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ASX RELEASE

ZIRCON Phase III Kidney Cancer Imaging Study Completes Enrolment

Melbourne (Australia) – 11 July 2022. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that it has dosed the final patient and completed recruitment into the Phase III pivotal study ZIRCON (Zirconium in Renal Cancer Oncology, NCT03849118) of its investigational renal (kidney) cancer imaging agent TLX250-CDx (^{89}Zr-DFO-girentuximab). This global study has dosed 300 patients to date, exceeding the target enrolment of 252 patients, announced on 8 March 2022.

TLX250-CDx, which has received "Breakthrough Designation" from the U.S. Food and Drug Administration (FDA)[1], is being developed as an imaging agent for use in the characterization of indeterminate renal masses previously identified on computed tomography (CT) or magnetic resonance imaging (MRI) as clear cell renal cell cancer (ccRCC) or non-ccRCC.

The detection of renal masses is increasing due to widespread use of cross-sectional imaging. Many of these are small renal masses and represent a diagnostic challenge as current imaging cannot reliably distinguish benign or malignant lesions from renal cell carcinoma, leading to invasive biopsy or partial nephrectomy to confirm the diagnosis. These procedures are not always necessary and can lead to complications[2]. It is estimated that up to 80% of small renal masses are malignant[3].

If the study is successful, TLX250-CDx may provide a non-invasive method to aid in diagnosis and staging of ccRCC and the identification of metastatic disease through whole body imaging, ultimately leading to improved patient management by minimizing the need for surgical intervention for diagnosis and guiding treatment decisions.

In addition to its potential use as a diagnostic and staging tool, Telix is considering the potential for TLX250-CDx to also be used as an active surveillance tool for patients not deemed surgical candidates.

Brian M Shuch, MD, Director of the Kidney Cancer program at UCLA said: "We may well be on the cusp of a paradigm shift in how we manage renal masses. The incidence of small renal masses is increasing, yet there is currently no imaging tool that can effectively diagnose or stage clear cell renal cancer. Most patients are scheduled for the operating room without a firm diagnosis and often surgery is found to be unnecessary. Should this study report positive results, it may provide the non-invasive imaging tool to aid in accurate diagnosis that patients and clinicians have been waiting for. Congratulations to Telix for completing this ambitious international trial."

Renal cell carcinoma (RCC) is the deadliest of all urological cancers with a late-stage 5-year survival rate of 14%[4]. ccRCC is the most common sub-type and accounts for approximately 80% of all renal cell carcinoma cases[5]. RCC is also an increasingly frequent cancer, having more than doubled in incidence in the developed world over the last 50 years.[6] Worldwide, there were more than 400,000

[1] Telix ASX disclosure 1 July 2020.
[2] Amir H. Khandani, MD*‡ and W. Kimryn Rathmell, MD, PhD†‡ Positron Emission Tomography in Renal Cell Carcinoma: An Imaging Biomarker in Development. Semin Nucl Med. 2012 Jul; 42(4): 221–230.
[3] Rothman J, Egleston B, Wong YN, Iffrig K, Lebovitch S, Uzzo RG. Histopathological characteristics of localized renal cell carcinoma correlate with tumor size: a SEER analysis. The Journal of urology. 2009;181:29–33. discussion 33-24.
[4] https://www.cancer.org/cancer/kidney-cancer/detection-diagnosis-staging/survival-rates.html
[5] Source: National Cancer Institute
[6] Padala et al, World Journal of Oncology, 2020

new cases in 2020, and >175,000 people died from their disease.[7]

TLX250-CDx will be available in selected countries to eligible patients under an Expanded Access Program (EAP) (also known as early access, pre-approval access or emergency use), in accordance with Telix's Compassionate Use Policy and subject to jurisdictional regulatory requirements.[8]

Dr Colin Hayward, Telix's Chief Medical Officer said, "The completion of this trial will bring us a step closer to commercialization for this diagnostic imaging agent which may address a significant unmet need in the diagnosis and management of ccRCC. It also builds on Telix's commitment to urologic oncology, with the potential of delivering a major new imaging indication. This milestone could have not been achieved without the support of our many collaborators including the 36 clinical sites who participated in the trial, our global manufacturing teams and the associated auxiliary team who have supported this study. Most of all we wish to thank the patients who have volunteered to participate in this study."

ZIRCON is a confirmatory, prospective, open-label, multi-centre phase III study to evaluate sensitivity and specificity of ^{89}Zr-TLX250-CDx PET/CT imaging to non-invasively detect clear cell renal cell cancer (ccRCC) in adult patients with indeterminate renal masses (IDRM), scheduled for partial or total nephrectomy. Telix expects to report the outcome from the ZIRCON study in 2H, 2022.

About TLX250-CDx

TLX250-CDx (^{89}Zr-girentuximab) is an investigational product being developed by Telix for the purpose of non-invasive detection of clear cell renal cancer in patients with "indeterminate renal masses" (IDRMs) are, typically identified based on CT or MRI imaging and are an increasing medical dilemma as more scans are performed and more IDRMs are identified. Girentuximab is a monoclonal antibody that targets carbonic anhydrase IX (CAIX), a cell surface target that is highly expressed in several human cancers including renal, lung and oesophageal cancers. In July 2020, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy (BT) designation for TLX250-CDx, reflecting the significant unmet clinical need to improve the characterization of indeterminate renal masses previously identified on CT or MRI as ccRCC or non-ccRCC. ccRCC is the most common and aggressive form of kidney cancer.

About the ZIRCON Study

ZIRCON (Zirconium Imaging in Renal Cancer Oncology, NCT03849118) is an international multicentre Phase III study at 34 sites in Europe, Australia, Turkey, Canada and the United States. ZIRCON is a prospective imaging trial in renal cancer patients undergoing kidney surgery with the objective of determining the sensitivity and specificity of TLX250-CDx PET imaging to detect clear cell renal cell cancer (ccRCC) in comparison with histologic "standard of truth" determined from surgical resection specimens**.**

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic products using Molecularly Targeted Radiation (MTR). Telix is headquartered in Melbourne, Australia with international operations in Belgium, Japan, Switzerland, 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.

[7] World Health Organisation, 2020

[8] https://telixpharma.com/wp-content/uploads/Policy-on-Offering-Compassionate-Use-to-Investigational-Medicines.pdf

Telix's lead product, gallium-68 (^{68}Ga) gozetotide (also known as ^{68}Ga PSMA-11) injection, has been approved by the U.S. Food and Drug Administration (FDA),[9] and by the Australian Therapeutic Goods Administration (TGA).[10] Telix is also progressing marketing authorisation applications for this investigational candidate in Europe[11] and Canada.[12]

Telix Investor Relations

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This announcement has been authorised for release by Dr. Christian Behrenbruch, Managing Director and Group Chief Executive Officer.

[9] ASX disclosure 20 December 2021.
[10] ASX disclosure 2 November 2021.
[11] ASX disclosure 10 December 2021.
[12] ASX disclosure 16 December 2020.