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Telix Update on FDA New Drug Application Review for Illuccix®

Melbourne (Australia) and Indianapolis, IN (U.S.A.) – 17 June 2021. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that the Company has participated in a late-cycle review meeting with the U.S. Food and Drug Administration ('FDA', the 'Agency') regarding the ongoing review of the New Drug Application (NDA) for its prostate cancer imaging investigational product Illuccix® (kit for the preparation of 68Ga-PSMA-11 injection). During the meeting, the FDA indicated that there are no outstanding substantive review issues with Telix's submission.

Telix Chief Executive Officer, Dr. Christian Behrenbruch stated, "The late-cycle review meeting with the FDA continued a series of productive meetings with the Agency and sets the stage for the concluding phase of the NDA review process, including alignment on the final Illuccix® product label. We remain optimistic about a positive outcome and, accordingly, are working closely with our commercial partners to prepare for the U.S. launch of Telix's lead product for prostate cancer imaging, pending approval. Delivering patient access to this important technology to support the management of prostate cancer remains a major corporate objective for Telix."

Together with regulatory submissions in Australia, Canada, and Europe, Illuccix® presently has regulatory reviews in progress in 17 countries globally.

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,[1] and is under priority evaluation by the Australian Therapeutic Goods Administration (TGA).[2] Telix is also progressing marketing authorisation applications for Illuccix® in the European Union[3] and Canada.[4] None of Telix's products have received a marketing authorisation in any jurisdiction.

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

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