Title: cGMP Manufacturing of TLX250 (Renal Cancer Therapy) Complete

Date: 20th March 2019

Program relevance: TLX250 (^{177}Lu-girentuximab) for the treatment of clear cell renal cell cancer (kidney cancer)

Synopsis:

Over the past (approximately) nine months, Telix has been manufacturing cGMP (Current Good Manufacturing Practice) grade material for the production of TLX250. cGMP material is required to be able to conduct clinical trials in humans. The completion of manufacturing and release of the material is the final major step before being able to commence further clinical trials in kidney cancer patients. Telix expects to be able to start clinical trials in the US mid-2019, subject to receiving permission from the Food and Drug Administration (FDA).

Key points for investors:

- Manufacturing of an antibody conjugate is a technically challenging process. Telix has been able to complete the manufacturing process within budget although approximately 3-4 additional months were required to validate certain analytical methods involved in the process.
- Telix intends to study TLX250 in patients with metastatic kidney cancer. TLX250 will be studied in combination with immunotherapy ("checkpoint inhibitors") as this is now the current standard of care in second-line kidney cancer therapy.
- Telix expects to launch at least two distinct clinical studies involving TLX250 at leading US cancer hospitals in the next few months. Clinical protocols are being finalized and regulatory submission paperwork is in progress.

cGMP Manufacturing of TLX250 (Renal Cancer Therapy) Complete

Melbourne (Australia), Indianapolis (USA) – 20th March 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 manufacturing of material suitable for clinical trials has been completed for TLX250.

The manufacturing of TLX250, including fill/finish, was conducted under Current Good Manufacturing Practice (cGMP) by suitable contract manufacturing vendors in the United States. In addition, the Company has now developed the radiolabeling process for conjugating the therapeutic radionuclide ^{177}Lu (lutetium) to TLX250 and will commence technology transfer to clinical sites later this month. Sufficient quantities of material have been produced to enable the Company to complete clinical development up to Phase III.

Telix Pharmaceuticals USA President and COO, Dr. Bernard Lambert said, "We have now developed and implemented the processes for GMP manufacturing and radiolabeling for TLX250. The analytical methods and manufacturing records are suitable for conducing further clinical studies at key US cancer centers and we are very excited to be able to formally commence therapeutic studies in clear cell renal cell patients in the near future, subject to FDA approval."

About TLX250

TLX250 (Girentuximab) is being developed by Telix Pharmaceuticals both as a diagnostic PET agent - ^{89}Zr-Girentuximab (Phase III, NCT03849118) and as 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 over-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 therapeutic development of TLX250 for metastatic renal cell cancer (RCC), specifically the clear cell variant (ccRCC), which almost ubiquitously over-expresses CAIX. Clinical trials of TLX250 in combination with immunotherapy are expected to commence in the United States mid-2019, subject to FDA approval.

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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