



Telix FAP-targeting Therapeutic Published in Thyroid Journal: Demonstrates Encouraging Efficacy

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MELBOURNE, Australia and INDIANAPOLIS, May 08, 2025 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, Telix, the Company) today announces that its Fibroblast Activation Protein (FAP)-targeting therapy candidate, TLX400, has been published in *Thyroid*, the official journal of the American Thyroid Association. The candidate demonstrated an encouraging safety profile and efficacy in aggressive, radioiodine-resistant (RAI-R) thyroid cancer¹.

TLX400 (¹⁷⁷Lu-DOTAGA.Glu.(FAPi)₂) has been in-licensed by Telix as part of a portfolio of next-generation therapeutic and diagnostic ("theranostic") radiopharmaceutical candidates². TLX400 has potential clinical utility in several oncology indications. The publication provides further validation of the safety profile and potential efficacy of Telix's lead FAP therapeutic candidate.

In this peer-reviewed manuscript, Dr. Sanjana Ballal and colleagues report results from 73 heavily pre-treated patients with RAI-R follicular thyroid carcinoma³. The authors conclude that TLX400 therapy demonstrated a promising safety profile and efficacy in aggressive, RAI-R thyroid cancer, achieving a median progression-free survival (PFS) and overall survival (OS) of 29 and 32 months, respectively, with a manageable adverse event profile.

The therapeutic approach to radioiodine-refractory thyroid cancer has advanced with tyrosine kinase inhibitors (TKIs) such as sorafenib and lenvatinib, supported by the DECISION trial⁴ and SELECT study⁵ results. However, their potential risks, including significant side effects, require careful management, particularly in patients with comorbidities such as cardiac issues, hypertension, stroke, and kidney dysfunction, who may not be optimal candidates for TKI therapy. Lutetium-177 (¹⁷⁷Lu)-FAP inhibitor therapy marks a significant advancement in thyroid cancer theranostics, where FAP in cancer-associated fibroblasts (CAFs) influences the tumor microenvironment (TME), angiogenesis, and chemotherapy resistance. CAFs interact with cancer cells, fostering tumor growth and aggressiveness, highlighting their significance as therapeutic targets and in elucidating tumor progression mechanisms.

Dr. Sanjana Ballal, Senior Researcher at the All India Institute of Medical Sciences (AIIMS, New Delhi), investigator and lead author, commented, "This preliminary study highlights the promising safety profile and efficacy of TLX400 therapy in aggressive radioiodine-resistant thyroid cancer, including refractory cases. Notably, in the cohort of patients with reported efficacy, the treatment demonstrated median OS and PFS durations of 32 and 29 months, with a promising 50% partial response rate. Adverse events, primarily hematotoxicity – typical of radiopharmaceuticals – were manageable, emphasizing potential as a promising treatment option for this challenging patient population."

TLX400 is differentiated by a novel structure that drives prolonged tumor retention while minimizing off-target uptake, designed to overcome the limitations seen with first-generation FAP-targeting compounds. These candidates have extensive pre-clinical and clinical data covering a range of tumors⁶. Telix is exploring the clinical utility of the FAP portfolio across a range of solid tumors, including bladder cancer.

Dr. David N. Cade, Group Chief Medical Officer, Telix, added, "We are highly encouraged by these data for TLX400, which compare favourably to TKIs – the standard of care treatment in patients with thyroid cancer – for OS and PFS. This provides further validation of the safety profile and efficacy potential enabled by the novel design of these FAP-targeting therapeutic candidates."

The *Thyroid* publication is available online at: <https://www.liebertpub.com/doi/10.1089/thy.2024.0229>

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, 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. 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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TLX400 has not received a marketing authorization in any jurisdiction.

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¹ Ballal et al. *Thyroid*. 2025. <https://www.liebertpub.com/doi/10.1089/thy.2024.0229>

² Telix ASX disclosure 12 March 2025.

³ The data were collected as part of a compassionate use program covered by an overarching protocol, approved by the institutional ethics board.

⁴ Brose et al. *Lancet*. 2014.

⁵ Schlumberger et al. *N Engl J Med*. 2015.

⁶ See Telix investor presentation lodged with the ASX on 19 November 2024.