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Two New Studies to Explore Telix Assets in Breast Cancer Theranostics

- *Breast cancer one of several important indication expansion opportunities for the Telix portfolio*
- *First patient dosed at Emory University (Atlanta, USA) in a Phase I study of TLX591-CDx for the staging of lobular breast cancer*
- *'OPALESCENCE', a Phase II study to assess feasibility of using TLX250-CDx to detect carbonic anhydrase IX (CA9[1]) expression in triple-negative breast cancer, now open for enrolment at ICO Nantes (France).*

Melbourne (Australia) – 18 August 2021. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today announces the initiation of two new investigator-led studies to evaluate the potential utility of the Company's late-stage imaging portfolio in women's health, initially in two sub-types of breast cancer with a significant unmet medical need. Both TLX591-CDx and TLX250-CDx have potential utility in breast cancer imaging, particularly for specific phenotypes that are not consistently well imaged using existing techniques.

A first patient has been dosed in an NIH sponsored (R21CA256280) Phase I Feasibility Trial, 'Improved Staging of Lobular Breast Cancer with Novel Amino Acid Metabolic and Tumor Neovasculature Receptor Imaging' (NCT04750473) using TLX591-CDx (Kit for the preparation of ^{68}Ga-PSMA-11 injection) for the detection of occult metastases of lobular breast cancer (also called invasive lobular carcinoma, or ILC). The study is led by Dr. David Schuster at Winship Cancer Institute of Emory University and will recruit 20 patients over two years.

TLX591-CDx targets glutamate carboxypeptidase II (GCPII), also more generally known as prostate specific membrane antigen (PSMA), a protein that is highly expressed in many cancers, including ILC. While Telix has filed for regulatory approval of TLX591-CDx in prostate cancer imaging (investigational product illuccix® kit)[2], this study marks the first formal clinical investigation of TLX591-CDx in another indication of interest. ILC is the second most common form of breast cancer, affecting about 10 per cent of people with invasive breast cancer.[3] Currently there are no accurate imaging techniques for staging lobular breast cancer, adversely impacting clinicians' ability to inform decisions about optimal treatment and management of the disease.

Schuster, Principal Investigator of the study, said, "Ga-PSMA imaging is being used increasingly for prostate cancer assessment, but it also has potential to be utilized in areas such as ILC where PSMA is expressed but patients are under-served by current imaging techniques. In this trial, women with ILC with clinical or imaging suspicion of metastatic disease will undergo both ^{68}Ga-PSMA-11 and (^{18}F) fluciclovine PET-CT to determine if occult lesions may be detected by either or both PET radiotracers."

OPALESCENCE study in triple negative breast cancer, now recruiting patients

'OPALESCENCE', is a Phase II study of Telix's TLX250-CDx (^{89}Zr-DFO-girentuximab) in patients with triple negative breast cancer (TNBC).

[1] CA9 is a transmembrane protein that is highly over-expressed in various cancer cells, including TNBC: https://www.ncbi.nlm.nih.gov/gene/768.
[2] TLX591-CDx is awaiting approval in 17 countries for prostate cancer imaging, as the investigational product illuccix®.
[3] https://www.breastcancer.org/symptoms/types/ilc.

The objective of this study is to evaluate the feasibility of using TLX250-CDx PET/CT[4] to detect CA9 expression as the basis of a potential future therapeutic strategy for TNBC.[5] TNBC is a subtype of breast cancer that has poorer prognosis than other breast cancer subtypes. Identifying new targets and treatment strategies for TNBC is a major unmet need, given the aggressive behaviour and distinct patterns of metastasis that characterise this cancer, and the lack of targeted therapies. The study will be led by Dr. Caroline Rousseau at the Institut de Cancérologie de l'Ouest in St Herblain, France, and will recruit 12 patients.

OPALESCENCE is the second of a comprehensive series of studies that will evaluate CA9 expression in cancers other than clear cell renal cell carcinoma (ccRCC), currently the focus of the ZIRCON (imaging) and STARLITE (therapy) studies. The goal of these studies is to evaluate how CA9 imaging can be utilised in cancer diagnosis and staging, and to develop a deeper understanding of the utility of CA9 as a therapeutic target in this patient population. It follows a first patient being dosed in June in the ZiP-UP study of patients with urothelial carcinoma or bladder cancer[6], with other collaborations being developed for head and neck, lung, and pancreatic cancers in order to develop CA9-targeted radiation as a truly pan-cancer approach.

Telix Chief Medical Officer, Dr. Colin Hayward added, "We are privileged to be working with these leading institutions to expedite the evaluation of our technologies in women's health, and in particular in areas where there is an urgent need to provide better options for patients. Both ILC and TNBC can be extremely aggressive and there are unmet needs in both accurate staging and therapeutic delivery. These investigator-led studies support our goal of rapid indication expansion, alongside executing our near term commercial and clinical goals for TLX591-CDx and TLX250-CDx. We would like to express our gratitude to Dr. Schuster, Dr. Rousseau and their respective clinical teams, as well as the patients that will contribute to these ground-breaking studies."

About Breast Cancer

Breast Cancer is the most commonly occurring cancer in women and the second most common cancer overall.[7] In 2020, over 2.2 million women were diagnosed with breast cancer and 685,000 died from their disease.[8]

Lobular breast cancer (also called invasive lobular carcinoma) is a type of breast cancer that begins in the milk-producing glands (lobules) of the breast. It is the second most common type of breast cancer, accounting for 10- 15% of all invasive breast cancers.

Triple-negative breast cancer accounts for 10-15% of all breast cancers with the term *triple-negative* referring to the fact that the cancer cells do not have any of the three markers commonly found on breast cancer cells – the oestrogen and progesterone receptors and HER2 protein. TNBCs differ from other types of invasive breast cancer in that they grow and spread faster, have limited treatment options, and a poorer prognosis.[9]

About TLX591-CDx

TLX591-CDx (Kit for the preparation of ^{68}Ga-PSMA-11) is a proprietary formulation of PSMA-HBED-CC (PSMA-11), a novel imaging agent targeting prostate-specific membrane antigen (PSMA), originally developed by the Heidelberg group of the Deutsches Krebsforschungszentrum (German Cancer Research Centre, DKFZ). The 'cold kit' format of TLX591-CDx enables rapid radiolabelling at room temperature with high radiochemical purity and production consistency.

[4] Positron emission tomography/computed tomography.
[5] ClinicalTrials.Gov Identifier: NCT04758780.
[6] ASX disclosure 23/06/21.
[7] World Cancer Research Fund (WCRF): https://www.wcrf.org/dietandcancer/breast-cancer-statistics/.
[8] GLOBOCAN 2020.
[9] American Cancer Society: https://www.cancer.org/cancer/breast-cancer/about/types-of-breast-cancer/triple-negative.html.

About TLX250-CDx

TLX250-CDx (^{89}Zr-girentuximab) is being developed by Telix for the purpose of determining whether "indeterminate renal masses", typically identified based on CT or MRI imaging, are either clear cell renal cell cancer (ccRCC) or non-ccRCC, using Positron Emission Tomography (PET) imaging. Girentuximab is a monoclonal antibody that targets carbonic anhydrase IX (CAIX), a cell surface target that is highly expressed in several human cancers including renal, lung and oesophageal cancers. In July 2020, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy (BT) designation[10] for TLX250-CDx, reflecting the significant unmet clinical need to improve the diagnosis and staging of ccRCC, the most common and aggressive form of kidney cancer.

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,[11] and is under priority evaluation by the Australian Therapeutic Goods Administration (TGA).[12] Telix is also progressing marketing authorisation applications for illuccix® in the European Union[13] and Canada.[14] None of Telix's products have received a marketing authorisation in any jurisdiction.

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[10] ASX disclosure 1/07/20.
[11] ASX disclosure 24/11/20.
[12] ASX disclosure 14/04/21.
[13] ASX disclosure 1/05/20.
[14] ASX disclosure 16/12/20.