue to meet the needs of healthcare professionals and their patients. We now look forward to working with the FDA to bring TLX007-CDx to American men living with prostate cancer, including those residing in underserved communities and regions where access to state-of-the art imaging remains limited."

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of therapeutic and diagnostic 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).

[1] Imaging of prostate-specific membrane antigen with positron emission tomography.
[2] Prescription Drug User Fee Act.
[3] Telix ASX disclosure 11 April 2024. For further information visit: https://www.artms.ca/
[4] FASTlab is a trademark of GE Healthcare and its affiliates.
[5] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.4.2024.
[6] NIH Common Cancer Sites — Cancer Stat Facts. Accessed May 2024.
[7] Company analysis based on proprietary and public domain data.

Telix's lead imaging product, gallium-68 (^{68}Ga) gozetotide injection (also known as ^{68}Ga PSMA-11 and marketed under the brand name Illuccix®), has been approved by the FDA[8], by the Australian Therapeutic Goods Administration (TGA)[9], and by Health Canada[10]. 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.

Telix Investor Relations

Ms. Kyahn Williamson
Telix Pharmaceuticals Limited
SVP Investor Relations and Corporate Communications
Email: kyahn.williamson@telixpharma.com

This announcement has been authorised for release by the Telix Pharmaceuticals Limited Disclosure Committee on behalf of the Board.

[8] Telix ASX disclosure 20 December 2021.
[9] Telix ASX disclosure 2 November 2021.
[10] Telix ASX disclosure 14 October 2022.