

Australia's Telix receives US FDA approval for brain cancer imaging drug Pixclara

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Pixclara® is the first FDA-approved FET-PET imaging drug for glioma (brain cancer)



Australia-based Telix Pharmaceuticals has announced that the United States (US) Food and Drug Administration (FDA) has approved its New Drug Application (NDA) for Pixclara® (floretyrosine F 18 or ^{18}F -FET), an amino acid positron emission tomography (PET) drug for imaging gliomas (brain cancer).

Pixclara is a radioactive diagnostic drug indicated for use with positron emission tomography (PET) to differentiate recurrent or progressive glioma from treatment-related change, in conjunction with other diagnostic evaluations, in adults and pediatric patients 1 month of age and older.

PET imaging with floretyrosine F 18 (FET-PET) is recommended in international clinical practice guidelines for the imaging of gliomas, including NCCN Guidelines®, but until now there has not been an FDA-approved product available in the US.

Gliomas are the most common form of central nervous system (CNS) cancer, accounting for approximately 30% of all brain and CNS tumors and 80% of all malignant brain tumors. In the U.S., approximately 24,000 new glioma cases are diagnosed each year, representing a significant unmet addressable need.