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ASX RELEASE

TLX250-CDx Indication Expansion: Preliminary Data Presented at EANM

- OPALESCENCE Phase II feasibility study of TLX250-CDx in patients with triple-negative breast cancer – early results suggest potential to detect carbonic anhydrase IX (CAIX) expression, theranostic potential in this difficult to treat disease.
- PERTINENCE Early Phase I feasibility study of TLX250-CDx in patients with non-muscle-invasive bladder cancer, a collaboration with ATONCO – early results support translation to first-in-human therapeutic studies with the alpha-emitting radioisotope astatine-211 (^{211}At).
- Both investigator-initiated studies being undertaken by Dr. Caroline Rousseau at the Institut de Cancérologie de l'Ouest (ICO) in St Herblain (France).
- Results delivered at the European Association of Nuclear Medicine (EANM) Annual Congress currently taking place in Barcelona, Spain.

Melbourne (Australia) – 18 October 2022. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces preliminary data from two separate investigator-initiated studies of TLX250-CDx (^{89}Zr-DFO-girentuximab) in triple negative breast cancer (TNBC) and non-muscle-invasive bladder cancer (NMIBC), part of a comprehensive series of studies evaluating CAIX expression in cancers other than clear cell renal cell carcinoma (ccRCC), supporting Telix's goal to rapidly expand the CAIX program into other indications beyond kidney cancer.

OPALESCENCE Phase II study of TLX250-CDx in triple-negative breast cancer reports preliminary data as a top-rated oral presentation at EANM

The primary objective of OPALESCENCE (NCT04758780) is to evaluate how carbonic anhydrase IX (CAIX) targeting imaging with positron emission tomography (PET) can be utilised for the diagnosis and staging of triple-negative breast cancer (TNBC) and to develop a deeper understanding of CAIX as a potential therapeutic target in this patient population with a significant unmet medical need.

Preliminary data demonstrates the feasibility of girentuximab to target CAIX expression in TNBC. Early results suggest potential for girentuximab as an imaging agent and therapeutic in this poor prognosis disease: 83% patient lesions had a CAIX strong expression allowing TLX250-CDx immunoPET detection, showing promise for further investigation. Three patients have all of their lesions detected by TLX250-CDx immunoPET. The best detected metastatic sites are bone.

Based on these results, TLX250-CDx is an attractive novel investigative targeting agent for TNBC and potential alternative to biopsy and immunohistochemistry (IHC) for staging metastatic disease and targeted radioligand therapy.

Should the targeting properties of this PET/CT imaging tracer be established in TNBC, Telix's intention is to broaden future applications for lutetium-177 and actinium-225 based CAIX therapies.

Principal Investigator for the OPALESCENCE study, Dr. Caroline Rousseau stated, "We are pleased to announce preliminary results of this prospective pilot study of Telix's investigational CAIX -targeting imaging agent in TNBC. Early indications are that TLX250-CDx is showing promise as a diagnostic targeting agent in this disease, and we look forward to completing the study and presenting full results."

Telix Chief Medical Officer, Dr. Colin Hayward stated, "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. Whilst a small patient population at this stage, early data from the OPALESCENCE study is encouraging as an indicator for future therapy applications of TLX250 and demonstrating the value of a "theranostic" approach" with this radiolabelled antibody. We would like to thank Dr. Caroline Rousseau and her clinical team at ICO for their commitment to this important study, and the patients who have contributed to date."

PERTINENCE pilot open-label, feasibility study of alpha therapy target reports preliminary data

The objective of PERTINENCE (NCT04897763), an open-label, proof of concept study, is to evaluate safety profile, biodistribution and tumour targeting properties of TLX250-CDx given directly into the bladder in patients with NMIBC and to establish carbonic anhydrase IX (CAIX) as a potential therapeutic target in this condition.

Preliminary data from this feasibility, dosimetry and imaging study at ICO,[1] shows encouraging tumour targeting and biodistribution with TLX250-CDx, and no systemic distribution of radiation.

Based on these results, Telix's partner ATONCO intends to progress TLX250 labelled with the alpha-emitter astatine-211 (^{211}At) into a first-in-human Phase I targeted alpha therapy (TAT) study.

Patients with NMIBC currently have few therapeutic options with the risk of complete cystectomy (bladder removal). Therefore, new treatment options with preservation of the urinary bladder are urgently needed to address unmet medical need. Carbonic anhydrase (CAIX) is a cell surface protein that is highly expressed in many hypoxic solid tumours and a potential therapeutic target in NMIBC using a novel approach with TAT instilled directly into the bladder. This is aligned with Telix's strategy to develop diagnostics and radioconjugates as therapeutics with both alpha and beta emitters in new indications beyond kidney cancer.

Alpha emitters such as ^{211}At have the potential to deliver very high amounts of energy to cancer tissue whilst the short path length can decrease the risk of damage to surrounding healthy cells, increasing both the selectivity and potency of the radiation treatment. The prospective indications for alpha emitters are complementary to beta emitters due to their different properties: alpha therapies have a shorter penetration depth into tumours to suit smaller or disseminated tumours or micro-metastatic disease.

Preliminary Results

Four of six patients refractory to prior BCG therapy are included in current analysis:

- TLX250-CDx PET/CT showed intravesical radioactivity confined to the bladder and good tumour targeting.
- TLX250-CDx positivity was concordant to positive and negative immunohistochemistry results for CAIX expression.
- TLX250-CDx was well tolerated with an encouraging safety profile, suggesting feasibility for future alpha-immunotherapy development in patients with NMIBC.

Principal investigator for the PERTINENCE study, sponsored by ICO, Dr. Caroline Rousseau said, "We are pleased to present preliminary data from this proof-of-concept study of TLX250-CDx in NMIBC. Early results for safety profile, biodistribution and dosimetry are encouraging and support translation to therapeutic studies with the alpha-emitting radioisotope astatine-211 (^{211}At)."

Telix Chief Medical Officer, Dr Colin Hayward and ATONCO Chief Medical Officer, Dr Jean-François Chatal together added, "These results are an important step towards using TLX250 with an alpha emitting isotope for the first time in humans." Dr Colin Hayward continued, "Telix is looking forward

[1] Telix press release 24 August 2022.

to continuing to support ATONCO in its development of ^{211}At-labelled TLX250 for patients with NMIBC and establishing CAIX as a therapeutic target beyond kidney cancer in a series of important scientific studies."

About Carbonic Anhydrase IX (CAIX)

CAIX is a transmembrane protein that is highly over-expressed in clear cell renal cancer (ccRCC) as well as a number of other different cancer types, with very limited expression on normal healthy tissues, making it an attractive potential target for both new imaging and therapeutic modalities. Telix's core CAIX program is focused on ccRCC, the most common and aggressive form of kidney cancer, and is the subject of the ZIRCON Phase III (imaging) study, which recently completed enrolment,[2] and the STARLITE Phase II (therapy) studies.[3] In addition to OPALESENCE in TNBC, and PERTINENCE in NMIBC, a study targeting CAIX is also underway in urothelial carcinoma or bladder cancer,[4] with other collaborations being developed for ovarian, colorectal, head and neck, lung, and pancreatic cancers.

About Triple-Negative Breast Cancer

Breast cancer is the most common cancer in women and the second most common cancer overall.[5] In 2020, over 2.2 million women were diagnosed with breast cancer and 685,000 died from their disease.[6] Triple-negative breast cancer accounts for about 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.[7]

About Bladder Cancer

Bladder cancer is the sixth most commonly occurring cancer in men, and the tenth most common cancer overall worldwide.[8] In 2020, 573,278 people worldwide were diagnosed with bladder cancer and 212,536 people died from their disease.[9] NMIBC is found in the tissue that lines the inner surface of the bladder and is responsible for approximately 75-85% of newly diagnosed bladder cancers.[10]

About TLX250-CDx

TLX250-CDx (^{89}Zr-girentuximab) is an investigational product being developed by Telix for the purpose of non-invasive detection of ccRCC in patients with "indeterminate renal masses" (IDRMs). IDRMs are typically identified based on computed tomography (CT) or magnetic resonance imaging (MRI) and are an increasing medical dilemma as more scans are performed and more IDRMs are identified. Girentuximab is a monoclonal antibody that targets 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 for TLX250-CDx,[11] reflecting the significant unmet clinical need to improve the characterization of IDRMs previously identified on CT or MRI as ccRCC or non-ccRCC. TLX250-CDx does not currently hold a marketing authorisation in any jurisdiction worldwide.

About the Institut de Cancérologie de l'Ouest (ICO)

[2] ASX disclosure 11 July 2022.
[3] ASX disclosure 14 September 2021.
[4] ASX disclosure 23 June 2021.
[5] World Cancer Research Fund (WCRF): https://www.wcrf.org/dietandcancer/breast-cancer-statistics/.
[6] GLOBOCAN 2020.
[7] American Cancer Society: https://www.cancer.org/cancer/breast-cancer/about/types-of-breast-cancer/triplenegative.html.
[8] World Cancer Research Fund (WCRF).
[9] Globocan 2021.
[10] Somuncu et al. *Nature*. 2020.
[11] ASX disclosure 1 July 2020.

ICO is a 1,400 professional strong not-for-profit center fighting against cancer. It welcomes close to 48,000 patients per year, and conducts the mission and service of a public hospital. Strengthened by its 4 missions – Prevention, Care, Research and Teaching – ICO offers broad, state-of-the-art expertise that is exclusively dedicated to cancerology.

The integration of care, research and innovation is integral to ICO. Research activities, which are a specific mission at ICO, are undertaken from concept all the way through to clinical trials. Research is conducted in all disciplines of cancerology: medical oncology, radiotherapy, surgery, anaesthesia, nuclear medicine, medical imagery, support care, and human sciences. Patients who are cared for at ICO receive privileged access to cutting edge clinical trials in cancerology. The Innovation Centre, opened in 2021, is dedicated to accompanying innovation in oncology, and thus supports internal and external projects, from concept, all the way to operational deployment.
For more information contact: promotionrc@ico.unicancer.fr

About ATONCO

ATONCO is a privately held French company that develops molecularly targeted radiopharmaceuticals for oncology applications. Originating from the world-class nuclear medicine cluster in Nantes, France, ATONCO and its partners are committed to the clinical use of alpha-emitting radionuclides, in particular astatine-211 (^{211}At).
For more information visit https://atonco-pharma.com/ or contact: info@atonco-pharma.com

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic radiopharmaceuticals. Telix is headquartered in Melbourne, Australia with international operations in the United States, Europe (Belgium and Switzerland), and Japan. Telix is developing a portfolio of clinical-stage products that aims to 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 product, gallium-68 (^{68}Ga) gozetotide (also known as ^{68}Ga PSMA-11) injection, has been approved by the U.S. Food and Drug Administration (FDA),[12] and by the Australian Therapeutic Goods Administration (TGA),[13] and by Health Canada.[14]

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This announcement has been authorised for release by the disclosure committee of Telix Pharmaceuticals Limited.

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[12] ASX disclosure 20 December 2021.
[13] ASX disclosure 2 November 2021.
[14] ASX disclosure 14 October 2022.

achievements expressed or implied by these forward-looking statements. Forward-looking statements are based on the Company's good-faith assumptions as to the financial, market, regulatory and other risks and considerations that exist and affect the Company's business and operations in the future and there can be no assurance that any of the assumptions will prove to be correct. In the context of Telix's business, forward-looking statements may include, but are not limited to, statements about: the initiation, timing, progress and results of Telix's preclinical and clinical studies, and Telix's research and development programs; Telix's ability to advance product candidates into, enrol and successfully complete, clinical studies, including multi-national clinical trials; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities; the commercialisation of Telix's product candidates, if or when they have been approved; estimates of Telix's expenses, future revenues and capital requirements; Telix's financial performance; developments relating to Telix's competitors and industry; and the pricing and reimbursement of Telix's product candidates, if and after they have been approved. Telix's actual results, performance or achievements may be materially different from those which may be expressed or implied by such statements, and the differences may be adverse. Accordingly, you should not place undue reliance on these forward-looking statements. You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the ASX or on our website.

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