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FDA Approves Phase II Kidney Cancer Therapy Study

Melbourne (Australia) and Indianapolis, IN (U.S.A.) – 14 September 2021. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that the United States Food and Drug Administration (FDA) has accepted the Investigational New Drug Application ("IND") to undertake a clinical study of the Company's investigational kidney cancer therapy, TLX250 (^{177}Lu-DOTA-girentuximab).

The STARLITE 2 study is a single arm, investigator-led Phase II study in patients with advanced clear cell renal cell carcinoma (ccRCC), the most common and aggressive form of kidney cancer. TLX250 targets carbonic anhydrase IX (CA9), a protein that is highly expressed in patients that are likely to demonstrate a more limited response to cancer immunotherapy.[1] The study will evaluate TLX250-delivered radiation as an immune system "primer" in combination with the anti-PD-1[2] immunotherapy Opdivo®[3] (nivolumab). The primary endpoint is to determine the efficacy of combining immunotherapy with TLX250 as assessed by the number of tumours responding to the Telix therapy versus the current standard of care alone. The study is expected to enrol 29 patients.

Principal Investigator for the STARLITE 2 study, Darren R. Feldman, MD, Medical Oncologist at Memorial Sloan Kettering Cancer Center (MSK) in New York said, "Each year 76,000 Americans will be diagnosed with kidney cancer[4], therefore it is important we continue to explore new treatment options. The selective targeting of TLX250 to CA9 delivers radiation therapy directly to ccRCC tumours. Combining this innovative approach with anti-PD-1/PD-L1 therapy could enhance existing immune-based treatments."

Telix Chief Medical Officer, Dr. Colin Hayward added, "The introduction of immunotherapy agents has improved the outlook for patients with advanced clear cell renal cancer, but most patients eventually progress. This therapy, along with patient selection and treatment response assessment with our CA9-targeting imaging agent TLX250-CDx may potentially offer a new paradigm of more accurate staging and personalised treatment for kidney cancer patients through a "theranostic" approach."

Disclosure: MSK has institutional financial interests related to Telix.

About TLX250

TLX250 (^{177}Lu-DOTA-girentuximab) is an antibody-based therapeutic platform that targets carbonic anhydrase IX (CA9), a cell surface protein that is highly expressed in several human cancers including ccRCC. High CAIX tumour expression is generally correlated with poor prognosis. Telix's companion investigational diagnostic imaging agent TLX250-CDx (^{89}Zr-DFO-girentuximab) is currently the subject of a global Phase III trial (ZIRCON trial, NCT03849118).

[1] Giatromanolaki et al. *British Journal of Cancer*. 2020.
[2] Programmed cell death protein 1
[3] Opdivo® is a registered trade mark of Bristol Myers Squibb
[4] American Cancer Society, 2021

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, 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.

Telix's lead investigational product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been accepted for filing by the U.S. FDA,[5] and is under priority evaluation by the Australian Therapeutic Goods Administration (TGA).[6] Telix is also progressing marketing authorisation applications for Illuccix® in the European Union[7] and Canada.[8] None of Telix's products have received a marketing authorisation in any jurisdiction.

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[5] ASX disclosure 24/11/20.
[6] ASX disclosure 14/04/21.
[7] ASX disclosure 1/05/20.
[8] ASX disclosure 16/12/20.