

First Patient Dosed in Phase II STARBURST Study of TLX250-CDx Exploring Indication Expansion

Melbourne (Australia) – 19 June 2023. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that the first patient has been dosed in a Phase II study of the Company's carbonic anhydrase- (CAIX)-targeting PET/CT¹ imaging agent TLX250-CDx (⁸⁹Zr-DFO-girentuximab), exploring this potential target across a broad range of cancer indications.

The STARBURST study (ClinicalTrials.gov Identifier: [NCT05563272](https://clinicaltrials.gov/ct2/show/study/NCT05563272)) is a prospective, open label Phase II “basket” study to investigate CAIX expression in patients with a diverse range of solid tumours – including breast, cervix, colorectal, gastric, esophageal, head and neck, lung, ovarian, pancreatic and vulval cancers² – for potential diagnostic and therapeutic applications.

CAIX is a protein overexpressed on the surface of clear cell renal cell carcinoma (ccRCC), the cancer target in Telix's highly successful Phase III ZIRCON study.³ It is also expressed to varying degrees in many other advanced-stage solid tumours with poor prognosis. Tumours that express CAIX are typically hypoxic, more aggressive and feature a tumour micro-environment (TME) that can be resistant to therapy, particularly immunotherapies.

STARBURST is exploring these tumour types in the refractory setting to assess whether tumour sites can be targeted, both for imaging and potentially therapeutic purpose. The study builds on encouraging preliminary data from two investigator-initiated studies in triple-negative breast cancer and non-muscle-invasive bladder cancer, which demonstrate the potential of TLX250-CDx in these disease settings with unmet medical need. The half-life of ⁸⁹Zr means that imaging these tumours with TLX250-CDx will enable predictive dosimetry for therapeutic radionuclides, effectively serving as a theranostic “scouting” study for future studies harnessing therapeutic radionuclides.

Principal Investigator for the STARBURST study, Dr Jackson Kiser, Medical Director Molecular Imaging at Carilion Clinic in Roanoke, Virginia (U.S.) stated, “CAIX is a cancer target that has now been validated in Telix's Phase III ZIRCON study in ccRCC, and so it is very interesting to explore expanding the potential utility of the same investigational agent in a series of other tumour types known to express this important target.”

Dr Colin Hayward, Telix Chief Medical Officer, said, “Building on the success of ZIRCON and positive preliminary results in investigator-initiated studies of TLX250-CDx in bladder and breast cancer,⁴ dosing a first patient in the STARBURST study is a strategically important milestone for Telix. This study will add value and clinical insight to the platform and enable Telix to assess the potential of CAIX as a biomarker as we continue to scout the theranostic potential of targeting CAIX beyond renal cancer. We would like to thank Dr Kiser and his clinical team at Carilion Clinic, as well as the patients who will contribute to the study.”

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

¹ Positron emission tomography/computed tomography.

² Literature reports of CAIX expression.

³ Telix ASX disclosure 7 November 2022.

⁴ Telix ASX disclosure 18 October 2022.

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).

Visit www.telixpharma.com for further information about Telix, including details of the latest share price, announcements made to the ASX, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on [Twitter](#) (@TelixPharma) and [LinkedIn](#).

Telix's lead product, gallium-68 (⁶⁸Ga) gozetotide (also known as ⁶⁸Ga PSMA-11) injection, has been approved by the U.S. Food and Drug Administration (FDA),⁵ and by the Australian Therapeutic Goods Administration (TGA),⁶ and by Health Canada.⁷ Telix is also progressing a marketing authorisation application for this investigational candidate in the United Kingdom and the European Union.⁸

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This announcement has been authorised for release by the Telix Pharmaceuticals Limited Disclosure Committee on behalf of the Board.

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⁵ Telix ASX disclosure 20 December 2021.

⁶ Telix ASX disclosure 2 November 2021.

⁷ Telix ASX disclosure 14 October 2022.

⁸ Telix ASX disclosure 3 April 2023.