
Telix Commences ZIRCON Phase III Renal Cancer Imaging Trial

Melbourne (Australia) – 23 October 2018. 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 Company is preparing to commence recruitment for its ZIRCON Phase III trial for imaging of clear cell renal cell cancer (ccRCC) with ⁸⁹Zr-girentuximab (TLX250).

Concurrent with ongoing submissions to regulatory authorities and clinical sites in Europe, Telix has successfully completed a Clinical Trial Notification (CTN) submission to the Therapeutic Goods Administration (TGA) and has now received its first Human Research Ethics Committee (HREC) approval in Australia. The Company is planning to recruit patients at a total of four clinical sites in Australia.

Telix CEO Dr. Christian Behrenbruch stated, “As an Australian-headquartered company, it’s very pleasing to be able to start to recruit patients in our own backyard while we finalize the regulatory documentation in the various international jurisdictions. Our EU submissions are progressing well with several key review milestones in November that should enable us to bring further international sites online before end-year. In all the countries we plan to run the ZIRCON study, there has been a high level of clinician engagement and we expect this trial to recruit well.”

About the ZIRCON Study

ZIRCON (“Zirconium Imaging in Renal Cancer Oncology, EudraCT 2018-002773-21) is 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 trial in approximately 250 renal cancer patients undergoing kidney surgery, and will 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 (girentuximab) is being developed by Telix Pharmaceuticals both as a therapeutic drug (177Lu-girentuximab, in Phase II) and a diagnostic PET imaging agent, denoted as TLX250-CDx (“Companion Diagnostic”). 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.

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 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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