Title: FDA Pre-NDA Meeting Outcomes : TLX591-CDx (*illumet*™)

Date: 28 August 2019

Program relevance: TLX591-CDx (^{68}Ga-PSMA) for the imaging of prostate cancer with positron emission tomography (PET).

Overview:

Telix had a pre-NDA meeting with the United States Food and Drug Administration (FDA) on the 24th of July to discuss the Company's plan for the submission of a New Drug Application (NDA) for TLX591-CDx, (kit for the preparation of ^{68}Ga-PSMA, trademarked as *illumet*™ in the United States). The Company has now received the formal meeting minutes from the FDA and can reliably report on the outcomes.

Key points for investors:

- The United States is the most commercially important jurisdiction for Telix's products, including TLX591-CDx (*illumet*™).
- The FDA is the regulatory body that has jurisdiction over the conduct of clinical trials and product approvals in the United States.
- An NDA is the process by which a company applies for a marketing approval for a pharmaceutical product in the US.
- Telix has formally commenced the process of engaging with the FDA to apply for a marketing authorisation for the TLX591-CDx (*illumet*™) prostate cancer imaging product in the United States.
- The Company's NDA submission builds on the prior submission of a Drug Master File (DMF) and multiple studies in the USA and Europe (both academic and Company-generated data).
- The pre-NDA meeting held between the Company and the FDA provided clear manufacturing and clinical guidance in relation to Telix's planned submission.

FDA Pre-NDA Meeting Outcomes : TLX591-CDx (illumet™)

Melbourne (Australia) and Indianapolis (USA) – 28 August 2019. Telix Pharmaceuticals Limited (ASX.TLX) ("Telix", the "Company"), a clinical-stage biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or "molecularly-targeted radiation" (MTR) today provides an update on the progress of its TLX591-CDx prostate cancer imaging product, trademarked as *illumet™* (kit for the preparation of ^{68}Ga-PSMA, the "Kit") in the United States.

The Company held a pre-NDA (New Drug Application) meeting with the FDA on 24th of July to discuss and agree on the content and format of the submission for a marketing authorisation in the United States. Such consultations are a standard and important process of regulatory engagement for drug development and submission.

The Company received clear and valuable advice from the FDA to guide its NDA submission in the United States. The key outcomes from the pre-NDA FDA meeting are:

Manufacturing (Chemistry, Manufacturing and Control or "CMC"):

- The FDA and Telix agreed that the NDA will rely predominately on the Drug Master File (DMF) that the Company submitted in July 2018. Since then, multiple Investigational New Drug (IND) applications have referenced Telix's DMF, including the Endocyte (Novartis) VISION Phase III trial and several other significant academic studies that are generating important prospective data, expanding the clinical experience and exploring new indication areas for the prostate imaging agent.

- The FDA agreed that the specifications for the drug substance precursor and other Kit components, including sterility and final release specifications appear reasonable.

- The FDA clarified the required product stability data to support an NDA as part of Telix's transition to large-scale US-based commercial manufacturing for the product. The FDA's data requirements are consistent with the Company's current data capture activity.

- The FDA agreed with Telix's proposed manufacturing validation plan.

- The Company indicated to FDA that Telix intends to include the use of ^{68}Ga produced by cyclotron, to be supported by the manufacturing validation data that has been collaboratively generated with GE Healthcare. The FDA indicated that this plan was acceptable and would review these data in the application. The inclusion of data to support the use of ^{68}Ga product produced by cyclotron in the NDA, if approved, will expand the deployment flexibility of the product.

Clinical

- The FDA and Telix agreed that the NDA would be regulated under the 505(b)(2) pathway. This pathway is appropriate when part of the information required for approval comes from studies not conducted by or for the Sponsor (e.g., literature available in the public domain) and for which the Sponsor has not specifically obtained a right of reference.

- The FDA agreed that part of Telix's NDA submission will be based on supporting literature for ^{68}Ga-PSMA-11 in over 10,000 patients in published clinical studies around the globe. The FDA and Telix also agreed on the literature search parameters and paper eligibility criteria (study type, patient population, reference standard, efficacy endpoints, and safety assessments) to support the NDA submission.

- The FDA agreed that Telix's rationale for the proposed clinical dose in the NDA was acceptable.

- The FDA made several recommendations around data requirements to support the efficacy and safety of the product. The recommendations are consistent with Telix's existing and ongoing clinical data capture activity.

Telix Pharmaceuticals (USA) President, Dr. Bernard Lambert stated, "We are appreciative of the FDA for the clear guidance in relation to our NDA as we prepare our final package for submission. Telix is currently preparing to file a DMF amendment to include the Company's new US-based manufacturer of record, with the FDA's requested stability and validation data. This will be followed by the NDA submission itself."

About Telix Pharmaceuticals Limited

Telix Pharmaceuticals Limited (Telix) is a global biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or "molecularly-targeted radiation" (MTR). The company is headquartered in Melbourne with international operations in Brussels (EU), Kyoto (JP) and Indianapolis (US). Telix is developing a portfolio of clinical-stage oncology products that address significant unmet medical need in renal, prostate and brain (glioblastoma) cancer. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com.

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