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Drug Master File for Glioblastoma Therapy Product Filed with FDA

Melbourne (Australia) and Indianapolis, IN (USA) – 11th August 2020. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today announces that it has submitted a Drug Master File (DMF) to the United States Food and Drug Administration (FDA DMF No. 034931) for TLX101 (4-[^{131}I]Iodo-l-phenylalanine injection). TLX101 is a clinical-stage drug candidate targeting Large Neutral Amino Acid Transporter (LAT-1) for the treatment of glioblastoma multiforme (GBM).

Telix CEO Dr Christian Behrenbruch said, "The filing of a Drug Master File with the FDA for our GBM therapy product is an important step towards enabling luminary academic and pharma collaborators to initiate investigator-led studies with this product in the U.S., as well as potentially expanded access use in the longer term, subject to the requisite FDA approvals.[1] TLX101 has previously been granted orphan drug status by the FDA and we believe that the filing of a DMF for this product will potentially accelerate the generation of further clinical data in both glioblastoma and other LAT-1 expressing malignancies.

TLX101 is presently undergoing Phase I/II development in the IPAX-1 clinical trial in combination with external beam radiation therapy (EBRT).[2] IPAX-1 is recruiting at five sites in Europe and Australia. Telix expects preliminary data to be available from the IPAX-1 study late Q4 2020.

About Glioblastoma

Glioblastoma, also known as glioblastoma multiforme or GBM, is the most aggressive form of primary brain cancer, with approximately 10,500 new cases diagnosed annually in the United States.[3] The mainstay of treatment for GBM typically comprises surgical resection, followed by radiotherapy and the chemotherapy agent temozolomide. However, despite these treatment options the majority of patients experience recurrence of their GBM and median survival is approximately 14 months from diagnosis.[4] TLX101 is presently being developed as a therapy for recurrent GBM in combination with external beam radiation therapy in the IPAX-1 Phase I/II clinical trial (NCT03849105).

About Telix Pharmaceuticals Limited

Telix is a clinical-stage biopharmaceutical company focused on the development of diagnostic and therapeutic products using Molecularly Targeted Radiation (MTR). Telix is headquartered in Melbourne with international operations in Belgium, Japan and the United States. Telix is developing a portfolio of clinical-stage oncology products that address significant unmet medical needs in prostate, kidney and brain cancer. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com.

[1] TLX101 does not have a marketing authorization in any jurisdiction.

[2] ClinicalTrials.gov Identifier: NCT03849105

[3] Ostrom QT *et al.* CBTRUS statistical report: Primary brain and central nervous system tumors diagnosed in the United States in 2006–2010. Neuro Oncol. 2013.

[4] Ohgaki H *et al.* Epidemiology and etiology of gliomas. Acta Neuropathol 2005; 109:93–108.

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