# Telix Doses First Patient in SOLACE Trial for Metastatic Bone Pain

22 Oct 2025

MELBOURNE, Australia and INDIANAPOLIS, Oct. 23, 2025 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today announces that it has dosed the first patient in a Phase 1 clinical trial of TLX090 ( $^{153}$Samarium (Sm)-DOTMP), a therapeutic radiopharmaceutical candidate for treating pain associated with bone metastasis.

TLX090 is designed to deliver targeted radiation to bone tumors while minimizing damage to surrounding healthy tissues. SOLACE (Samarium Optimized for Long-lasting Analgesia in Cancerous End-stage bone pain) is an open-label Phase 1 clinical trial enrolling up to 33 patients with advanced cancer that has metastasized to the bony skeleton[1]. The trial is designed to evaluate the pharmacokinetics, dosimetry, safety, and pain palliation of TLX090, a next-generation radiopharmaceutical candidate optimized for improved safety profile and efficacy. Data from SOLACE aims to establish clinical comparability to legacy $^{153}$Sm treatments, which in turn is expected to support a streamlined registration pathway as an analgesic, paving the way for a much-needed, non-opioid solution for patients living with bone pain in the late stages of advanced cancer.

Pain from osteoblastic bone metastases is one of the most common and debilitating symptoms in advanced cancer, with approximately 400,000 new cases diagnosed[2] each year. Up to 90% of patients with metastatic prostate cancer[3,4] are affected, contributing to reduced quality of life and mental health. Despite the availability of opioids and external beam radiation therapy (EBRT), many patients remain under-treated — underscoring a critical unmet need for a systemic, targeted, and non-opioid solution that can deliver durable relief across multiple cancer types.

The current standard of care can provide only partial relief[5] and comes with significant drawbacks. Opioids are associated with sedation, constipation, dependency, and regulatory scrutiny, especially in the post-Purdue litigation era[6]. Health systems face high costs and administrative burdens in managing chronic opioid use, including monitoring, compliance, and risk mitigation. EBRT is often ineffective[7] as it is localized, logistically intensive, and not suitable for patients with multifocal or diffuse bone pain.

By comparison, TLX090 offers the potential for a cost-effective, systemic, targeted and non-opioid alternative that may treat pain, reduce reliance on chronic pain medications and improve quality-of-life through a single administration that could deliver up to 3-4 months of pain relief, with the ability to provide repeat doses. An earlier study[8] demonstrated a favorable early safety profile and encouraging efficacy signal, while the potential to treat pain associated with multiple cancer types expands Telix's clinical reach into disease areas such as prostate, and breast cancer. The novel cold-kit formulation and pharmacy-based distribution of TLX090 may also aid in overcoming barriers to treatment due to cost and supply chain limitations associated with legacy products.

Julio A. Peguero MD, Medical Director of Research, Oncology Consultants, Houston (TX), said, "We are proud to support the SOLACE trial, which brings new hope to patients living with metastatic bone pain. Existing treatments often fall short—whether through limited effectiveness, incomplete pain relief, or burdensome side effects. TLX090 offers the potential for a better tolerated and more effective approach to pain management, with the goal of meaningfully improving patients' quality of life."

David N. Cade MD, Group Chief Medical Officer, Telix, said, "Even with the introduction of new treatments, including targeted radiation therapy, most metastatic cancer patients will eventually progress and need treatment for bone pain. TLX090 has the potential to bridge cancer treatment and quality-of-life care by offering a single-dose, systemic option for these patients addressing the significant unmet need across multiple cancer types. This presents a major clinical opportunity, aligned with our commitment to prostate cancer, and a potential commercial entry point into the therapeutic market. Thank you to Oncology Consultants in Houston for partnering with us on this important clinical trial."

TLX090 has not received a marketing authorization in any jurisdiction.

**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, United Kingdom, Brazil, 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. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (NASDAQ: TLX).

Visit www.telixpharma.com for further information about Telix, including details of the latest share price, ASX and U.S. Securities and Exchange Commission (SEC) filings, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on LinkedIn, X and Facebook

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[1] ClinicalTrials.gov ID: NCT07197645.

[2] Huang et al. *Ann Transl Med*. 2020.

[3] Guo et al. *Skelet Radiol.* 2025

[4] Woolf et al. *Annals of Oncology.* 2015.

[5] Corli et al. *Annals of Oncology.* 2016.

[6] The period following the landmark legal actions against Purdue Pharma, the maker of OxyContin, for its role in the U.S. opioid crisis.

[7] De Felice et al. *Oncotarget.* 2017; Huisman et al. *Int J Radiat Oncol Biol Phys.* 2012.

[8] QSAM-101 Study data on file.