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**Title:** Renal Cancer Imaging Program – Japanese Regulatory Progress Update

**Date:** 19th December 2018

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

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**Synopsis:**

The Japanese market is an important market for nuclear medicine products and Telix has elected to include Japan in its development strategy for TLX250-CDx. The Pharmaceuticals and Medical Devices Agency (PMDA) regulates pharmaceutical products in Japan. The PMDA has a three-step consultation process that leads to the submission of a Clinical Trial Notification (CTN) and the approval to commence a clinical trial in Japanese patients. Telix has progressed through the first two stages and has now been permitted to prepare for the final formal stage that will lead to the submission of a CTN early next year.

**Key points for investors:**

- This update is provided in order to give visibility of Telix's activities in Japan from a regulatory perspective
- Telix is planning a Phase I/II trial that will enable the utility of TLX250-CDx to be evaluated in Japanese patients, alongside extensive US and EU patient data. The planned study is expected to start in late calendar Q1 or early Q2 next year and will involve 30-40 subjects (subject to final agreement on the trial design with the PMDA and CTN approval) and will take 9-12 months to complete
- The purpose of the study is to bridge Japanese patient experience to the ZIRCON multi-centre Phase III trial and to establish a path to approval in Japan alongside other commercial territories
- Pharmaceutical companies are typically required by the PMDA to show specific safety/efficacy in Japanese patients because of differing population characteristics



## ***Renal Cancer Imaging Program – Japanese Regulatory Progress Update***

Melbourne (Australia), Kyoto (Japan) – 19<sup>th</sup> December 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 it has completed first and second stage consultations with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) and has been granted permission to submit a final stage application by the 11<sup>th</sup> January 2019 for a Phase I/II study of <sup>89</sup>Zr-girentuximab (TLX250-CDx) in Japan.

The objective of the study is to validate the existing US and EU experience of imaging kidney cancer with girentuximab (anti-CAIX antibody) in Japanese patients. The study, as proposed, will build on the EU experience with TLX250-CDx, particularly the ZIR-DOSE study (EudraCT 2017-004769-2). The trial, which is expected to commence in Q2 2019 (subject to regulator approval), will use product manufactured in Japan by Telix’s partner JFE Engineering and will bridge to the global ZIRCON Phase III study (EudraCT 2018-002773-21).

Telix Pharmaceuticals Japan President, Dr. Shintaro Nishimura stated, “Over the past 6 months, Telix has made considerable progress with TLX250-CDx in Japan and our preliminary engagement with the PMDA has been very helpful in terms of developing a roadmap for this product in Japan. The imaging of CAIX in Japanese patients has potential utility in a wide variety of cancers, including renal cancer, and we are pleased with the progress in both manufacturing and regulator engagement.”

### **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](http://www.telixpharma.com).

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*None of the products described in this release have obtained a marketing authorization from the US Food and Drug Administration or the Japanese PMDA.*