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First US Patients Dosed in Phase III ZIRCON Trial of Renal Cancer Imaging Product

Melbourne (Australia) and Indianapolis, IN (U.S.A.) – 25th January 2021. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today announces that the first patients have been dosed in the Phase III ZIRCON[1] clinical trial of Telix's renal cancer diagnostic imaging product TLX250-CDx (^{89}Zr-girentuximab) in the United States.

The objective of the ZIRCON trial is to evaluate the sensitivity and specificity of PET/CT imaging with TLX250-CDx to non-invasively detect clear cell renal cell carcinoma (ccRCC) in patients with indeterminate renal masses in comparison with surgical resection (histology), as the standard of truth.

The ZIRCON trial, which includes twelve participating clinical study sites across the U.S. and Canada, initiated patient recruitment in U.S. on Friday, with the first patients being dosed with TLX250-CDx at University of California, Los Angeles (UCLA), and Seattle Cancer Care Alliance, University of Washington, Seattle (SCCA). The remaining seven U.S. sites[2] and three sites[3] in Canada are expected to commence patient recruitment progressively over the next month.

Telix Chief Medical Officer, Dr. Colin Hayward, stated, "We are pleased to have commenced the Phase III ZIRCON clinical trial in North America and wish to express our gratitude to Prof. Allan Pantuck and Dr. Delphine Chen, principal investigators at UCLA and SCCA, respectively, as well as their clinical research teams and patients, who have made this important milestone possible."

About the ZIRCON Study

ZIRCON ("Zirconium Imaging in Renal Cancer Oncology") is an international multi-centre Phase III study at 36 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 "ground truth" determined from surgical resection specimens.

About TLX250-CDx

TLX250-CDx (^{89}Zr-girentuximab) is 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 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.

[1] ClinicalTrials.Gov Identifier: NCT03849118.
[2] City of Hope, Duarte California; Advanced Molecular Imaging and Therapy, Maryland; Barbara Ann Karmanos Cancer Hospital, Detroit;; Emory University, Atlanta Georgia; John Hopkins, Baltimore; Washington University, St Louis; Memorial Sloan Kettering, New York City.
[3] Sir Mortimer B. Davis Jewish General Hospital, Montreal; CHU de Québec-Université Laval, Quebec City; Centre de Recherche du Centre Hospitalier de l'Université de Montréal, Montreal.

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, please follow Telix on Twitter @TelixPharma and LinkedIn, and visit www.telixpharma.com.

Telix's lead product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been accepted for filing by the U.S. FDA[4], and has been granted Priority Review status by the Therapeutic Goods Administration (TGA) in Australia.[5] Telix is also progressing marketing authorisation applications for Illuccix® in the European Union[6] and Canada.[7] None of Telix's products have currently received a marketing authorisation in any jurisdiction.

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[4] ASX release 24th November 2020.
[5] ASX release 7th December 2020.
[6] ASX release 1st May 2020.
[7] ASX release 16th December 2020.