

Telix Announces Positive Topline Results of ZIRCON Phase III Kidney Cancer Imaging Study

Summary of Study Outcomes

- ZIRCON Phase III study of Telix's investigational imaging agent TLX250-CDx in clear cell renal cell carcinoma (ccRCC) has met all of its primary and secondary endpoints
- The study delivered co-primary endpoints of 86% sensitivity and 87% specificity and 93% positive predictive value (secondary endpoint) considerably exceeding sensitivity and specificity targets
- These ground-breaking results indicate that TLX250-CDx has the potential to become a new clinical standard in the diagnosis of ccRCC and deliver an unmet medical need for a non-invasive diagnostic tool in this disease setting
- Based on these positive results, Telix will progress towards a Biologics License Application (BLA) filing with the U.S. Food and Drug Administration (FDA) and worldwide regulatory filings in key commercial jurisdictions

Melbourne (Australia) – 7 November 2022. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces highly positive top-line results from the pivotal Phase III ZIRCON study (Zirconium in Renal Cancer Oncology, [NCT03849118](#)) of its investigational renal (kidney) cancer positron emission tomography (PET) imaging agent, TLX250-CDx (⁸⁹Zr-DFO-girentuximab). The study has met its co-primary and secondary endpoints.

The study results delivered 86% sensitivity and 87% specificity, exceeding the pre-determined threshold required to demonstrate the ability of TLX250-CDx to reliably detect the clear cell phenotype and provide a non-invasive method of diagnosing the presence and spread of ccRCC. The study has also met the key secondary endpoint, achieving 85% sensitivity and 89% specificity in detecting ccRCC in tumours <4cm ("T1a" classification), currently a significant clinical challenge in the diagnosis of ccRCC.

A total of 300 patients were dosed with TLX250-CDx resulting in 284 evaluable patients. Each patient received a single dose of TLX250-CDx and a histological tumour sample from surgical resection was used as the truth comparator.

The results mean that, for the first time, urologists and urologic oncologists may have a non-invasive way to determine if small renal masses are the clear cell phenotype, the most aggressive and common form of renal malignancy. TLX250-CDx has received "Breakthrough Designation" from the FDA.¹

¹ Telix ASX disclosure 1 July 2020.

Investigators in the ZIRCON study commented:²

A/Prof Brian Shuch, MD, Director, Kidney Cancer Program, UCLA Institute of Urologic Oncology (Los Angeles, California) said, “The positive result from the study is a critical step in better diagnosing clear cell renal cancer. Having an imaging product like TLX250-CDx will be so important in managing the continued increase in incidence of small renal masses and reducing the need for unnecessary invasive surgery for lesions that in the prior era were often found to be benign at the time of surgery.”

Mr Gregory Jack, F.R.A.C.S., General Urological Surgeon Austin Health and Olivia Newton John Cancer Centre (Melbourne, Australia) added, “Kidney cancer is a diagnostic dilemma for the majority of our patients. Without biopsy or surgery, we can’t currently give them the information they need. Based on this result from the ZIRCON Phase III study, TLX250-CDx may help us to be more accurate in who we treat, whilst also providing reassurance for those patients who don’t need treatment.”

Professor Françoise Kraeber-Bodéré, MD, PhD, Nuclear Medicine Department - CHU Nantes (Nantes, France), said, “Results from the Phase III ZIRCON study of TLX250-CDx should represent a major milestone in the management of small renal lesions and the diagnosis of clear cell renal cell carcinoma. There is so much potential in optimal targeting of CAIX, paving the way for better staging of this neoplasia and a theranostic approach.”

Based on these outstanding results Telix intends to file a BLA for regulatory approval with the FDA and global regulatory agencies as a positron emission tomography/computed tomography (PET/CT) imaging agent for use in the characterisation of indeterminate renal masses previously identified on CT or MRI as ccRCC or non-ccRCC. Potential future utility may include active surveillance, surgical staging and treatment response assessment and the Company is actively engaged in clinical research at leading cancer centres to demonstrate the potential of these indications.

Dr Colin Hayward, Chief Medical Officer at Telix said: “The excellent sensitivity and specificity demonstrated in the ZIRCON study, validates that the CAIX target could be just as ground-breaking in ccRCC as PSMA³ and its application in PSMA-PET imaging has been for prostate cancer. It could optimise surgical intervention – particularly in the incidence of very small renal masses. These results provide confidence that TLX250-CDx is an important tool not only for initial diagnosis but potentially also for active surveillance and disease staging.”

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic radiopharmaceuticals. Telix is headquartered in Melbourne, Australia with international operations in the United States, Europe (Belgium and Switzerland), and Japan. Telix is developing a portfolio of clinical-stage products that aims to 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](https://twitter.com/TelixPharma) (@TelixPharma) and [LinkedIn](https://www.linkedin.com/company/telix-pharmaceuticals).

² Independent study investigator views and opinions.

³ Prostate specific membrane antigen, positron emission tomography.

TLX250-CDx has not received a marketing authorisation in any jurisdiction. Telix's lead product, gallium-68 (⁶⁸Ga) gozetotide (also known as ⁶⁸Ga PSMA-11) injection, has been approved by the U.S. Food and Drug Administration (FDA),⁴ the Australian Therapeutic Goods Administration (TGA)⁵ and by Health Canada.⁶

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This announcement has been authorised for release by the disclosure committee of Telix Pharmaceuticals Limited.

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⁴ ASX disclosure 20 December 2021.

⁵ ASX disclosure 2 November 2021.

⁶ ASX disclosure 14 October 2022.