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

ASX RELEASE

FDA Approves Expanded Indication for Telix's Illuccix® to Include Patient Selection for PSMA-Directed Radioligand Therapy

Melbourne (Australia) – 16 March 2023. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that the United States Food and Drug Administration (FDA) has approved a supplementary New Drug Application (sNDA) for Illuccix® (kit for the preparation of gallium Ga 68 gozetotide injection) to enable its use for the selection of patients with metastatic prostate cancer, for whom lutetium-177 (^{177}Lu) PSMA-directed therapy is indicated.[1]

The label expansion means Illuccix is now approved in the U.S. to identify and select patients who are candidates for the only FDA-approved prostate-specific membrane antigen (PSMA)- directed radioligand therapy (Pluvicto®), [2] providing doctors with critical information to guide patient management and help optimise treatment outcomes. To qualify for radioligand therapy, patients must be imaged with an approved gallium-based PSMA-PET agent.[3]

As the only diagnostic agent for prostate cancer that combines the accuracy of gallium imaging with the reliability and flexibility of Telix's distribution network, the expanded indication for Illuccix has the potential to improve access to imaging for patients who are candidates for radioligand therapy.

Kevin Richardson, Chief Executive Officer for Telix Americas said, "We welcome the FDA's decision to expand the label indication for Illuccix. This additional indication further demonstrates our continued commitment to support patients fighting prostate cancer and to empower the doctors who treat them. Clinicians now have the ability to use Illuccix in more stages of the patient journey, to confidently and accurately detect and help manage this disease."

Use of Illuccix in the VISION Phase III study (ClinicalTrials.gov Identifier: NCT03511664)[4] helped doctors detect prostate cancer and identify the appropriate patients for PSMA-based radioligand therapy. Telix wishes to acknowledge collaboration with Novartis to deliver this outcome to patients.

Dr Oliver Sartor, Medical Director at Tulane Cancer Center, added, "As radioligand therapy for prostate cancer becomes more prevalent, it is critical for doctors to understand who may or may not respond to those treatments. There's no doubt that appropriate selection of patients for PSMA targeted radioligand therapy is dependent on appropriate imaging. Ga-68 PSMA-11 PET was used in the VISION trial and, when used in combination with contrast-enhanced CT, represents a powerful tool for detecting prostate cancer and helping manage patients."

It is estimated that 32,000 patients per year in the U.S. may be considered for PSMA-directed radioligand therapy.[5]

[1] Specifically, lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy.
[2] Pluvicto® is a registered trademark of Novartis AG and/or its affiliates.
[3] Per the Pluvicto® package insert.
[4] VISION study sponsored by Endocyte, a Novartis company. Telix provided Illuccix (TLX591-CDx) for ^{68}Ga-PSMA-11 Positron Emission Tomography (PET)/Computed Tomography (CT) imaging.
[5] American Cancer Society (ACS). Key Statistics for Prostate Cancer | Prostate Cancer Facts. 2023.

About Illuccix

Illuccix is a kit for the preparation of gallium-68 (68Ga) gozetotide (also known as PSMA-11) injection, a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in patients with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy;
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level;
- for whom lutetium Lu 177 vipivotide tetraxetan PSMA-directed therapy is indicated.

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). For more information visit www.telixpharma.com and follow Telix on Twitter (@TelixPharma) and LinkedIn.

Telix's lead product, Illuccix, has been approved by the FDA,[6] and by the Australian Therapeutic Goods Administration (TGA),[7] and by Health Canada.[8]

Telix Investor Relations

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

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

[6] ASX disclosure 20 December 2021.
[7] ASX disclosure 2 November 2021.
[8] ASX disclosure 14 October 2022.

Except as required by applicable laws or regulations, Telix does not undertake to publicly update or review any forward-looking statements. Past performance cannot be relied on as a guide to future performance. Readers should read this announcement together with our material risks, as disclosed in our most recently filed reports with the ASX and on our website.