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NCCN Guidelines Updated To Include PSMA-PET Imaging

Melbourne (Australia) and Indianapolis, IN (U.S.A.) – 14 September 2021. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) has today welcomed the updated National Comprehensive Cancer Network® (NCCN) Guidelines® for prostate cancer,[1] which includes prostate specific membrane antigen (PSMA) positron emission tomography (PET) imaging modalities, including Ga-68 PSMA-11.

Telix's New Drug Application (NDA) for its investigational imaging product Illuccix® (Kit for the preparation of ^{68}Ga-PSMA-11 injection) is in the late stages of review by the United States Food and Drug Administration. The NCCN Guidelines® are a recognised standard for clinical direction and policy in cancer care and are used widely by clinicians and payors.

The NCCN panel has recognised the increased sensitivity and specificity of PSMA-PET tracers, compared to conventional imaging (CT, MRI) for detecting micrometastatic disease, at both initial staging and biochemical recurrence. The updated guidelines state that the NCCN Panel does not feel that conventional imaging is a necessary prerequisite to PSMA-PET and that PSMA-PET/CT or PSMA-PET/MRI can serve as equally effective, if not more effective front-line imaging tools for these patients. **The updated guidelines now include Ga-68 PSMA-11 PET/CT to be considered as an alternative to standard imaging of bone and soft tissue.**

Dr Colin Hayward, Chief Medical Officer of Telix said, "This is an important change to the guidelines which will influence a shift in clinical practice to consider PSMA-PET imaging as an alternative to standard imaging of bone and soft tissue for the detection of unfavorable intermediate, high and very high risk as well as recurrent prostate cancer.

"The NCCN guidelines are considered a global standard to guide oncology practice and reimbursement. The inclusion of PSMA-PET imaging, including with Ga-68, the isotype used in our investigational imaging product Illuccix® further signals the emergence of PSMA-PET imaging as a state-of-the-art imaging modality."

Dr Oliver Sartor, Medical Director at Tulane Cancer Center said, "The updated guidelines will encourage clinicians to use PSMA-PET as a primary imaging modality in patients and will deliver the benefit of a more streamlined approach. We look forward to having access to this functional form of imaging as new products come into the market."

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,[2] and is under priority evaluation by the Australian Therapeutic

[1] https://www.nccn.org/guidelines/category_1.
[2] ASX disclosure 24/11/20.

Goods Administration (TGA).[3] Telix is also progressing marketing authorisation applications for Illuccix® in the European Union[4] and Canada.[5] None of Telix's products have received a marketing authorisation in any jurisdiction.

Telix Investor Relations

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