



Telix Pharmaceuticals Files Phase III Trial for Kidney Cancer Imaging in Europe

Melbourne (Australia) – 23 August 2018. Telix Pharmaceuticals Limited (ASX.TLX) (“**Telix**”, the “**Company**”), an Australian biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or “molecularly-targeted radiation” (“**MTR**”) is pleased to announce that the Company has filed to initiate a Phase III trial in Europe for ⁸⁹Zr-DFO-girentuximab (TLX250) for the imaging of renal (kidney) cancer with Positron Emission Tomography (PET).

The study – referred to as ZIRCON (“**Z**irconium Imaging in **R**enal **C**ancer **O**ncology, EudraCT 2018-002773-21) will be a global multi-centre Phase III study with at least 15 sites in Europe, Australia and the United States, subject to regulator approval in the various jurisdictions. ZIRCON is a prospective imaging study in approximately 250 kidney cancer patients undergoing kidney surgery, and will determine the sensitivity and specificity of TLX250 PET imaging to detect clear cell renal cell cancer (ccRCC) in comparison with histologic “ground truth” determined from surgical resection specimens.

Telix CEO Dr. Christian Behrenbruch stated, “The filing of this clinical trial in Europe marks a major operational milestone for the Company in terms of realizing the value of our product pipeline. We would like to express our sincere appreciation to our partner, Heidelberg Pharma, for their extensive and practical support over the last 18 months with respect to getting this program launched, as well as our academic collaborators in the US, Australia and Europe.”

The development of TLX250 imaging builds on over a decade of academic and commercial experience in the use of girentuximab (a monoclonal antibody targeting carbonic anhydrase IX or ‘CAIX’) as a PET molecular imaging probe. In close collaboration with Heidelberg Pharma AG (formerly Wilex AG), Radboud University Medical Centre (RUMC) and Memorial Sloan Kettering (MSK), Telix has progressed a renal cancer PET imaging program that has the potential to deliver a significant unmet need to a population of cancer patients that are commonly mis-staged. The trial is expected to take 9-12 months to fully recruit.

Telix CMO Dr. Andreas Kluge noted, “It has been a major undertaking by the Telix team to build the manufacturing network and clinical infrastructure to support this trial, particularly given the production complexity of radioactive drugs. With this initial filing in Europe, the Company will be focused on adding sites, including in Australia and the US in the coming months. We look forward to keeping shareholders closely informed of our progress.”

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.



About the Renal Cancer Imaging Market

The opportunity for advanced renal cancer imaging techniques consists of several distinct clinical needs, ranging from patients that have had an incidental finding in the kidney, to diagnosed patients undergoing staging (or re-staging) and for treatment response assessment. Kidney cancer patients are commonly mis-staged as metastases may be very small and do not typically image well using conventional techniques. Between the US and EU5 there are about 120,000 new diagnoses a year (*Globocan*), where more precise diagnostic imaging tools would significantly impact patient care. In the US alone the prevalence of clear cell renal cell cancer (ccRCC) is approximately 450,000 patients (*SEER*), a large proportion of which would benefit from better imaging for staging and treatment response.

About TLX250

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

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None of the products referred to in this release have obtained a marketing authorization from EMA, TGA or FDA.