



First Patients Dosed with Telix's FDA-Approved Brain Cancer Imaging Drug Pixclara® (floretyrosine F 18)

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- First doses of Pixclara administered in Cleveland (OH) and Indianapolis (IN) marking the start of U.S. commercial availability.
- Pixclara is the only FDA-approved radiopharmaceutical imaging drug for glioma (brain cancer).
- Pixclara addresses a significant unmet need helping physicians differentiate recurrent or progressive glioma from treatment-related change in adult and pediatric patients 1 month of age and older.

MELBOURNE, Australia and INDIANAPOLIS, Oct. 06, 2026 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today announces that the first patients in the United States (U.S.) have been dosed with Pixclara® (floretyrosine F 18 or ¹⁸F-FET), its FDA-approved, amino acid positron emission tomography (PET) drug for glioma (brain cancer) imaging.

The doses were administered at the Indiana University Health (IU Health) Neuroscience Center in Indianapolis and the University Hospitals, Cleveland Medical Center, Cleveland. The milestone marks the start of commercial availability for Pixclara, with Telix's U.S. manufacturing and pharmacy distribution partner, PharmaLogic Holdings Corp. (PharmaLogic), supplying finished unit doses to the U.S. market.

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

Na Tosha N. Gatson, MD, PhD, FAAN, director of the Center for Neuro-Oncology as part of the Neuroscience & Cancer Institutes with IU Health-Indiana University School of Medicine; tenured professor, Neurology, Neurosurgery, & Medicine, IUSM, and Founding President of the nonprofit, Living Oncology said, "Distinguishing recurrent or progressive gliomas from treatment-related change is one of the most difficult and consequential challenges in brain cancer. Having access to FDA-approved FET-PET¹ imaging with Pixclara will help clinicians make more timely and accurate decisions, minimizing uncertainty in their diagnoses and supporting more confident treatment planning for patients with gliomas."

Clement Pillainayagam, MD, Specialist in Neurology and Neuro-oncology, University Hospitals Cleveland Medical Center, Seidman Cancer Center, Cleveland, added, "The approval and commercial availability of Pixclara represents an advance for patients with glioma in the U.S. FET-PET imaging is recommended in international clinical practice guidelines, including NCCN Guidelines², and having an FDA-approved, commercially available option can help translate this established clinical approach into broader access for patients, adding another tool to help in their care."

Kevin Richardson, Chief Executive Officer, Telix Precision Medicine, continued, "The first commercial dose of Pixclara is an important milestone for a patient community that has seen limited advances in diagnosis and treatment for many years. We are proud to support patients with glioma and their care teams by bringing this important new precision diagnostic to the U.S., and we thank the clinicians, patients, advocates and broader neuro-oncology community who helped make this possible."

About gliomas

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 tumors³. In the U.S., approximately 24,000 new glioma cases are diagnosed each year⁴, representing a significant unmet addressable need.

About Pixclara (floretyrosine F 18)

Pixclara® is an intravenous positron emission tomography (PET) imaging drug for the differentiation of 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. It comprises a small molecule targeting compound labeled with a diagnostic radioisotope, fluorine-18. After administration into the bloodstream, Pixclara targets membrane transport proteins known as L-type amino acid transporters 1 and 2 (LAT1 and LAT2). Once bound, energy emissions from the radioisotope can be detected by a PET scanner. Pixclara (TLX101-Px) is also the subject of a Phase 3 registrational study for potential indication expansion for the diagnosis of brain metastases⁵.

Pixclara is the only FDA-approved radiopharmaceutical imaging drug for glioma (brain cancer).

INDICATIONS AND USAGE

PIXCLARA is 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.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Risk for Misinterpretation

Image misinterpretation may occur with PIXCLARA PET. A negative image does not rule out the presence of recurrent or progressive glioma and a

positive image does not confirm the presence of recurrent or progressive glioma. Equivocal findings may occur with PIXCLARA PET, including low-level or atypical uptake patterns, which may result in false positive or false negative interpretations.

Interpret PIXCLARA PET findings with caution and correlate results with available clinical evaluations, such as histopathology, cross-sectional imaging, and/or clinical history to support appropriate clinical decision-making.

Radiation Risks

PIXCLARA contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Ensure safe drug handling to protect patients and health care providers from unintentional radiation exposure. Advise patients to hydrate before and after administration and to void frequently after administration.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of PIXCLARA was evaluated in 382 patients with gliomas. Among these 382 patients, 371 adult patients received at least one intravenous dose of PIXCLARA at a mean activity of 204 ± 18 MBq (5.5 ± 0.47 mCi). The remaining 11 pediatric patients received at least one intravenous dose of PIXCLARA at a mean activity of 155 ± 53.5 MBq (4.2 ± 1.4 mCi).

The mean age of the patients was 57 years (range: 5 years to 86 years). Sex was 59% male, 37% female, and 3% unreported. Distribution by race was 26% White, 6% Asian, <1% Black or African American, and 67% other or unreported. Distribution by ethnicity was 3% Hispanic/Latino, 96% non-Hispanic/Latino, and <1% unknown or unreported.

Adverse reactions that occurred in $\geq 0.5\%$ of patients receiving PIXCLARA were headache (0.5%).

Adverse reactions that occurred in $<0.5\%$ of patients were nausea, injection site reaction, fatigue, and malaise.

Adverse Reactions in Pediatric Patients

Overall, the safety profile observed in pediatric patients from the clinical study was consistent with the safety profile in adult patients.

Please note that this information is not comprehensive.

Please see the Full Prescribing Information at https://telixpharma.com/wp-content/uploads/2026/09/USPI_PIXCLARA_Sep2026.pdf

You are encouraged to report suspected adverse reactions of prescription drugs to the FDA. Visit MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report adverse reactions to Telix Pharmaceuticals (US) by calling 1-844-455-8638 or emailing pharmacovigilance@telixpharma.com.

About Telix Pharmaceuticals Limited

Telix Pharmaceuticals (ASX: TLX, NASDAQ: TLX) is a commercial-stage global radiopharmaceutical company, advancing targeted theranostics to improve outcomes for people with cancer across the patient journey. Theranostics pairs a precision diagnostic with a targeted therapy to both diagnose and treat disease.

Telix's commercial franchise is anchored by its precision diagnostics portfolio: Illuccix® (kit for the preparation of gallium-68 gozetotide injection), commercially available in 22 countries including the U.S., and Gozellix® (kit for the preparation of gallium-68 gozetotide injection), approved by the U.S. Food and Drug Administration (FDA) for prostate imaging, and Pixclara® (floretyrosine F 18) approved by the FDA for glioma imaging. The Company's late-stage therapeutic pipeline includes three investigational assets in pivotal-stage trials: TLX591-Tx (lutetium-177 (^{177}Lu) rosopatumab tetraxetan) in prostate cancer, TLX101-Tx (iodofalan ^{131}I) in recurrent glioblastoma, and TLX250-Tx (lutetium (^{177}Lu) girentuximab tetraxetan) in kidney cancer, additionally complemented by a deep pipeline of next generation candidates. TLX591-Tx, TLX101-Tx and TLX250-Tx have not received marketing authorizations in any jurisdiction.

Telix is headquartered in Melbourne, Australia, with operations across North America, Europe, Latin America and Asia-Pacific. For more information, visit www.telixpharma.com or follow Telix on [LinkedIn](#), [X](#) and [Facebook](#).

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Legal Notices

Cautionary Statement Regarding Forward-Looking Statements.

You should read this announcement together with our risk factors, as disclosed in our most recently filed reports with the Australian Securities Exchange (ASX), U.S. Securities and Exchange Commission (SEC), including our Annual Report on Form 20-F filed with the SEC, or on our website.

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¹ Imaging of floretyrosine F 18 with positron emission tomography.

² Galldiks et al. Lancet Oncol. 2025 (Joint guidelines from the European Association of Nuclear Medicine (EANM), European Association of Neuro-Oncology (EANO), Society of Nuclear Medicine and Molecular Imaging (SNMMI), Response Assessment in Neuro-Oncology (RANO), The European Society for Pediatric Oncology and The Response Assessment in Pediatric Neuro-Oncology for the characterization of recurrence in glioma patients); National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Central Nervous System Cancers V3.2026.

³ Goodenberger et al. *Cancer Genet.* 2012.

⁴ CBTRUS Statistical Report: Primary Brain and Other Central Nervous System Tumors Diagnosed in the United States in 2018-2022. *Neuro-Oncology.* 2025.

⁵ Investigational New Drug (IND) application successfully cleared, with Study May Proceed notification received from FDA. Telix ASX disclosure August 20, 2026.