Illuccix Approved in U.S. for Patient Selection for Pre-Taxane RLT

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MELBOURNE, Australia and INDIANAPOLIS, June 23, 2025 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix", "the Company") today announces that the United States (U.S.) Food and Drug Administration (FDA) has approved a label expansion for Illuccix® (kit for the preparation of gallium Ga-68 gozetotide, for injection) to include patient selection for radioligand therapy (RLT) in the pre-taxane setting.

The update applies to Illuccix's third indication, for selection of patients who are indicated for PSMA [1]-directed therapy *as described in the Prescribing Information of the therapeutic products*. The label expansion follows the FDA's approval of an expanded label for Pluvicto® [2] (lutetium Lu177 vipivotide tetraxetan) for use in metastatic castration-resistant prostate cancer (mCRPC) patients after treatment with androgen receptor pathway inhibitor (ARPI) therapy and before chemotherapy[3]. With RLT now approved for use earlier in the patient journey, the clinical utilization of Illuccix® is expected to increase by at least 20,000 scans annually[4].

Scott T. Tagawa, MD, a genitourinary (GU) oncologist in New York said, "It is pleasing to see the ability to use gallium-68 PSMA-PET for patient selection expanded. This empowers clinicians to make more informed, personalized decisions earlier in the disease course and access life-prolonging targeted radionuclide therapy for more patients with prostate cancer."

Kevin Richardson, Chief Executive Officer, Precision Medicine, Telix, said, "We're pleased that the U.S. label for Illuccix has been expanded to support patient selection for RLT in the pre-taxane setting, aligning with the evolving treatment landscape. PSMA-PET imaging has become a standard of care in the detection and management of prostate cancer. With this update, patients can now benefit from the high diagnostic accuracy of Illuccix to identify those most likely to respond to PSMA-targeted therapy, even earlier in their treatment journey."

INDICATIONS AND USAGE

Illuccix, after radiolabeling with Ga 68, is for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- With suspected metastasis who are candidates for initial definitive therapy
- With suspected recurrence based on elevated serum prostate-specific antigen (PSA) level
- For selection of patients who are indicated for PSMA-directed therapy as described in the Prescribing Information of the therapeutic products

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

Risk for Misinterpretation
Image interpretation errors can occur with Illuccix PET. A negative image does not rule out the presence of prostate cancer, and a positive image does not confirm the presence of prostate cancer. Gallium Ga 68 gozetotide uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes such as Paget's disease, fibrous dysplasia, and osteophytosis. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended.

Imaging Prior to Initial Definitive or Suspected Recurrence Therapy
The performance of Illuccix for imaging of biochemically recurrent prostate cancer seems to be affected by serum PSA levels and by site of disease. The performance of Illuccix for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by Gleason score.

Radiation Risks
Gallium Ga 68 gozetotide 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 handling to minimize radiation exposure to the patient and healthcare providers. Advise patients to hydrate before and after administration and to void frequently after administration.

ADVERSE REACTIONS
The safety of gallium Ga 68 gozetotide was evaluated in 960 patients in the PSMA-PreRP and PSMA-BCR studies, each receiving one dose of gallium Ga 68 gozetotide. The average injected activity was 188.7 ± 40.7 MBq (5.1 ± 1.1 mCi). The most commonly reported adverse reactions were nausea, diarrhea, and dizziness, occurring at a rate of <1%.

In the VISION study, 1003 patients received one dose of gallium Ga 68 gozetotide intravenously with the amount of radioactivity 167.1 ± 23.1 MBq (4.52 ± 0.62 mCi). Adverse reactions occurring at ≥0.5% in patients with metastatic prostate cancer who received gallium Ga 68 gozetotide injection in the clinical study were fatigue (1.2%), nausea (0.8%), constipation (0.5%), and vomiting (0.5%). Adverse reactions occurring at a rate of < 0.5% in the VISION study were diarrhea, dry mouth, injection site reactions, including injection site hematoma and injection site warmth and chills.

DRUG INTERACTIONS
Androgen deprivation therapy and other therapies targeting the androgen pathway
Androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, can result in changes in uptake of gallium Ga 68 gozetotide in prostate cancer. The effect of these therapies on performance of gallium Ga 68 gozetotide PET has not been established.

Please note that this information is not comprehensive.
Please see the Full Prescribing Information here.

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 by calling 1-844-455-8638 or emailing: pharmacovigilance@telixpharma.com.

Dr. Tagawa has served as a paid consultant to Telix and his institution has received research funding.

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About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialization of therapeutic and diagnostic radiopharmaceuticals and associated medical technologies. Telix is headquartered in Melbourne, Australia, with international operations in the United States, Brazil, Canada, Europe (Belgium and Switzerland), and Japan. Telix is developing a portfolio of clinical and commercial stage products that aims to address significant unmet medical needs in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (NASDAQ: TLX).

Illuccix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection), Telix's first generation PSMA-PET imaging agent, is approved and commercially available in multiple countries globally. Gozellix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection) has been approved by the U.S. FDA[5].

Visit www.telixpharma.com for further information about Telix, including details of the latest share price, ASX and SEC filings, investor and analyst presentations, news releases, event details and other publications that may be of interest. You can also follow Telix on LinkedIn, X and Facebook.

Legal Notices

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] Prostate-specific membrane antigen

[2] Pluvicto is a registered trademark of Novartis AG and/or its affiliates.

[3] 28 March 2025, FDA Statement: for patients who have been treated with ARPI therapy and are considered appropriate to delay taxane-based chemotherapy.

[4] Based on licensed indication for Pluvicto in mCRPC patients who have been treated with androgen receptor (AR) pathway inhibition.

[5] Telix ASX disclosure 21 March 2025.