Telix Doses First Patient in Phase 3 LUTEON Trial of TLX250-Tx for Renal Cancer

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- First patient dosed in Phase 3 LUTEON[1] trial evaluating TLX250-Tx in relapsed or recurrent clear cell renal cell carcinoma (ccRCC).
- LUTEON is the first Phase 3 study of a CAIX[2]-targeted radiopharmaceutical therapy in ccRCC.

MELBOURNE (Australia) and INDIANAPOLIS, July 21, 2026 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today announced that the first patient has been dosed with TLX250-Tx (lutetium-177 (^{177}Lu) girentuximab tetraxetan) in the LUTEON study, the first radiopharmaceutical therapy to enter Phase 3 development for ccRCC. LUTEON is a randomized, prospective, open label, multi-center study evaluating a CAIX-targeting radionuclide therapy in patients with relapsed or recurrent ccRCC.

The patient was dosed at GenesisCare Murdoch (Western Australia), under the supervision of Dr. Aviral Singh.

Dr. Aviral Singh, Clinical Head of Theranostics and Nuclear Medicine at GenesisCare Murdoch and Principal Investigator on the LUTEON trial, commented, "Dosing the first patient in the LUTEON study marks an important milestone in the development of potential new treatment options for patients with relapsed or recurrent clear cell renal cell carcinoma. Despite advances in care, outcomes remain poor for many patients, underscoring the need for innovative therapeutic approaches. This study will play a critical role in evaluating the safety, tolerability and efficacy of this investigational CAIX-targeted radiopharmaceutical for patients globally, and we look forward to helping advance the clinical evidence for this promising therapeutic candidate."

Dr. David N. Cade, Telix Group Chief Medical Officer, added, "LUTEON represents the next stage in Telix's global clinical development of TLX250-Tx and reflects our commitment to developing precision radiopharmaceuticals for patients with difficult-to-treat cancers. We aim to further evaluate the potential of TLX250-Tx that is designed to utilize the high prevalence of CAIX expression in ccRCC to deliver targeted radiation directly to tumor sites, while limiting exposure to healthy tissue."

About TLX250-Tx

TLX250-Tx is a first-in-class CAIX-targeting rADC[3] therapy candidate composed of a high-specificity monoclonal antibody chelated to the therapeutic radionuclide lutetium-177. CAIX is an attractive therapeutic target because it is expressed in more than 95% of ccRCC, while demonstrating limited expression in normal tissues, including kidney tissue[4,5].

LUTEON is being run under a Phase 3 protocol in Australia and forms part of Telix's global development program for TLX250-Tx, which includes the separate Phase 2a LUTEON ATLAS study in the United States and Europe.

The LUTEON study utilizes Telix's investigational PET [6] imaging agent, TLX250-Px (Zircaix®[7], zirconium-89 (^{89}Zr) girentuximab senvedoxam), to identify eligible patients with CAIX-positive tumors.

About clear cell Renal Cell Carcinoma

Renal Cell Carcinoma, RCC, is the most common form of kidney cancer, accounting for approximately 9 out of 10 diagnoses[8]. Within this category, ccRCC is the most common and often the most aggressive subtype, representing about 85% of all RCC cases[9] with up to 30% of patients presented with metastatic disease at diagnosis, which has a 20% 5-year survival rate[10,11].

About Telix Pharmaceuticals Limited

Telix Pharmaceuticals (ASX: TLX, NASDAQ: TLX) is a commercial-stage global radiopharmaceutical company, advancing targeted theranostics to improve outcomes for people with cancer across the patient journey. Theranostics pairs a precision diagnostic with a targeted therapy to both diagnose and treat disease.

Telix's commercial franchise is anchored by its prostate cancer imaging portfolio: Illuccix® (kit for the preparation of gallium-68 gozetotide injection), commercially available in 22 countries including the U.S. and Gozellix® (kit for the preparation of gallium-68 gozetotide injection), approved by the U.S. Food and Drug Administration (FDA). The Company's late-stage therapeutic pipeline includes three assets in pivotal-stage trials - TLX591-Tx (lutetium-177 (^{177}Lu) rosopatamab tetraxetan) in prostate cancer, TLX101-Tx (^{131}I-iodofalan) in recurrent glioblastoma, TLX250-Tx (lutetium (^{177}Lu) girentuximab tetraxetan) in kidney cancer, complemented by a deep pipeline of next generation assets. TLX250-Tx and TLX250-Px have not received a marketing authorization in any jurisdiction.

Telix is headquartered in Melbourne, Australia, with operations across North America, Europe, Latin America and Asia-Pacific. For more information, visit www.telixpharma.com or follow Telix on LinkedIn, X and Facebook.

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