IPAX-Linz Study Reports Promising Efficacy for TLX101 Glioma Therapy Candidate

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MELBOURNE, Australia and INDIANAPOLIS, April 16, 2025 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, Telix, the Company) today announces preliminary results from the Phase 2 IPAX-Linz study of TLX101 (^{131}I-iodofalan[1]) in recurrent high-grade glioma (brain cancer), substantiating the patient benefit seen in the IPAX-1 study[2].

IPAX-Linz is a single-arm Phase 2 investigator-initiated trial (IIT). IPAX-Linz evaluates the safety, tolerability and preliminary efficacy of TLX101 therapy, in combination with external beam radiation therapy (EBRT). The target patient population is patients at first or second recurrence with high-grade gliomas (HGG), including glioblastoma.

Treatment with TLX101 was well tolerated with no serious adverse events reported. IPAX-Linz demonstrated encouraging preliminary efficacy data, indicating a median overall survival (OS) of 12.4 months from the initiation of treatment with TLX101, or 32.2 months from initial diagnosis[3]. This is consistent with the positive efficacy signal generated in the IPAX-1 study in patients at first recurrence, with only one prior resection and treatment with standard chemoradiotherapy. IPAX-1 reported a median OS of 13 months from the initiation of treatment with TLX101, or 23 months from initial diagnosis[4]. In comparison, recurrent glioblastoma patients treated with EBRT alone have a reported median survival of 9.9 months from treatment[5].

Eight patients were included in the study with adaptive dosing of intravenous TLX101 up to administered activity of 4 GBq before, and up to 2 GBq after, second line EBRT, administered in sequential injections. Inclusion criteria comprised patients with glioblastoma with current evidence of first or second recurrence after standard radiochemotherapy, at least six months since end of first line EBRT, and molecular imaging with Telix's investigational PET[6] agent for glioma, TLX101-CDx (Pixclara®[7], ^{18}F-floretyrosine, or ^{18}F-FET), indicating pathologically increased amino acid uptake. Surgery for relapsed tumors was allowed. Of the eight IPAX-Linz patients, five had MGMT unmethylated tumors[8], typically associated with especially poor prognosis.

Professor Josef Pichler, Kepler University Hospital, Austria, Principal Investigator in the IPAX-Linz, IPAX-1, and IPAX-2 studies, commented, “These preliminary results in relapsed patients showed that TLX101 treatment was very well tolerated, with no serious adverse events, at a higher dose than in previous studies. Early efficacy from IPAX-1 was corroborated, despite the poor prognostic parameters with MGMT unmethylated tumors and multiple relapses before commencing experimental therapy in this IPAX-Linz study. TLX101 continues to show significant potential to improve outcomes for patients living with high-grade glioma. These results also potentially support higher therapeutic doses in subsequent prospective controlled studies.”

Dr. David Cade, Chief Medical Officer at Telix, said, “These are encouraging results, offering new options for patients with historically poor outcomes. We are grateful to Dr. Pichler and his team for building on the IPAX-1 study in a more advanced and complex study cohort that is also representative of a real-world patient population.”

Preliminary results from IPAX-Linz will be presented by Dr. Pichler at the Nuclear Medicine and Neurooncology (NMN) Symposium taking place in Vienna, Austria from 9 – 10 May 2025. Visit the event website for further information: https://www.nmn-society.org/

TLX101 Development Program and Registration-Enabling Study Update

Telix continues to investigate TLX101 in front-line and recurrent settings. IPAX-2, a Phase 1/2 study in front-line glioblastoma in combination with standard of care and using TLX101-CDx as a companion diagnostic, continues to recruit patients.

Telix has submitted for ethics approval a registration-enabling study of TLX101 in recurrent glioblastoma. Subject to approval this will enable patient enrolment to commence at Australian sites in H2 2025, ahead of international expansion. Following the successful pre-IND[9] meeting with the U.S. Food and Drug Administration (FDA) in Q4 2024, the Company is also on track to submit an IND application in H1 2025, with the goal of commencing the study at U.S. sites in H2 2025.

About TLX101

TLX101 (^{131}I-iodofalan or ^{131}I-IPA) is a systemically administered targeted radiation therapy that targets L-type amino acid transporter 1 (LAT1), which is typically over-expressed in glioblastoma. TLX101 therapy utilizes a small molecule approach due to the need to cross the blood brain barrier, the normal protective barrier that prevents many potential drug candidates entering the brain. TLX101 has received orphan drug designation in the U.S. and Europe for the treatment of glioma. TLX101 and TLX101-CDx have 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, 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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This announcement has been authorised for release by the Telix Pharmaceuticals Limited Disclosure Committee on behalf of the Board.

Legal Notices

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[1] ^{131}I-iodofalan is the International Nonproprietary Name (INN) assigned to TLX101 by the World Health Organization. TLX101 is also known as 4-L-[^{131}I] iodo-phenylalanine, or ^{131}I-IPA.

[2] Telix ASX disclosure 21 September 2022. Pichler et al. *Neurooncol Adv.* 2024. ClinicalTrials.gov ID: NCT03849105.

[3] Primary endpoints were safety and tolerability; secondary endpoints comprised progression-free survival and overall survival.

[4] Collation of available data, not from head-to-head data. Cross-trial results should be interpreted with caution and may require further follow-up or validation.

[5] Kulinich et al. *Acta Neurochir (Wien)*. 2021.

[6] Positron emission tomography.

[7] Brand name subject to final regulatory approval.

[8] MGMT (O^6-methylguanine-DNA methyltransferase) is an enzyme that repairs DNA damage caused by chemotherapy, leading to resistance.

[9] Investigational New Drug.