IPAX-2 Study of TLX101-Tx in First-line Glioblastoma Completes Enrolment and Confirms Dosing

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- IPAX-2 study of TLX101-Tx (^{131}I-iodofalan) has completed patient enrolment.
- Maximum dose reached with no dose-limiting toxicities observed.
- TLX101-Tx is also the subject of a pivotal trial, IPAX BrIGHT, which is actively dosing patients with recurrent glioblastoma.

MELBOURNE, Australia and INDIANAPOLIS, May 19, 2026 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today announces that the IPAX-2 study [1] of TLX101-Tx (^{131}I-iodofalan) in patients with newly diagnosed glioblastoma has completed patient enrolment. No dose-limiting toxicities (DLTs) have been observed to date, including with two doses of 5GBq (total administered activity of 10GBq), the maximum administered dose in the study.

IPAX-2 is an international, multicenter, open-label Phase 1 dose finding study to evaluate the safety and tolerability of TLX101-Tx in combination with post-surgical standard-of-care treatment (external beam radiation therapy and temozolomide) in primary glioblastoma. Twelve patients were enrolled into three dose escalating cohorts across four sites in Australia, Austria and the Netherlands to assess the safety and tolerability, and to assess the maximum tolerated dose (MTD) for further development. Patients remain on standard-of-care treatment until study completion, after which the MTD primary endpoint will be confirmed.

Dr. David N. Cade, Group Chief Medical Officer, Telix, commented, "We are pleased to have completed enrolment in IPAX-2, an important milestone in the development of TLX101-Tx as a potential treatment for first-line glioblastoma. The tolerability amongst patients, and the absence of dose-limiting toxicities observed on this study strongly support the continued development of this targeted radiopharmaceutical candidate. We thank the principal investigators, their clinical teams, and the patients who have participated in this important research."

TLX101-Tx is currently also under evaluation in the pivotal IPAX BrIGHT[2] trial to assess the safety and efficacy of TLX101-Tx in combination with chemotherapy (lomustine), compared to chemotherapy alone in patients with recurrent glioblastoma (last line). IPAX BrIGHT is actively enrolling and dosing patients in Australia and the Netherlands and is also approved in Austria and Belgium with enrollment to begin soon. This marks the first radiopharmaceutical therapy to enter Phase 3 development for glioblastoma.

Telix's PET imaging candidate TLX101-Px (floretyrosine F 18) has been used across the IPAX series of trials to identify participants with overexpressed LAT1 as suitable candidates for TLX101-Tx therapy, and to provide baseline and follow-up information on tumor response and progression.

About TLX101-Tx

TLX101-Tx (^{131}I-iodofalan) is a systemically administered radiopharmaceutical therapy that targets L-type amino acid transporter 1 (LAT1), which is typically over-expressed in glioblastoma. TLX101-Tx 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. In addition to IPAX-2, TLX101-Tx was also the subject of the IPAX-1 study[3] in recurrent glioblastoma, which reported a median overall survival (OS) of 13 months from the initiation of treatment with TLX101-Tx, or 23 months from initial diagnosis[4]. Preliminary results from the IPAX-Linz investigator-initiated trial of TLX101-Tx in the recurrent setting were consistent and confirmatory to IPAX-1, with a median OS of 11.9 months from the relapse prior to trial enrollment and 32.2 months from initial diagnosis[5]. Beyond the clinical trial setting, an early access program for TLX101-Tx in Europe has dosed 18 patients at first recurrence or later, further establishing the clinical utility of TLX101-Tx.

TLX101-Tx has received orphan drug designation in the U.S. and Europe for the treatment of glioma. TLX101-Tx and TLX101-Px have not received a marketing authorization in any jurisdiction and are for investigational use only.

About glioblastoma

Glioblastoma (GBM), is a high-grade glioma and the most common and aggressive form of primary brain cancer, with approximately 22,000 new cases diagnosed annually in the U.S.[6]. The mainstay of treatment for GBM comprises surgical resection, followed by combined radiotherapy and chemotherapy. Despite such treatment, recurrence occurs in almost all patients[7], with an expected survival duration of 12-15 months from diagnosis[8].

About Telix Pharmaceuticals Limited

Telix is a global biopharmaceutical company focused on the development and commercialization of radiopharmaceuticals with the goal of addressing significant unmet medical need in oncology and rare diseases. 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 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: NCT05450744.
[2] ClinicalTrials.gov ID: NCT07100730.
[3] ClinicalTrials.gov ID: NCT03849105.
[4] Pichler et al. *Neurooncol Adv.* 2024. https://doi.org/10.1093/noajnl/vdae130
[5] Telix ASX disclosure April 16, 2025. Data presented by Professor Josef Pichler at the Nuclear Medicine and Neurooncology (NMN) Symposium in Vienna (Austria), May 2025.
[6] Ostrom 2022, CBTRUS (Central Brain Tumor Registry of the United States) Statistical Report.
[7] Park et al. *Journal of Clinical Oncology.* 2010.
[8] Ostrom et al. *Neuro Oncol.* 2018.

Source: Telix Pharmaceuticals Limited