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Lancet Publication of ^{68}Ga-PSMA vs ^{18}F-Fluciclovine (Axumin®) Demonstrates Superiority of PSMA Imaging

Melbourne (Australia) – 1 Aug 2019. Telix Pharmaceuticals Limited (ASX.TLX, "Telix") a clinical-stage biopharmaceutical company focused on the development of diagnostic and therapeutic products based on "molecularly-targeted radiation" (MTR) has today announced the publication in *Lancet Oncology* of an independent academic study comparing ^{68}Ga-PSMA-11 imaging with ^{18}F-Fluciclovine (marketed as Axumin® by Blue Earth Diagnostics, a Bracco company). Publication reference : https://doi.org/10.1016/S1470-2045(19)30415-2.

The published study (NCT02940262) by Calais et al., conducted at the University of California, Los Angeles (UCLA), evaluated patients with prostate cancer biochemical recurrence after radical prostatectomy and PSA levels ranging from 0·2 to 2·0 ng/mL. Patients in the study received both a ^{68}Ga-PSMA-11 Positron Emission Tomography (PET) scan and an Axumin® PET scan within 15 days. Each PET scan was interpreted by three independent blinded readers and a consensus majority interpretation was generated to determine positive findings. The study demonstrated clear superiority of lesion detection by ^{68}Ga-PSMA-11 compared with Axumin® in the biochemical recurrence (early metastatic) setting. Detection rates in this relatively low PSA population for PSMA imaging (56%) were more than double that for Axumin® (26%).

Telix CEO Dr. Christian Behrenbruch noted, "This is a nicely executed study that clearly demonstrates the clinical efficacy of PSMA imaging in a very important prostate cancer population. The ability to detect disease in this early metastatic setting has the potential to deliver important new intervention options for these patients. The clear superiority of ^{68}Ga-PSMA-11 compared with the existing approved Axumin® product (in the United States) bodes well for the clinical adoption of this technology."

Telix is developing a proprietary "cold kit" (Kit) for the preparation of ^{68}Ga-PSMA-11 (branded as *illumet*™ in the United States). Telix recently (24/07/19) held a pre-NDA meeting with the US Food and Drug Administration (FDA) to discuss the approval process for *illumet*™. Concurrently the Company has received positive preliminary guidance regarding EU approval for the product (ASX release: 22/07/19). Telix is also collaborating with Emory University (Atlanta, GA) on an NIH-funded study to compare ^{68}Ga-PSMA-11 with Axumin® in the radiation therapy setting (NCT03762759), an additional clinical indication to the biochemical recurrence setting described in the *Lancet* publication (ASX release: 31/05/2019).

Axumin® is currently approved in the United States for the imaging of biochemical recurrence. Axumin® has limited adoption in the EU/UK as it is considered to be clinically equivalent to ^{18}F-Choline (a generic product). Axumin® is marketed by Blue Earth Diagnostics, recently acquired (27/07/209) by Bracco Imaging for USD $450m (A$657m).

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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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