Telix Announces First Patient Dosed in First-in-Human ZOLAR Trial of TLX300-CDx in Advanced Soft Tissue Sarcoma

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MELBOURNE, Australia, April 02, 2025 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX; NASDAQ: TLX, Telix, the Company) today announces that a first patient has been dosed in the Phase 1 ZOLAR[1] trial of TLX300-CDx (^{89}Zr-olaratumab) in patients with advanced, metastatic soft tissue sarcoma (STS) at the Melbourne Theranostic Innovation Centre (MTIC) in Melbourne, Australia.

ZOLAR is a first-in-human, proof-of-concept and biodistribution trial that uses positron emission tomography (PET) to evaluate olaratumab, a monoclonal antibody, as a therapeutic radiopharmaceutical targeting platform. Olaratumab targets platelet-derived growth factor receptor alpha (PDGFRα) a cell surface protein often over-expressed in STS.

The aim of the trial is to evaluate the safety, pharmacokinetics, biodistribution and dosimetry, and establish the optimal dose of TLX300-CDx in patients with advanced STS, prior to therapeutic studies, based on a theranostic approach. As part of the study, it is also expected that the patient dosimetry and target expression characteristics will inform the final selection of therapeutic radionuclide for this candidate, in conjunction with currently active non-clinical radiation biology studies.

Telix intends to develop a novel targeted radionuclide therapy, specific for PDGFRα, which could be used to treat patients with STS. Telix holds the exclusive worldwide rights to develop and commercialize radiolabelled forms of olaratumab, which was originally developed by Eli Lilly and Company (Lilly).

Professor Rodney Hicks AM, Founder, Chair, and Chief Medical Officer at MTIC, and Principal ZOLAR Investigator, said, “Sarcomas are individually very rare and they can arise from a variety of different tissues. Unfortunately, they tend to respond rather poorly to chemotherapy. While localized STS generally responds to radiotherapy, it is challenging to treat once it has spread. Targeted radionuclide therapy, which targets cancer cells throughout the body, is therefore an attractive option to treat disseminated disease. At MTIC, we're fortunate to be the first site validating this investigational agent as a precision diagnostic and to inform the design of future therapeutic studies.”

Dr. David N. Cade, Telix Group Chief Medical Officer, added, “We are pleased that a first patient has been imaged in the first-in-human ZOLAR trial, which is designed to inform both the potential efficacy (dosimetry) and safety profile of this research candidate as a therapeutic, based on a theranostic approach. We would like to thank Professor Hicks and his team at MTIC for their commitment to addressing unmet medical need in STS, as well as the patients who will contribute to this important trial.”

Visit the Telix website to view a short video of Professor Hicks explaining the theranostic approach in soft tissue sarcoma here.

TLX300-CDx has not received a marketing authorization in any jurisdiction.

About Soft Tissue Sarcoma (STS)

Soft tissue sarcoma is a complex disease that encompasses a diverse group of relatively rare cancers, with more than 50 malignant histological subtypes. In the United States (U.S.), it is estimated that there will be approximately 13,520 new diagnoses and 5,420 deaths from STS in 2025, representing 0.66% of overall cancer incidence and 0.88% of overall cancer mortality[2]. Standard treatment for soft tissue sarcoma includes surgery, radiation therapy and/or chemotherapy. For patients with advanced, unresectable, or metastatic disease, treatment typically involves chemotherapy with single agents (e.g., doxorubicin) or anthracycline-based combination regimens. However, the prognosis for these patients remains poor, with treated patients with metastatic disease having a median overall survival of around 12–18 months[3].

About olaratumab

Olaratumab (previously marketed under the brand name, Lartruvo®) was originally developed by Lilly as a monoclonal antibody targeting PDGFRα. Olaratumab was granted "Accelerated Approval" in the U.S. and "Conditional Approval" in the EU based on Phase 2 trial data. Olaratumab was voluntarily withdrawn from the market by Lilly following the failure of the Phase 3 ANNOUNCE clinical trial, in which olaratumab in combination with standard chemotherapy did not improve survival for patients compared to chemotherapy alone.

In April 2022, Telix secured the exclusive worldwide rights to develop and commercialize radiolabelled forms of olaratumab for the diagnosis and treatment of human cancers[4]. Olaratumab has a well-established clinical safety profile and a favorable toxicology dataset, which Telix is leveraging for radiopharmaceutical development.

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals and associated medical technologies. Telix is headquartered in Melbourne, Australia, with international operations in the United States, Canada, Europe (Belgium and Switzerland), and Japan. Telix is developing a portfolio of clinical and commercial stage products that aims to address significant unmet medical needs in oncology and rare diseases. ARTMS, IsoTherapeutics, Lightpoint, Optimal Tracers and RLS are Telix Group companies. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (NASDAQ: TLX).

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[1] ClinicalTrials.gov ID: NCT06537596.

[2] American Cancer Society 2025.

[3] In et al. *Ther Adv Med Oncol.* 2017.

[4] Telix ASX disclosure 11 April 2022.