Telix Receives Ethics Approval to Commence Glioblastoma Therapeutic Study

Melbourne (Australia), Brussels (Belgium) – 4th September 2018. Telix Pharmaceuticals Limited (ASX:TLX) (“Telix”, the “Company”), a biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or “molecularly-targeted radiation” (“MTR”) is pleased to announce that the Company has received ethics approval to commence a Phase I/II study for the use of TLX101 to treat recurrent glioblastoma. The ethics approval pertains to the lead clinical sites of Kepler University (Linz) and University Hospital Vienna.

The study is an international multi-centre, open-label phase I/II dose-ranging study to evaluate the safety, tolerability, dosing schedule and preliminary efficacy of carrier-added 4-L-[^131]I iodo-phenylalanine ([^131]I-IPA, denoted by Telix as TLX101). TLX101 is applied as single or repeated injections in patients with recurrent glioblastoma multiforme (GBM) in conjunction with external radiotherapy (XRT) – clinical trial designation “IPAX-1” (IPA+XRT). Additional sites in Belgium, the Netherlands, Germany, Switzerland and Australia will follow, subject to relevant ethics and regulatory approvals.

Telix CMO Dr. Andreas Kluge stated, “IPAX-1 is a unique study that combines the benefits of external-beam radiation with molecularly-targeted radiation. By simultaneously irradiating both bulky lesions and small metastases, we hope to demonstrate improved survival in GBM patients, a cancer patient population that has few good therapeutic options at this time.”

Concurrent with ethics review, Telix has responded to minor manufacturing and clinical protocol clarifications from the Bundesamt für Sicherheit im Gesundheitswesen (BASG), the Austrian Federal Office for Safety in Health Care. The Company expects the trial to begin patient recruitment in late September or early October, subject to final regulator approval.

About TLX101 (Glioblastoma)

TLX101 is a small molecule MTR therapeutic product that specifically targets L-Type amino-acid transport 1 (LAT-1), which is highly expressed in many aggressive cancers including glioblastoma and multiple-myeloma. Telix has recently completed GMP manufacturing of TLX101 at Seibersdorf Laboratories (https://www.seibersdorf-laboratories.at) and has achieved product stability in excess of 96 hours, supporting international clinical trial use and eventual commercial distribution. TLX101 has received orphan drug designation from both the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

About Telix Pharmaceuticals Limited

Telix Pharmaceuticals Limited (Telix) is a global biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or “molecularly-targeted radiation” (MTR). The company is headquartered in Melbourne with international operations in Brussels (EU), Kyoto (JP) and Indianapolis (US). Telix is developing a portfolio of clinical-stage oncology products that address significant unmet medical need in renal, prostate and brain (glioblastoma) cancer. Telix is listed on the Australian Securities Exchange (ASX:TLX). For more information visit www.telixpharma.com.
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