# First U.S. Patient Dosed in BiPASS: Phase 3 Prostate Cancer Diagnosis Study

16 Jan 2026

MELBOURNE, Australia, Jan. 17, 2026 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today announces that the first patient in the United States (U.S.) has been dosed in BiPASS™ (**Bi**opsy of the **P**rostate **A**voidance **S**tratification **S**tudy), a Phase 3 trial to evaluate the use of Telix's commercial PSMA-PET [1] imaging agents, Illuccix® (kit for the preparation of gallium Ga 68 gozetotide injection) and Gozellix® (kit for the preparation of gallium Ga 68 gozetotide injection) in the initial prostate cancer diagnosis setting. The dose was administered under the supervision of Dr. Brian Mazzarella at Urology Austin and supplied by RLS Radiopharmacies.

BiPASS™ is the first study designed to gain marketing authorization for $^{68}$Ga-PSMA-PET[2] imaging in the pre-biopsy setting. The prospective, open-label Phase 3 trial will enroll 250 patients across sites in the U.S. and Australia. The study aims to determine whether combining MRI[3] with Illuccix/Gozellix $^{68}$Ga-PSMA-11 PET can improve diagnostic accuracy and reduce unnecessary biopsies compared to current standard practice. Men with elevated PSA[4] often proceed from an inconclusive MRI to template prostate biopsy. This procedure is stressful and unpleasant, can lead to complications[5] and frequently proves to be of no benefit to the patient[6].

In the U.S., more than one million prostate biopsies are performed annually, yet up to 75% are negative[6], and one in four patients declines the physician recommendation of receiving a biopsy[7]. The objective of BiPASS™ is to demonstrate improved lesion detection and patient stratification by integrating non-invasive molecular Illuccix/Gozellix $^{68}$Ga-PSMA-11 PET imaging early in the diagnostic pathway, to enable biopsy de-escalation or, alternatively, greater biopsy precision when administered.

If the BiPASS™ study achieves its primary objectives, it could lead to a reduction in unnecessary biopsies, improved patient experience, and a significant expansion of access to precision imaging for patients with suspected prostate cancer, potentially increasing the use of $^{68}$Ga-PSMA-11 PET in a large new patient population.

Dr. Mazzarella, Vice President of Research for Urology America, said, "We're excited to participate in the BiPASS trial at Urology Austin, which brings together promising technologies and emerging trends in patient care. If BiPASS is successful in meeting its primary endpoint, it could eliminate the need for biopsy—reducing risks, side effects, and costs—and improve decision-making for providers and patients."

Kevin Richardson, Chief Executive Officer, Telix Precision Medicine, added, "Illuccix and Gozellix are already transforming how clinicians treat and manage prostate cancer. By initiating this trial, we are reinforcing Telix's commitment to patient centricity, clinical innovation, and industry leadership—with the goal of eliminating invasive biopsy."

**About BiPASS™**

BiPASS™ (ClinicalTrials.gov ID: NCT07052214) leverages promising clinical findings from the PRIMARY[8] and PRIMARY2[9] studies, which demonstrated that MRI combined with $^{68}$Ga-PSMA-11 PET can better define or rule out prostate cancer and guide active surveillance before invasive biopsy. Professor Louise Emmett, Principal Investigator for PRIMARY, serves on the BiPASS™ Steering Committee and as an Investigator on the study.

**About Illuccix® (kit for the preparation of gallium Ga 68 gozetotide injection)**

Illuccix, after radiolabeling with $^{68}$Ga, is indicated for PET scanning of PSMA positive lesions in men with prostate cancer who have suspected metastasis and are candidates for initial definitive therapy, those with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level, and 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.**

**About Gozellix® (kit for the preparation of gallium Ga 68 gozetotide injection)**

Gozellix, after radiolabeling with $^{68}$Ga, is indicated for PET scanning of PSMA positive lesions in men with prostate cancer who have suspected metastasis and are candidates for initial definitive therapy, and those with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

**IMPORTANT SAFETY INFORMATION**
**WARNINGS AND PRECAUTIONS**

**Risk for Misinterpretation**
Image interpretation errors can occur with GOZELLIX 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 GOZELLIX for imaging of biochemically recurrent prostate cancer seems to be affected by serum PSA levels and by site of disease. The performance of GOZELLIX 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.

**Hypersensitivity Reactions to Sulfites**
Ascorbic Acid Stabilizer contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

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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, United Kingdom, 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, Telix's first generation PSMA-PET imaging agent, has been approved in multiple markets globally. Gozellix has been approved by the U.S. FDA[10]. Illuccix and Gozellix have not received regulatory approval for initial diagnosis of prostate cancer in any jurisdiction.

Visit www.telixpharma.com for further information about Telix, including details of the latest share price, ASX and U.S. Securities and Exchange Commission (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.

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**Legal Notices**

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[1] Imaging of prostate-specific membrane antigen with positron emission tomography.
[2] Positron emission tomography.
[3] Magnetic resonance imaging.
[4] Prostate-specific antigen.
[5] Durkan G et al. *Prostate Cancer Prostatic Dis*. 2000.
[6] Vickers et al. J Clin Oncol. 2010.
[7] Schaufler C et al. *Urologic Oncology: Seminars and Original Investigations*. 2022.
[8] Emmett et al., *Eur Urol.* 2021.
[9] ClinicalTrials.gov ID: NCT05154162. Sponsor: Peter MacCallum Cancer Centre, Australia.
[10] Telix ASX disclosure 21 March 2025.