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NDA Clinical Briefing Package Submitted to the US FDA

Melbourne (Australia) – 27th December 2019. Telix Pharmaceuticals Limited (ASX: TLX), is pleased to announce that it has submitted a complete clinical briefing package to the US FDA for its first product TLX591-CDx[1], following the procedural guidance received from its pre-NDA[2] meeting (reported 28th August 2019).

Telix has also completed the additional manufacturing and product release analytics that were recommended by the FDA. Consequently, the amended Drug Master File (DMF) will be filed with the FDA during January 2020 as part of the company's ongoing NDA submission process.

Telix CEO Dr. Christian Behrenbruch said, "We have now been able to assemble a complete manufacturing, safety and efficacy package for the NDA submission of our first product. We expect to be able to inform shareholders in February 2020 whether our clinical package is sufficient to finalize the NDA submission process with the FDA."

About TLX591-CDx (^{68}Ga-PSMA-11)

TLX591-CDx is a small molecule-based imaging agent for use with Positron Emission Tomography (PET). TLX591-CDx targets a cell surface antigen called Prostate-Specific Membrane Antigen (PSMA) that is over-expressed on most prostate cancer cells.

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.

[1] ^{68}Ga-PSMA-11, for the imaging of prostate cancer with Positron Emission Tomography
[2] New Drug Application

Important Information

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