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ASX RELEASE

Final IPAX-1 Study Data Confirms Safety and Tolerability Profile for TLX101, Preliminary Efficacy Data

Melbourne (Australia) – 21 September 2022. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today reports the final results from the IPAX-1 Ph I/II study of TLX101 therapy (4-L-[^{131}I] iodo-phenylalanine, or ^{131}I-IPA) in combination with external beam radiation therapy (EBRT) in recurrent glioblastoma multiforme (GBM).

The primary objective of the IPAX-1 study was to evaluate the safety and tolerability profile of intravenous ^{131}I-IPA administered concurrently with second line EBRT in patients with recurrent GBM. Secondary objectives were to determine optimal dosing, biodistribution and radiation absorption into the tumour, as well as assess preliminary efficacy through clinical and imaging-based assessment of tumour response.

Final data up to the completion of the post-study follow-up period confirms the study has met its primary objective, demonstrating the safety and tolerability profile of TLX101 at the dosing range tested. The study also delivered encouraging preliminary efficacy data for further evaluation, demonstrating a median overall survival (OS) of 13 months from the initiation of treatment in the recurring setting, or 23 months from initial diagnosis. Given that GBM has a median survival from initial diagnosis of 12-15 months, the overall survival improvement trend seen in this patient population clearly warrants further evaluation in a larger patient population.

Recurrent GBM is a highly aggressive cancer that progresses rapidly, and for which there are few effective treatment options. TLX101 is a systemically administered targeted radiation therapy that targets L-type amino acid transporter 1 (LAT-1), which is typically over- expressed in GBM. TLX101 has been granted orphan drug designation in the United States and Europe.

IPAX-1 Results Summary

10 patients were enrolled of whom 9 received the full study treatment dosing of ~2GBq (2000 MBq) of TLX101, either in the form of a single administration or one of two triple-fractionated regimens. The results demonstrated all dosing regimens, in combination with EBRT, were well tolerated:

- Dosimetric analysis demonstrates that radiation exposure to key organs is well within acceptable safety limits.
- The most frequent treatment emergent adverse events (TEAEs) were decreased lymphocyte count, fatigue, headache and hiccups, which occurred in three patients (30%), followed by decreased platelet count, diarrhea, cerebral oedema (swelling), and insomnia, which occurred in two patients (20%).
- Except for cerebral oedema (swelling), a typical side-effect of radiation to the brain, adverse events were of low grade, did not show any trends or patterns and were clinically manageable, with a significant proportion deemed unrelated to therapy. The therapy was generally well tolerated by patients.
- Overall survival (OS) was a median of 13 months, from initiation of therapy in the recurrent disease setting.
- Of the nine patients who received conventional imaging, four (44%) exhibited stable disease at day 135 and two (22%) at day 180, determined by longitudinal imaging.
- Two patients remain alive at the time of study report.

Dr. Colin Hayward, Chief Medical Officer at Telix said, “We are pleased to report this final outcome, which will be submitted for publication. We can reconfirm that TLX101 has demonstrated safety and tolerability profile and encouraging early efficacy data. The median overall survival of 13 months from initial treatment in the recurrent second line setting reinforces the validity of further investigation and dose escalation of TLX101 in patients with GBM. Due to the aggressive nature of this cancer and limited treatment options, we are experiencing a high level of interest in the follow-on study that Telix is now undertaking in newly diagnosed patients, as a front-line therapy in combination with standard of care treatment. In parallel we will continue to study TLX101 in the recurrent setting.”

Dr Josef Pichler, Kepler University Hospital, Austria and Principal Investigator in the IPAX-1 study said, “When you consider that GBM has a median survival from initial diagnosis of 12-15 months, the potential benefit demonstrated in relapsed patients, in a second-line setting is encouraging. We are very motivated to continue to investigate TLX101 in a larger patient population in the planned Phase II IPAX-L (Linz) study underway at Kepler University Hospital, with the goal of collecting additional safety and efficacy data for TLX101 in in combination with EBRT in patients with relapsed-glioblastoma.”

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic products using Molecularly Targeted Radiation (MTR). Telix is headquartered in Melbourne, Australia with international operations in Belgium, Japan, Switzerland, and the United States. Telix is developing a portfolio of clinical-stage products that address significant unmet medical need in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com and follow Telix on Twitter (@TelixPharma) and LinkedIn.

Telix’s lead product, gallium-68 (^{68}Ga) gozetotide (also known as ^{68}Ga PSMA-11) injection, has been approved by the U.S. Food and Drug Administration (FDA),[1] and by the Australian Therapeutic Goods Administration (TGA).[2] Telix is also progressing marketing authorisation applications for this investigational candidate in Europe[3] and Canada.[4]

Telix Investor Relations

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This announcement has been authorised for release the disclosure committee of Telix Pharmaceuticals Limited.

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[1] ASX disclosure 20 December 2021.
[2] ASX disclosure 2 November 2021.
[3] ASX disclosure 10 December 2021.
[4] ASX disclosure 16 December 2020.

studies, including multi-national clinical trials; the timing or likelihood of regulatory filings and approvals, manufacturing activities and product marketing activities; the commercialisation of Telix's product candidates, if or when they have been approved; estimates of Telix's expenses, future revenues and capital requirements; Telix's financial performance; developments relating to Telix's competitors and industry; and the pricing and reimbursement of Telix's product candidates, if and after they have been approved. Telix's actual results, performance or achievements may be materially different from those which may be expressed or implied by such statements, and the differences may be adverse. Accordingly, you should not place undue reliance on these forward-looking statements. You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the ASX or on our website.

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