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Telix New Drug Application for Prostate Cancer Imaging Product Accepted by US FDA

Melbourne (Australia) and Indianapolis, IN (U.S.A.) – 24th November 2020. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') announces today that its New Drug Application (NDA) 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), has been accepted for filing by the United States Food and Drug Administration (FDA).

Telix submitted its NDA for TLX591-CDx on 23rd September 2020 seeking an indication for the diagnostic imaging of prostate cancer, including from the early pre-treatment setting through to the later stages of advanced disease.[1] In its submission, the Company included a request for priority review, the outcome of which Telix expects to be notified around 10th December 2020.

Telix's Chief Medical Officer, Dr Colin Hayward said, "The use of ^{68}Ga-PSMA PET imaging is rapidly becoming the standard of care for prostate cancer imaging across a broad range of clinical settings. PSMA imaging is already included in the leading clinical practice guidelines in the United States and Europe, based on evidence that definitively demonstrates superiority over conventional imaging.[2, 3] This is highly supportive of rapid adoption of Telix's product upon approval."

Telix CEO, Dr Christian Behrenbruch said, "We are delighted to have achieved this significant milestone with the FDA's acceptance for filing of the first commercial NDA for PSMA imaging in the United States. This represents a major step towards our goal of providing this highly anticipated product to patients in the United States and beyond. From acquiring ANMI[4] and its advanced chemistry platform in December 2018, to successfully filing an NDA less than two years later, represents an extraordinary achievement by the Telix team. We now look forward to working with the FDA to bring TLX591-CDx to American patients living with prostate cancer as expeditiously as possible."

Telix's NDA submission for TLX591-CDx included clinical data from over 600 patients obtained from studies performed by Telix or in collaboration with research partners. The NDA also included clinical evidence reported in the peer-reviewed medical literature, a significant proportion of which originated from research undertaken at leading academic centres including the University of California, Los Angeles (USA), the Peter MacCallum Cancer Centre (Australia) and Heidelberg University Hospital (Germany).

About Prostate Cancer

Prostate cancer is the second most common cancer in men following skin cancer and, in 2018, 1.3 million men were diagnosed with prostate cancer for the first time.[5] Despite advances in treatment, prostate cancer still accounts for a large number of deaths and in 2018 more than 365,000 men died from their disease. Rates of diagnosis are increasing, with the highest incidences of prostate cancer occurring in Europe, the United States, Europe and Australia and New Zealand.

[1] ASX release 23rd September 2020.
[2] For example: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30314-7/fulltext.
[3] https://ascopubs.org/doi/full/10.1200/JCO.19.02757. https://uroweb.org/guideline/prostate-cancer/#5.
[4] Advanced Nuclear Medicine Ingredients SA.
[5] GLOBOCAN 2018.

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).[6] 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.

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.

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[6] Eder, et al. Bioconjugate Chem Apr 18, 2012; 23(4): 688-97.