Telix Pharmaceuticals Limited
ACN 616 620 369
Suite 401, 55 Flemington Road
North Melbourne
Victoria, 3051
Australia

Telix Granted FDA Orphan Drug Designation for Glioma Imaging Agent

Melbourne (Australia) – 6th October 2020. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today announces that the United States Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for O-(2-[^{18}F]fluoroethyl)-L-tyrosine (^{18}F-FET), for the positron emission tomography (PET) imaging of glioma, a type of brain tumour. The granting of an ODD for ^{18}F-FET qualifies Telix for various drug development incentives which may include FDA-administered market exclusivity for seven years, waived FDA prescription drug user fees, and tax credits for R&D and clinical development costs.

Gliomas comprise a group of primary brain tumours arising from glial cells which surround and support the neurons of the brain, exhibiting an annual incidence of over 22,000 cases in the United States and representing over 80% of all malignant brain tumours.[1] ^{18}F-FET has been widely used in clinical research settings while recently, new practice guidelines have been developed for the imaging of gliomas using PET with radiolabeled amino acids, of which ^{18}F-FET is a key enabling radiopharmaceutical.[2] ^{18}F-FET targets the amino acid transport system L (LAT) and is therefore highly suitable for use as a 'companion diagnostic' to TLX101, Telix's therapeutic drug candidate for treating glioblastoma, a highly aggressive form of glioma. ^{18}F-FET is used to select patients and track disease response in Telix's IPAX-1 Phase I/II clinical trial (ClinicalTrials.gov Identifier: NCT03849105), which is currently recruiting patients in Europe and Australia.

Telix CEO Dr Christian Behrenbruch said, "PET imaging of the brain is increasingly used to supplement conventional imaging with MRI, which for many years has been the primary clinical imaging modality in patients with glioma at all stages of disease. The granting of an Orphan Drug Designation by the FDA for ^{18}F-FET provides Telix with the option to develop this valuable PET imaging agent commercially, to ensure it is available to patients with glioma across the disease spectrum. ^{18}F-FET's relevance as a patient selection and therapeutic monitoring tool for TLX101 is particularly beneficial to the Company."

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, Australia 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.

Telix Corporate Contact

Dr Christian Behrenbruch
Telix Pharmaceuticals Limited
CEO
Email: chris@telixpharma.com

Telix Investor Relations

Dr David N. Cade
Telix Pharmaceuticals Limited
CBO and Head of Investor Relations
Email: david.cade@telixpharma.com

[1] Li K, Lu D, Guo Y et al. Trends and patterns of incidence of diffuse gliomas in adults in the United States, 1973 – 2014. Cancer Medicine 2018 Oct; 7(10): 5281 - 5290.
[2] Law I, Albert NL, Arbizu J et al. Joint EANM/EANO/RANO practice guidelines/SNMMI procedure standards for imaging of gliomas using PET with radiolabelled amino acids and [^{18}F]FDG: version 1.0. Eur J Nucl Med Mol Imaging. 2019; 46(3): 540–557.

Important Information

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