
First Patient Dosed in Phase I/II Trial of Renal Cancer Imaging Product in Japan

Melbourne (Australia) – 18th August 2020. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today announces that the first patient has been dosed in a Phase I/II study of Telix's renal cancer diagnostic imaging product TLX250-CDx (⁸⁹Zr-girentuximab) in Japan.

The objective of the study, termed the "ZIRDAC-JP" (Zirconium Dosing and Comparison in Japan) study is to confirm the safety and tolerability, as well as sensitivity and specificity of positron emission tomography (PET) imaging with TLX250-CDx to detect clear cell renal cell cancer (ccRCC) in Japanese patients. The patient population for the ZIRDAC-JP trial has been selected to be identical to the global Phase III ZIRCON trial, with comparison to surgical resection (histology) as standard of truth. The study has been carefully designed in consultation with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) to collect the necessary data to potentially bridge to the ZIRCON study by confirming that dosing and pharmacology in Japanese patients is consistent with the rest-of-world experience.

Telix Pharmaceuticals Japan K.K. President, Dr. Shintaro Nishimura stated, "The ZIRDAC-JP study is the first commercially sponsored clinical trial in Japan in which a zirconium-based diagnostic agent has been studied. Dosing the first patient in the ZIRDAC-JP study represents a significant first step for the Japanese nuclear medicine community to deliver benefit to Japanese cancer patients and to pave the way for the future use of theranostics in Japan. We'd like to express our appreciation to Dr Nakaigawa, the study's principal investigator at Yokohama City University Hospital, the investigators and the study team for their excellent collaboration, and most importantly the patients who will participate in this trial."

Mr. Masahiro Tanaka, Director of the Medical Division of JFE Engineering Corporation stated, "We are very pleased to have contributed to the successful initiation of the ZIRDAC-JP study with the investigational drug manufactured by JFE Engineering at our Yokohama cyclotron facility. Our centralized manufacturing capabilities will provide the patients and medical community with flexible and convenient access to this novel radiopharmaceutical and will provide the pharmaceutical industry with a significant commercial opportunity."

About the ZIRDAC-JP Study

ZIRDAC-JP (Zirconium Dosing and Comparison in Japan, NCT04496089) is a Japanese multi-centre Phase I/II study that will recruit approximately 40 patients in total. The objectives of the study are to determine the safety, tolerability, radiation dosimetry and pharmacokinetics / pharmacodynamics (Phase I), and the sensitivity and specificity of TLX250-CDx PET imaging to detect clear cell renal cell cancer (ccRCC) compared to histologic 'ground truth' determined from surgical resection specimens (Phase II).

About Telix Pharmaceuticals Limited

Telix is a clinical-stage biopharmaceutical company focused on the development of diagnostic and therapeutic products using Molecularly Targeted Radiation (MTR). Telix is headquartered in Melbourne, Australia with international operations in Belgium, Japan and the United States. Telix is developing a portfolio of clinical-stage oncology products that address significant unmet medical needs in prostate, kidney and brain cancer. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com.

About JFE Engineering Corporation

JFE Engineering is continuing to accelerate the globalization of its engineering business and supply leading-edge technologies to countries around the world. JFE Engineering is committed to creating the foundation for life and a better standard of living through innovation in energy, construction and healthcare. For more information, please visit www.jfe-eng.co.jp.

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