FDA Accepts New Drug Application and Grants Priority Review for TLX101-CDx (Pixclara®) Brain Cancer Imaging Agent

24 Oct 2024

Telix today announces that the United States (U.S.) Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for TLX101-CDx (Pixclara®[1]), an agent for the imaging of glioma. The application has been granted priority review and designated a PDUFA[2] goal date of 26 April 2025, paving the way for a U.S. commercial launch in 2025[3].

Pixclara(^{18}F-floretyrosine or ^{18}F-FET) is a PET agent for the characterisation of progressive or recurrent glioma from treatment related changes in both adult and pediatric patients. FET PET is already included in international clinical practice guidelines for the imaging of gliomas[4], however there is currently no FDA-approved targeted amino acid PET agent for adult and pediatric brain cancer imaging commercially available in the U.S. Given its potential to address significant unmet medical need, Pixclara has been designated as an orphan drug[5] and granted fast track designation[6] by the FDA.

There is a critical unmet need to improve the diagnosis and management of gliomas, which are the most common primary brain tumours of the central nervous system, particularly in the post-treatment setting. Conventional MRI[7] imaging techniques have several limitations, including a lack of biological specificity, dependency on blood-brain barrier disruption, and an inherent inability to differentiate between tumour progression or treatment-related causes. This can yield inconclusive results and delay time-sensitive treatment decisions[8].

With low survival rates and the need to make rapid decisions, precision imaging is paramount. Subject to regulatory approval, Pixclara has the potential to address this need, enabling patients in the U.S. to receive greater clarity in their diagnosis and treatment decision making. Telix is also reviewing the potential use of Pixclara as a “companion” diagnostic agent for TLX101-Tx, the investigational neuro-oncology drug currently in development, which targets the same amino acid transporter mechanism with therapeutic targeted radiation.

Kevin Richardson, Chief Executive Officer, Telix Precision Medicine, said, “Telix believes that the FDA approval of Pixclara will drive a step-change for brain cancer imaging in the U.S., and bring it into line with a more advanced standard of care currently used in other markets. There is currently a critical need for better imaging in brain cancer, and Telix is dedicated to delivering precision medicine solutions that address patient needs and enhance both cancer imaging and treatment outcomes.”

To read the full ASX release click here

TLX101-CDx has not received a marketing authorisation in any jurisdiction.

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[1] Brand name subject to final regulatory approval.

[2] Prescription User Drug Fee Act.

[3] Subject to FDA marketing authorisation approval.

[4] Joint European Association of Nuclear Medicine//European Association of Neurooncology/Response Assessment in Neurooncology practice guidelines/Society for Nuclear Medicine and Molecular Imaging procedure standards for the clinical use of PET imaging in gliomas.

[5] Telix ASX disclosure 6 October 2020.

[6] Telix ASX disclosure 16 April 2024. Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. More: https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

[7] Magnetic resonance imaging.

[8] Smith NJ et al. *J Nucl Med.* 2023.