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Japanese Renal Cancer Imaging Trial Meets Study Objectives

Melbourne (Australia) and Kyoto (Japan) – 21 April 2021. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that the Phase I component of the Company's Phase I/II 'ZIRDAC-JP' clinical study of its renal cancer imaging product has reported results and met the study objectives, demonstrating safety and tolerability of TLX250-CDx (^{89}Zr-girentuximab) in Japanese patients.

The ZIRDAC-JP study (Zirconium Dosing and Comparison in Japan) is a Japanese Phase I/II study to evaluate the safety, tolerability, radiation dosimetry and pharmacokinetics of TLX250-CDx in Japanese patients.[1] The Phase I component of the ZIRDAC-JP study was conducted at Yokohama City University Hospital in Yokohama, Japan and all data were reviewed by the study's independent Data and Safety Monitoring Board (DSMB). In total, six patients with an indeterminate renal mass identified on pre-study CT or MRI imaging were enrolled from August to November 2020. All patients underwent dosing with TLX250-CDx followed by multi-timepoint positron emission tomography (PET) imaging. All enrolled patients completed the study.

No adverse events (AEs) or serious adverse events (SAEs) were observed in any of the study patients. The whole-body and organ-specific radiation dosimetry of TLX250-CDx demonstrated no difference between Japanese and Caucasian patient populations. The pharmacology of TLX250-CDx in Japanese patients was comparable to that of previous studies reported in other patient ethnic groups.[2]

Telix Chief Medical Officer Dr. Colin Hayward stated, "We are highly encouraged by both the safety and tolerability profile, as well as the comparability of the dosing and pharmacology of TLX250-CDx between Japanese and Caucasian patient populations. We now plan to consult with the Japanese regulator to confirm the design of the next stage of development for TLX250-CDx, with the objective of bridging to Telix's international Phase III ZIRCON study, currently enrolling patients at 36 sites globally. We wish to express our appreciation to the study's principal investigator at Yokohama City University Hospital, Dr. Nakaigawa, his research team and the patients who participated in this study."

About the ZIRDAC-JP Study

ZIRDAC-JP (Zirconium Dosing and Comparison in Japan, NCT04496089) is a Japanese clinical study to determine the safety, tolerability, radiation dosimetry and pharmacokinetics / pharmacodynamics (Phase I), and the sensitivity and specificity of TLX250-CDx PET imaging to detect clear cell renal cell cancer (ccRCC) (Phase II).

About Telix Pharmaceuticals Limited

Telix is a clinical-stage 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 needs 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.

[1] ClinicalTrials.Gov Identifier: NCT04496089.
[2] Merkx RIJ *et al.* Eur J Nucl Med Mol Imaging 2021.

Telix's lead investigational product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been accepted for filing by the U.S. FDA,[3] and is under priority evaluation by the Australian Therapeutic Goods Administration (TGA).[4] Telix is also progressing marketing authorisation applications for Illuccix® in the European Union[5] and Canada.[6] None of Telix's products have received a marketing authorisation in any jurisdiction.

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