Title: First Australian Patient Dosed in ZIRCON Phase III Trial

Date: 20th August 2019

Program relevance: TLX250-CDx (^{89}Zr-girentuximab) for the imaging of renal cancer with positron emission tomography (PET)

Synopsis:

TLX250-CDx (^{89}Zr-girentuximab) is being developed by Telix to non-invasively image patients with indeterminate renal (kidney) masses using positron emission tomography (PET) imaging. Current diagnostic practice involves the use of MRI or CT scans, which are less sensitive and specific, particularly for clear cell renal cell carcinoma (ccRCC), the most common variant of kidney cancer. Other diagnostic methods include the use of ultrasound guided kidney biopsy, which carries a higher risk of procedure complication and generally under-stages patients.

TLX250-CDx images the target carbonic anhydrase IX (CAIX), a target that is highly expressed by ccRCC. In a prior phase III study (REDECT[1]) the imaging of CAIX with girentuximab was shown to have diagnostic equivalence to biopsy with the added advantage of being able to detect metastatic disease. ZIRCON is a pivotal study to confirm the sensitivity and specificity of TLX250-CDx.

Key Points for Investors:

- The first Australian patient was dosed with TLX250-CDx at Olivia Newton John Cancer and Wellness Centre (Austin Health) on 20th August 2019, as part of the international ZIRCON (Zirconium Imaging in Renal Cancer Oncology) study.
- The ZIRCON study is a confirmatory, prospective, open-label, multi-centre phase III study to evaluate sensitivity and specificity of PET/CT imaging to non-invasively detect clear cell renal cell cancer (ccRCC) in adult patients with indeterminate renal masses (IRM), scheduled for partial or total nephrectomy.
- The ZIRCON study is recruiting and currently has regulatory approval in Australia, Netherlands, United Kingdom, France and Turkey, with Belgium and Spain expected shortly.
- Additionally, Telix is preparing CTN/IND submissions for Canada and the US (on the back of a successful pre-Phase III meeting with the FDA (ASX release 15/07/2019) and expects to be able to include North American patients by year-end (subject to regulatory approvals).

[1] Divgi CR et al. *J Clin Oncol* 2013 (https://www.ncbi.nlm.nih.gov/pubmed/23213092)

First Australian Patient Dosed in ZIRCON Phase III Trial

Melbourne (Australia) – 20th August 2019. Telix Pharmaceuticals Limited (ASX.TLX) ("Telix", the "Company"), a clinical-stage biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or "molecularly-targeted radiation" (MTR) has today announced that the first Australian patient has been added to the Phase III ZIRCON study.

The objective of the ZIRCON study is to evaluate sensitivity and specificity of PET/CT imaging with TLX250-CDx (^{89}Zr-girentuximab) to non-invasively detect clear cell renal cell cancer (ccRCC) in patients with indeterminate renal masses in comparison with surgical resection (histology) as standard of truth.

Telix Pharmaceuticals CEO, Dr. Christian Behrenbruch stated, "As a Melbourne-headquartered biotech company it is a privilege to work with world-class clinical sites in our backyard, and the ONJ Center is a very special place to do clinical research. We'd like to express our thanks to Prof. Andrew Scott, A/Prof. Dr Sze Ting Lee and the ONJ team for their excellent support and – most importantly – the patients that have consented to participate in our trial."

About the ZIRCON Study

ZIRCON ("Zirconium Imaging in Renal Cancer Oncology, NCT03849118) is an international multi-centre Phase III study at 25 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 / TLX250-CDx

TLX250 (Girentuximab) is being developed by Telix Pharmaceuticals both as a diagnostic PET agent - ^{89}Zr-Girentuximab (Phase III) and a therapeutic radiopharmaceutical – ^{177}Lu-Girentuximab (Phase II). TLX250 is an antibody-based platform that targets carbonic anhydrase IX (CAIX), a cell surface target that is highly expressed in several serious cancers, including renal, lung and esophageal cancer. High CAIX tumour expression is generally correlated with poor prognosis. Telix has prioritized the development of TLX250 for metastatic renal cell carcinoma (RCC), particularly the clear cell variant (ccRCC), which almost ubiquitously over-expresses CAIX.

About Telix Pharmaceuticals Limited

Telix Pharmaceuticals Limited (Telix) is a global biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or "molecularly-targeted radiation" (MTR). The company is headquartered in Melbourne with international operations in Brussels (EU), Kyoto (JP) and Indianapolis (US). Telix is developing a portfolio of clinical-stage oncology products that address significant unmet medical need in renal, prostate and brain (glioblastoma) cancer. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com.

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