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ZIRCON Phase 3 Renal Cancer Imaging Study: Progress Update

Melbourne (Australia) – 20th July 2021. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today provides an update on the progress of the ZIRCON Phase 3 study for the imaging of renal cancer with Positron Emission Tomography (PET).

Key Points:

- ZIRCON is a Phase 3 pivotal study of ^{89}Zr-DFO-girentuximab (TLX250-CDx), an investigational product for the imaging of clear cell renal cancer with PET
- ZIRCON is being actively recruited at 34 sites in the EU, Turkey, Australia, US and Canada
- Study has exceeded 50% recruitment with a total planned recruitment of 252 patients
- Recruitment hiatus due to COVID-19 has abated in most study territories with an increasingly predictable rate of patient enrolment into the study
- Indicative recruitment rate (globally) is between 5 and 10 patients / week
- TLX250-CDx has been granted FDA Breakthrough Therapy designation in the United States, which could potentially grant it an expedited review process.

ZIRCON is a 252 patient Phase 3 pivotal study, currently being conducted at 34 sites globally. The study has exceeded 50% recruitment despite significantly reduced recruitment over the last 12 months due to a pandemic operating environment. With at least 80% of sites in the study back recruiting into clinical trials, recruitment has significantly accelerated and indicative patient recruitment is 5-10 patients per week.

TLX250-CDx drug product for the ZIRCON trial is provided from Telix's manufacturing and dispensing sites in Canada, United States, Turkey and the Netherlands. Transportation and logistics have also largely enabled a resumption to normal drug product delivery schedules, including to Australia. The company expects the trial to complete recruitment in the next 4-5 months, subject to ongoing pandemic conditions. Telix expects to commence the FDA Biologics License Application (BLA) consultation process before end-calendar year, as planned. A Japanese bridging study to ZIRCON has also been successfully completed.

Telix Chief Medical Officer Dr Colin Hayward noted, "It's very pleasing to see the acceleration in the ZIRCON trial, having exceeded the half-way point of the study and a resumption to somewhat more normal clinical operating conditions. The feedback we are receiving from investigators is very positive and the company remains on track to achieve its stated objective of completing the trial this year, thus progressing a second FDA marketing authorisation submission after the Illuccix® prostate cancer imaging program."

Dr Brian Shuch, Director of the UCLA Kidney Cancer Program and the Alvin & Carrie Meinhardt Endowed Chair in Kidney Cancer Research added, "Having an imaging agent that will predict clear cell kidney cancer prior to treatment will likely spare unnecessary biopsies and limit unnecessary surgeries. Furthermore, we hope that future studies will show this technology will improve our ability to accurately stage kidney cancer and perhaps allow better selection of patients for adjuvant therapy."

Telix Chief Executive Officer Dr Christian Behrenbruch commented, "TLX250-CDx reinforces Telix's innovation leadership position in urologic oncology and it's exciting to see a second product heading down the final pathway towards commercialisation. Our clinical team and CROs have had to work extremely creatively to maintain the momentum of the study and we are grateful to our global

investigators and patients, who have gone above and beyond to ensure the success of the study."

About TLX250-CDx

TLX250-CDx (^{89}Zr-girentuximab) is an investigational product being developed by Telix for the purpose of determining whether "indeterminate renal masses", typically identified based on CT or MRI imaging, are either clear cell renal cell cancer (ccRCC) or non-ccRCC, using Positron Emission Tomography (PET) imaging. 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[1] for TLX250-CDx, reflecting the significant unmet clinical need to improve the diagnosis and staging of ccRCC, the most common and aggressive form of kidney cancer.

About the ZIRCON Study

ZIRCON (Zirconium Imaging in Renal Cancer Oncology, NCT03849118) is an international multi-centre Phase 3 study at 34 sites in Europe, Australia, Turkey, Canada and the United States (subject to regulatory approval in the various jurisdictions). ZIRCON is a prospective imaging trial in approximately 250 renal cancer patients undergoing kidney surgery, to determine 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 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,[2] and is under priority evaluation by the Australian Therapeutic Goods Administration (TGA).[3] Telix is also progressing marketing authorisation applications for Illuccix® in the European Union[4] and Canada.[5] None of Telix's products have received a marketing authorisation in any jurisdiction.

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[1] ASX disclosure 1/07/20.
[2] ASX disclosure 24/11/20.
[3] ASX disclosure 14/04/21.
[4] ASX disclosure 1/05/20.
[5] ASX disclosure 16/12/20.

Securities Act is available. None of the technologies or products described in this document have received a marketing authorisation in any jurisdiction. This announcement has been authorised for release by Dr Christian Behrenbruch, Managing Director and Chief Executive Officer.