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Telix Receives FDA Feedback on Phase 3 Trial Design for Prostate Cancer Therapy Product

Summary of FDA Feedback

- FDA has provided feedback on the design of Telix's Phase 3 PROSTACT trial of TLX591 (^{177}Lu-DOTA-rosopatamab) for the treatment of PSMA-expressing mCRPC.
- The feedback represents Telix's first formal interaction with the FDA for its Phase 3 prostate therapy program.
- Guidance was provided on the study design elements, statistical considerations, dosing strategy and safety monitoring to be employed in the PROSTACT trial.
- Patient selection for the PROSTACT trial will be confirmed via the use of Telix's prostate cancer imaging agent TLX591-CDx (^{68}Ga-PSMA-11).
- Telix intends to file a Phase 3 IND for TLX591 prior to the end of 2020.

Melbourne (Australia) – 8th July 2020. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today announces that the US Food and Drug Administration (FDA) has provided feedback that will enable the Company to finalize the Phase 3 PROSTACT trial design for the development of Telix's prostate cancer therapy product TLX591 (^{177}Lu-DOTA-rosopatamab) in patients with metastatic castration-resistant prostate cancer (mCRPC) that express Prostate-Specific Membrane Antigen (PSMA).

The FDA was broadly supportive of Telix's proposal to define PSMA-expression with TLX591-CDx (^{68}Ga-PSMA-11) imaging as the basis for selecting patients for the PROSTACT trial. The Company also received detailed feedback from the FDA relating to fundamental aspects of the proposed trial structure including study design elements, statistical considerations and dosing strategy for TLX591, as well as safety monitoring of study participants.

The detailed feedback Telix has received from the FDA provides clarifying information that will enable the Company to refine the design of the Phase 3 PROSTACT trial in the intended treatment population, with patient selection enriched via the use of TLX591-CDx companion diagnostic imaging to identify patients with PSMA-expressing prostate cancers. Telix plans to integrate the FDA's recommendations into the final design of the Phase 3 PROSTACT trial in order to be able to file an IND for TLX591 prior to the end of 2020.

Telix Chief Medical officer Dr Colin Hayward stated, "The valuable feedback Telix has received from the FDA provides clarifying information that will enable the Company to significantly improve the design of the Phase 3 PROSTACT trial. Particularly encouraging is the FDA's support for enriched patient selection via the use of PSMA imaging with TLX591-CDx to identify patients with PSMA-expressing prostate cancers. This aligns with the Company's strategy of integrating diagnostic imaging and targeted therapy as a "theranostic" pair, to optimally personalise the treatment of men with advanced prostate cancer."

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 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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