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Positive FDA Feedback on NDA Submission Process for TLX591-CDx (kit for the preparation of ^{68}Ga-PSMA-11)

Melbourne (Australia) – 25th February 2020. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today announces that it has received positive feedback from the US Food and Drug Administration (FDA) regarding its submission of a New Drug Application (NDA) for TLX591-CDx (kit for the preparation of ^{68}Ga-PSMA-11).

In line with prior guidance received from the FDA in a pre-NDA meeting, (ASX release: 28/08/19) Telix submitted an additional briefing package (ASX release: 27/12/19) for FDA's review and opinion on the clinical data proposed for its NDA submission. The Company has now received feedback on the briefing package.

Telix's clinical data proposed for its NDA submission is based on a combination of prospective and retrospective data, including imaging data from the Novartis VISION study (clinicaltrials.gov identifier: NCT03511664). The FDA has provided detailed feedback on the clinical briefing package for the efficacy data, which the Company expects to be able to satisfy, based on the planned submission dataset. The FDA has also indicated that the safety dataset is adequate, subject to formal NDA review.

Telix's CEO Dr Chris Behrenbruch said, "We appreciated the opportunity to put our proposed clinical data to the Agency as a further refinement of our NDA submission plan. The feedback from the FDA was supportive of our approach, with useful analytical recommendations that will further strengthen our submission. In taking an extra two months to engage with the FDA, we further reduce the risk to the NDA submission process."

Timeline to submission of the complete NDA package, incorporating additional FDA feedback and publishing, will be approximately 30-60 days. The Company has also amended its Drug Master File (DMF) to include manufacturing-related recommendations previously made by the FDA.

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 need in renal, prostate and brain cancer. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telix.com.

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