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Telix Granted FDA Approval for ZIRCON Renal Cancer Imaging Study

Melbourne (Australia) – 23 January 2020. Telix Pharmaceuticals Limited (ASX:TLX) has today announced that the US Food and Drug Administration has approved the ZIRCON study for recruitment of American patients. The receipt of an Investigational New Drug (IND) notice of allowance will enable patient recruitment to commence in the United States in thirty (30) days.

The ZIRCON (Zirconium Imaging in Renal Cancer Oncology) is an international Phase III study to evaluate the utility of TLX250-CDx (⁸⁹Zr-girentuximab) for the imaging of clear cell renal cell cancer (ccRCC) using Positron Emission Tomography (PET). The study aims to recruit approximately 250 patients and is currently recruiting at 19 sites in Australia and Europe. The IND allowance in the US will add up to a further 6 leading cancer centres in the United States. The trial is expected to complete enrolment around mid-year.

Telix CEO Dr. Christian Behrenbruch said, “This IND is a major milestone for the company in terms of moving ahead the ZIRCON study as well as engagement with US regulators for a late-stage trial. We are excited to be adding US patients to the study. We’d also like to thank our North American manufacturing and pharmacy partners – Isologic and Cardinal Health – for their support with this submission.”

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). The company is headquartered in Melbourne 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 need in renal, prostate and brain cancer. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com.

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