***Telix Pharmaceuticals Limited***
*ACN 616 620 369*
*Suite 401, 55 Flemington Road*
*North Melbourne*
*Victoria, 3051*
*Australia*



# FDA Extends New Drug Application Review Period for Illuccix®

*Melbourne (Australia) and Indianapolis, IN (U.S.A.) – 23 September 2021*. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that the U.S. Food and Drug Administration ('FDA', the 'Agency') has extended the review period for the Company's New Drug Application (NDA) for its prostate cancer imaging investigational product Illuccix® (TLX591-CDx, kit for the preparation of $^{68}$Ga-PSMA-11 injection) by three months.

The revised target Prescription Drug User Fee Act (PDUFA) goal date of 23 December 2021 will allow the FDA to review and consider further manufacturing-related information submitted by the Company and conclude the label review. This is a standard review extension period.

Telix attended a late-cycle review meeting with the FDA on the 17 June 2021. During the meeting, the FDA indicated that there were no outstanding substantive manufacturing or clinical review issues with Telix's submission. [1] However, the Company's Pre-Authorisation Inspection (PAI) fell subsequent to the late-cycle review meeting and raised a well-defined set of manufacturing-related observations. The Company has fully responded to those observations and the FDA is currently reviewing.

Telix CEO Dr Christian Behrenbruch stated, "The timing of our PAI relative to the late-cycle review meeting meant that additional review time was needed to address manufacturing-related observations. This has pressured the FDA's initial PDUFA review timeline and hence the Company has incurred this time extension. The final part of the NDA process is the label review, which we consider to be a straightforward matter, given the precedent of PSMA-PET imaging agents in the market and the clear adoption of PSMA PET in clinical practice guidelines. The FDA has not requested additional safety or clinical data. We look forward to being in a position to bring to patients in the US access to this flexible, highly specific and sensitive imaging tool for the detection of prostate cancer."

**About Telix Pharmaceuticals Limited**

Telix is a 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 products that address significant unmet medical need in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com and follow Telix on Twitter (@TelixPharma) and LinkedIn.

Telix's lead investigational product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been accepted for filing by the U.S. FDA,[2] and is under priority evaluation by the Australian Therapeutic Goods Administration (TGA).[3] Telix is also progressing marketing authorisation applications for Illuccix® in the European Union[4] and Canada.[5] None of Telix's products have received a marketing authorisation in any jurisdiction.

[1] ASX disclosure 17/06/21
[2] ASX disclosure 24/11/20.
[3] ASX disclosure 14/04/21.
[4] ASX disclosure 1/05/20.
[5] ASX disclosure 16/12/20.

**Telix Investor Relations**

Ms. Kyahn Williamson
Telix Pharmaceuticals Limited
SVP Corporate Communications and Investor Relations
Email: kyahn.williamson@telixpharma.com