Title: Telix Cleared to Commence Renal Cancer Imaging Study in Japan

Date: 30 Aug 2019

Program relevance: TLX250-CDx (^{89}Zr-girentuximab) for the imaging of renal cancer with Positron Emission Tomography (PET)

Overview:

Telix Pharmaceuticals Limited today announced the completion of a Clinical Trial Notification (CTN) review for a Phase I/II study for TLX250-CDx (^{89}Zr-girentuximab) in Japan. The Japanese Pharmaceutical and Medical Devices Agency (PMDA) has completed review of the proposed clinical trial and Telix is now permitted to proceed with the study. This study is the first of its kind in Japan.

Key Points for Investors:

- The Japanese oncology market is an important global market and potentially represents the second-largest homogeneous market for Telix's product pipeline after the United States.
- TLX-250CDx is a novel renal cancer imaging agent, currently the subject of an international Phase III trial – the ZIRCON study.
- The PMDA's Clinical Trials Notification (CTN) review for a Phase I/II trial for TLX-250CDx is now complete and Telix is now permitted to commence clinical activity in Japan.
- The Japanese Phase I/II is intended to bridge to the international ZIRCON Phase III trial.
- Enrolment is expected to commence in the next 60 days and is expected to take approximately 6-9 months to complete. The study will enrol 40 patients in total.

Telix Cleared to Commence Renal Cancer Imaging Study in Japan

Melbourne (Australia) and Kyoto (Japan) – 30 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) today announced successful completion of a Clinical Trial Notification (CTN) submission to the Japanese Pharmaceutical and Medical Devices Agency (PMDA) for TLX250-CDx (^{89}Zr-girentuximab).

The Company's wholly owned subsidiary Telix Pharmaceuticals Japan K.K. ("Telix Japan") submitted the CTN at the end of July after an extensive consultation process with the PMDA. The Company has resolved the PMDA's remaining questions and has also closely engaged with other key stakeholders such as Ministry of Health, Labour and Welfare (MHLW), the Japan Radioisotope Association (JRIA) and clinical key opinion leaders.

Telix Japan is now permitted to commence a Phase I/II trial that is designed to bridge to the Company's international ZIRCON Phase III study. The study will enrol 40 renal cancer patients. The Phase I portion is a single-site study that will evaluate an initial cohort of patients to confirm that pharmacology/dosimetry is equivalent in Japanese subjects. The Phase II portion will expand to a multi-centre study, operating under a protocol that is effectively identical to the ZIRCON trial.

Telix Pharmaceuticals Japan K.K. President Dr. Shintaro Nishimura, stated, "We believe this CTN is a transformative event for the Japanese Nuclear Medicine community as it is the first formal clinical trial for a zirconium-labeled PET imaging agent in Japan. TLX250-CDx has tremendous potential to deliver benefit to Japanese cancer patients and this accomplishment will help to pave the way for the future use of "theranostics" in Japan."

Telix CEO Dr. Christian Behrenbruch, added, "It's been a significant amount of effort to get this study up and running in Japan, particularly as we have also had to manufacture the radiopharmaceutical product locally within a very strict regulatory environment. We are appreciative to our clinical and business partners, particularly JFE Engineering (manufacturing partner) and Nihon Medi-Physics (commercial partner) for their excellent support and 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 cancer (glioblastoma). Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com.

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