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Telix Pharmaceuticals Submits New Drug Application to US FDA for Prostate Cancer Imaging Product

Melbourne (Australia) and Indianapolis, IN (U.S.A.) – 24th September 2020. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today announces it has submitted a New Drug Application (NDA) to the United States Food and Drug Administration (FDA) for TLX591-CDx (Kit for the preparation of ^{68}Ga-PSMA-11), a radiopharmaceutical targeting Prostate-Specific Membrane Antigen (PSMA) for the imaging of prostate cancer using Positron Emission Tomography (PET).[1]

Telix's NDA submission for TLX591-CDx includes clinical data from over 600 patients obtained from both prospective and retrospective clinical studies performed by Telix or in collaboration. The submission also builds on definitive peer-reviewed clinical research conducted at leading academic centres including the University of California, Los Angeles (USA), the Peter MacCallum Cancer Centre (Australia) and Heidelberg University Hospital (Germany).

Telix USA President Dr Bernard Lambert stated, "We are pleased to have achieved this significant milestone with the submission of the first commercial NDA for PSMA imaging in the United States. Telix has engaged with the FDA since July 2019, with valuable guidance resulting in what we believe to be a comprehensive submission. Subject to FDA approval, we look forward to bringing this product to market with our commercial partners to serve the needs of men living with prostate cancer."

Telix CEO Dr Christian Behrenbruch added, "Submitting an NDA to the US Food and Drug Administration for our first product is a major commercial inflection point for the Company and follows our European submission earlier this year. The Telix team and our advisors have done an outstanding job of preparing this submission, which we believe is founded on compelling clinical evidence that supports broad diagnostic utility in the management of prostate cancer. I'd like to acknowledge the commitment of our investigators, study teams and the independent physician readers who contributed to our clinical data package."

Telix would like to gratefully acknowledge Eckert & Ziegler AG, IRE ELiT and GE Healthcare, who collaborated closely with Telix to validate both ^{68}Ge/^{68}Ga generator and cyclotron-based ^{68}Ga production systems with TLX591-CDx for the NDA submission. The Company wishes to particularly acknowledge and thank Memorial Sloan Kettering Cancer Center (MSKCC) and Advanced Accelerator Applications (a Novartis Company) for their significant contribution to the NDA submission and their commitment to men's health.

About TLX591-CDx

TLX591-CDx (Kit for the preparation of ^{68}Ga-PSMA-11) is a proprietary formulation of PSMA-HBED-CC (PSMA-11), a novel imaging agent targeting prostate-specific membrane antigen (PSMA), originally developed by the Heidelberg group of the Deutsches Krebsforschungszentrum (German Cancer Research Centre, DKFZ).[2] The 'cold kit' format of TLX591-CDx enables rapid radiolabelling at room temperature with high radiochemical purity and production consistency, optimised for the radiopharmacy setting.

[1] TLX591-CDx is not currently approved in any jurisdiction including the United States and European Union.
[2] Eder, et al. Bioconjugate Chem Apr 18, 2012; 23(4): 688-97.

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

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