FDA Approves Telix's Brain Cancer Imaging Drug Pixclara

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- Pixclara® is the first FDA-approved FET-PET imaging drug for glioma (brain cancer).
- Approval addresses a significant unmet need, helping physicians to differentiate recurrent or progressive glioma from treatment-related change in adults and pediatric patients.
- FET-PET imaging is recommended in international clinical practice guidelines, including NCCN Guidelines®.
- Pixclara expands Telix's industry-leading Precision Medicine business and reinforces the Company's leadership in diagnostics and targeted radiopharmaceutical therapies (together, "theranostics").

MELBOURNE, Australia and INDIANAPOLIS, Sept. 14, 2026 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today announces that the United States (U.S.) 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®[1], but until now there has not been an FDA-approved product available in the U.S.

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[2]. In the U.S., approximately 24,000 new glioma cases are diagnosed each year[3], representing a significant unmet addressable need.

Kevin Richardson, Chief Executive Officer, Telix Precision Medicine, said, "FDA approval of Pixclara will enable broad access in the U.S. to FET-PET imaging, which is already recognized in international clinical practice guidelines. As the first FDA-approved PET imaging drug for glioma, Pixclara will provide physicians in the U.S. with more certainty in their diagnoses and greater confidence in their treatment planning for patients."

Kelly Sitkin, President and CEO, American Brain Tumor Association, said, "The approval of Pixclara will advance glioma care by enabling more precise monitoring, complementing the role of MRI. We welcome the FDA's decision, which provides a pathway to access this technology in the U.S. and helps address a critical unmet need in brain cancer diagnostics."

Patrick Wen, MD, E. Antonio Chiocca, MD, PhD, Family Endowed Chair in Neuro-Oncology at Mass General Brigham Cancer Institute, said, "Having an FDA-approved FET-PET product with high diagnostic accuracy will make a significant, positive difference to the management of patients with gliomas. This is a very positive step forward for brain cancer imaging and treatment planning."

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 metastases[4].

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 ≥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/pixclara-uspi

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 F18) 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) rosopatamab tetraxetan) in prostate cancer, TLX101-Tx (^{131}I-iodofalan) 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.

Investor Relations

Annie Kasparian
annie.kasparian@telixpharma.com

Charlene Jaw
charlene.jaw@telixpharma.com

Media

Eliza Schleifstein
917.763.8106 (Mobile)
eliza@schleifsteinpr.com

This announcement has been authorized for release by the Telix Pharmaceuticals Limited Disclosure Committee on behalf of the Board.

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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assumptions as to the financial, market, regulatory and other risks and considerations that exist and affect Telix's business and operations in the future and there can be no assurance that any of the assumptions will prove to be correct. In the context of Telix's business, forward-looking statements may include, but are not limited to, statements about: the initiation, timing, progress, completion and results of Telix's preclinical and clinical trials, and Telix's research and development programs; Telix's ability to advance product candidates into, enroll and successfully complete, clinical studies, including multi-national clinical trials; the timing or likelihood of regulatory filings and approvals for Telix's product candidates, manufacturing activities and product marketing activities; Telix's sales, marketing and distribution and manufacturing capabilities and strategies; the commercialization of Telix's product candidates, if or when they have been approved; Telix's ability to obtain an adequate supply of raw materials at reasonable costs for its products and product candidates; estimates of Telix's expenses, future revenues and capital requirements; Telix's financial performance; developments relating to Telix's competitors and industry; the anticipated impact of U.S. and foreign tariffs and other macroeconomic conditions on Telix's business, including as a result of war or other geopolitical conflicts; and the pricing and reimbursement of Telix's product candidates, if and after they have been approved. Telix's actual results, performance or achievements may be materially different from those which may be expressed or implied by such statements, and the differences may be adverse. Accordingly, you should not place undue reliance on these forward-looking statements.

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[1] 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.

[2] Goodenberger et al. *Cancer Genet.* 2012.

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

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

Source: Telix Pharmaceuticals Limited