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First Patient Dosed in CUPID Study of Telix's Targeted Alpha Therapy Candidate for Prostate Cancer

Melbourne (Australia) – 5 August 2021. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') announces today that the first patient has been dosed in its 'CUPID' first-in-human Phase I study of the Company's next generation prostate cancer therapy candidate TLX592 in patients with advanced prostate cancer.

The objective of the CUPID (^{64}Cu PSMA Imaging and (Bio)Distribution) study is to evaluate the safety, tolerability, pharmacokinetics, biodistribution and radiation dosimetry of TLX592. This investigational agent will become Telix's first targeted alpha therapy ("TAT") for the treatment of patients with advanced prostate cancer. The CUPID study, which is being conducted in collaboration with GenesisCare, will recruit up to 15 patients and will initially use copper-64 (^{64}Cu)-labelled TLX592, as a positron emission tomography (PET) imaging agent, to evaluate biodistribution and dosing, before proceeding to studies with actinium-225 (^{225}Ac) TAT.

TLX592 targets prostate specific membrane antigen (PSMA)[1], as does the Company's existing TLX591 (^{177}Lu-rosapatamab) prostate cancer therapy program. However, TLX592 has been engineered with Telix's proprietary RADmAb® antibody technology to clear far more rapidly from a patient's circulation than unmodified antibodies, while maintaining TLX591's specificity for tumour-expressed PSMA and hepatic (liver) clearance, rendering it potentially more suitable for use as a targeting agent for ^{225}Ac, a potent therapeutic alpha emitting radionuclide.[2]

Principal Investigator for the CUPID study and GenesisCare Group Clinical Director (Theranostics) Clinical Professor Nat Lenzo stated, "The initiation of the Phase I CUPID PET imaging study represents a significant milestone in the development of next generation alpha particle treatments, a promising new frontier in nuclear medicine, with the potential to significantly improve outcomes for patients. The very high energy, short range properties of targeted alpha therapy have the potential to offer a potent and highly selective anti-cancer therapy to patients with advanced prostate cancer."

Founder and Chief Executive Officer of GenesisCare, Dan Collins, said: "As one of the largest global providers of integrated cancer care, GenesisCare is uniquely positioned to partner with leading research institutions and pharmaceutical companies on bold new solutions to bring patients world-class cancer care, closer to home. We are proud to partner with Telix Pharmaceuticals on the CUPID trial which may bring new hope to thousands of men living with prostate cancer in Australia and around the globe."

Telix CEO, Dr. Christian Behrenbruch added, "One of Telix's key objectives is to establish category leadership in urologic oncology, thereby being able to offer patients with prostate cancer a broad suite of state-of-the-art diagnostic imaging and therapeutic options. With this objective in mind, TLX592 represents Telix's most significant proprietary antibody development to date. It is our aim to develop this program for both the early stages of metastatic prostate cancer, as well as for later stage patients no longer responding to lutetium therapy, in tandem with the ^{177}Lu-based TLX591. We wish to express our gratitude to Professor Nat Lenzo and his clinical collaborators, as well as the patients who have made this important milestone possible."

[1] Prostate-specific membrane antigen is a target highly expressed by prostate cancer cells.
[2] Refer to ASX disclosure 2/12/2020 for detailed briefing on CUPID study, TLX592 and targeted alpha therapy.

About the CUPID Study

CUPID (^{64}Cu PSMA Imaging and (Bio)Distribution) is a first-in-human, open-label, Phase I, dose escalation trial that will evaluate the safety, tolerability, pharmacokinetics, biodistribution and radiation dosimetry of TLX592 using positron emission tomography (PET) imaging, in up to 15 patients with advanced prostate cancer.[3] The CUPID study will employ ^{64}Cu-labelled TLX592 to enable PET imaging and evaluation of the study endpoints, prior to commencing therapeutic studies with ^{225}Ac-labelled TLX592, Telix's first Targeted Alpha Therapy (TAT) candidate. The use of ^{64}Cu is for drug development purposes only.

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,[4] and is under priority evaluation by the Australian Therapeutic Goods Administration (TGA).[5] Telix is also progressing marketing authorisation applications for Illuccix® in the European Union[6] and Canada.[7] None of Telix's products have received a marketing authorisation in any jurisdiction.

About GenesisCare

Sydney-headquartered GenesisCare is an Australian-founded global healthcare company and one of the largest integrated oncology companies. The company's mission is to design care experiences that get the best possible life outcomes. This is grounded in the belief that care should be focused on the individual, not the condition.

GenesisCare is the world's largest provider of radiotherapy – an important treatment option for cancer patients – and provides patients with access to diagnostics, medical oncology, surgical oncology, radiotherapy, and novel therapies alongside the ability to participate in the latest clinical trials. With a growing research and trials program numbering more than 150 clinical trials, a contract research organization, and global innovation programs focused on precision medicine and novel therapies, GenesisCare aims to bring new therapies to more patients in need in a more affordable way.

Every year, GenesisCare clinical teams see more than 400,000 people at more than 440 locations. For cancer treatment, that includes more than 300 locations in the U.S., 38 locations in Australia, 14 in the UK and 21 in Spain, with more than 30 new centers under development. The organization employs more than 5,500 highly trained physicians, healthcare professionals and support staff across Australia, Europe, and now the U.S. GenesisCare also offers cardiology and sleep services at more than 80 locations across Australia. For more information visit http://www.genesiscare.com/

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[3] ClinicalTrials.gov Identifier: NCT04726033.
[4] ASX disclosure 24/11/2020.
[5] ASX disclosure 7/12/2020.
[6] ASX disclosure 1/5/2020.
[7] ASX disclosure 16/12/2020.

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