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ASX RELEASE

Australian TGA Approves Illuccix® for Prostate Cancer Imaging

Melbourne (Australia) – 02 November 2021. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that the Australian Therapeutic Goods Administration (TGA) has approved Illuccix® (TLX591-CDx), the Company's lead prostate cancer imaging product.

Illuccix (Kit for the preparation of ^{68}Ga PSMA-11 Injection) is a positron emission tomography (PET) agent for the diagnostic imaging of men with prostate cancer. The TGA has granted Illuccix a broad clinical indication comprising:

1. Patients with prostate cancer who are at risk of metastasis and who are suitable for initial definitive therapy (also known as "primary staging"), and

2. Patients with prostate cancer who have suspected recurrence based on elevated serum prostate specific antigen (PSA) level (also known as "biochemical recurrence").

Illuccix, after radiolabeling with gallium-68, is the first commercially approved PSMA-PET imaging agent available in Australia. The TGA approval of Illuccix facilitates wide-spread clinical access to prostate cancer imaging for all men across Australia including rural and regional areas, enabling availability of state-of-the-art PSMA PET imaging across the country.

Telix President APAC Dr. David Cade stated, "The approval of Illuccix means Australian patients with prostate cancer will have broad access to a TGA-approved PSMA-PET imaging agent. This new mode of imaging has been recognised in leading clinical practice guidelines as superior to conventional imaging with CT[1] or MRI[2], for the staging of prostate cancer. Illuccix attaches to prostate cancer cells expressing PSMA and can be picked up by a PET scanner, giving physicians the ability to visualise tumour cells, including very small metastases, wherever they are in the body."

Telix CEO Dr. Christian Behrenbruch added, "PSMA-PET imaging has been one of the most important developments in prostate cancer management in recent years. As an Australian company, we are especially pleased to be delivering the first TGA-approved, GMP manufactured PSMA-PET imaging agent that will be widely available to Australian patients. The TGA is a sophisticated regulatory authority that is highly regarded in the Asia Pacific region. This approval is an important milestone for Telix, demonstrating the approvability of Illuccix and establishing a blueprint for a series of near-term regulatory submissions and reviews in other important markets across the Asia Pacific."

About Illuccix®

Illuccix (TLX591-CDx) is a preparation for imaging prostate cancer with positron emission tomography (PET), targeting prostate specific membrane antigen (PSMA), a protein that is overexpressed on the surface of more than 90% of primary and metastatic prostate cancer cells. Illuccix enables PSMA-11 to be labelled with the radionuclide Ga-68 directly before injection by medical professionals. After preparing the radiopharmaceutical and injecting it into the patient, PSMA positive lesions are localised by PET imaging.

[1] Computed Tomography
[2] Magnetic Resonance Imaging

Telix's lead investigational product, Illuccix (TLX591-CDx) for prostate cancer imaging has been approved by Australian Therapeutic Goods Administration (TGA).[3] Telix is also progressing marketing authorisation applications for Illuccix in the USA,[4] European Union[5] and Canada.[6]

About Prostate Cancer

Together with the United States and Canada, Australia has one of the highest rates of prostate cancer in the world. In 2020, prostate cancer was the most commonly diagnosed cancer in men in Australia with approximately 17,000 new cases. Prostate cancer was also the second most common cause of cancer death in men (after lung cancer), with almost 3,500 men dying from their disease in 2020 in Australia. More than 70,000 men in Australia were estimated to be living with prostate cancer in 2020.[7]

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development of diagnostic and therapeutic products using Molecularly Targeted Radiation (MTR). Telix is headquartered in Melbourne, Australia with international operations in Belgium, Switzerland, Japan, and the United States. Telix is developing a portfolio of clinical-stage products that 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.

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[3] ASX disclosure 14/04/21.
[4] ASX disclosure 24/11/20.
[5] ASX disclosure 01/05/20.
[6] ASX disclosure 16/12/20.
[7] Globocan 2021.