Telix Completes Enrollment in Phase 3 BiPASS Study, Aligns with FDA on NDA Pathway

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- The Phase 3 BiPASS™ study of Illuccix® and Gozellix® for prostate cancer imaging in the pre-biopsy setting has completed enrollment of 350 patients.
- Telix has positively engaged with the FDA on a New Drug Application (NDA) pathway in the U.S. that would support new product reimbursement and broaden access to ^{68}Ga-PSMA-PET imaging across a significantly larger patient population.
- BiPASS is designed to evaluate the diagnostic performance of ^{68}Ga-PSMA-11 PET combined with MRI for the detection of prostate cancer prior to biopsy.

MELBOURNE, Australia and INDIANAPOLIS, Sept. 02, 2026 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today announced completion of patient enrollment in the Phase 3 BiPASS™ study of its commercial PSMA-PET[1] imaging agents, Illuccix® (kit for the preparation of gallium Ga68 gozetotide injection) and Gozellix® (kit for the preparation of gallium Ga68 gozetotide injection) for prostate cancer imaging in the pre-biopsy setting. Telix has also aligned with the United States (U.S.) Food and Drug Administration (FDA) on a New Drug Application (NDA) pathway for BiPASS that, if approved, would support reimbursement as a new product and broaden patient access.

BiPASS (**Bi**opsy of the **P**rostate **A**voidance **S**tratification **S**tudy[2]) is the first registrational study of ^{68}Ga-PSMA-PET imaging in the pre-biopsy setting. The study aims to evaluate whether the combination of MRI[3] and PSMA-PET/CT[4] with Telix's proprietary ^{68}Ga-PSMA-PET agents can further improve diagnostic accuracy, reduce unnecessary biopsies, or improve targeting of biopsy compared with current standard practice. A total of 350 patients were enrolled in the U.S. and Australia in this prospective, open-label Phase 3 trial.

Globally, more than three million prostate biopsies are performed each year[5], yet up to 75% are found to be negative[6]. Patient compliance remains a significant clinical challenge with approximately one in four patients declining a physician recommendation to undergo biopsy[7]. Biopsy is often stressful and painful, may lead to complications, and delivers no real diagnostic benefit for many patients[8].

BiPASS builds on the clinical foundation established by the landmark PRIMARY[9] and PRIMARY2[10] studies, which demonstrated that combining ^{68}Ga-PSMA-PET imaging with MRI can significantly improve the detection of clinically significant prostate cancer while reducing unnecessary biopsies by almost 50 percent. If BiPASS meets its primary objectives, the data, alongside evidence from PRIMARY and PRIMARY2, have the potential to shift ^{68}Ga-PSMA-PET beyond its current use in initial staging and secondary re-staging at disease recurrence and establish precision imaging as a critical step in initial diagnosis. Earlier and more accurate identification of clinically significant disease could improve patient selection and treatment decisions, reduce unnecessary biopsies, and potentially decrease the long-term patient burden and healthcare cost of prostate cancer recurrence. Successful implementation of BiPASS could broaden access to ^{68}Ga-PSMA-PET imaging across a substantially larger patient population.

Professor Louise Emmett, Director of Theranostics and Nuclear Medicine, St Vincent's Hospital and BiPASS Investigator, said, "Completing patient enrollment in BiPASS is an important milestone for men with suspected prostate cancer, particularly those with equivocal MRI findings. The PRIMARY and PRIMARY2 studies demonstrated that ^{68}Ga-PSMA-PET, when used alongside MRI, can safely halve the number of biopsies required without missing clinically significant prostate cancer. BiPASS now has the potential to fundamentally change the current standard of care, streamlining the diagnostic pathway, accelerating treatment decision-making and helping to ensure that men receive the most appropriate therapy earlier in their treatment journey."

Dr. Brian Mazzarella, Vice President of Research for Urology America and BiPASS Investigator added, "PSMA-PET imaging with tracers such as Illuccix and Gozellix has already changed how we stage and manage prostate cancer. By combining the functional information from PSMA-PET with the detailed anatomic information provided by MRI, we have an unprecedented opportunity to improve the detection of clinically significant prostate cancer and guide more informed diagnostic decisions. For patients, this approach has the potential to reduce unnecessary procedures, lower procedural risk, ease anxiety, and ultimately enable more precise, individualized treatment decision-making."

Dr. David N. Cade, Telix Group Chief Medical Officer, commented, "Recruitment of BiPASS was completed rapidly, reflecting strong enthusiasm from clinicians and patients for a more accurate, non-invasive approach to diagnosis. We believe BiPASS may represent a transformative event in the management of prostate cancer, alongside the compelling data from the PRIMARY studies. Instead of asking how best to stage prostate cancer, clinicians may increasingly use advanced imaging to determine which men need to undergo biopsy in the first place. Telix is uniquely positioned to define and lead this patient-first approach that, if approved, would represent a new clinical application with a reimbursement pathway that facilitates much broader patient access to gallium-based PSMA-PET."

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.

Injection site pain has been identified during post-approval use of ILLUCCIX.

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
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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 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 prostate cancer imaging portfolio: Illuccix®, commercially available in 22 countries including the U.S. and Gozellix®, approved by the FDA. 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.

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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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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This announcement may contain forward-looking statements, including within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that relate to anticipated future events, financial performance, plans, strategies or business developments. Forward-looking statements can generally be identified by the use of words such as "may", "expect", "intend", "plan", "estimate", "anticipate", "believe", "outlook", "forecast" and "guidance", or the negative of these words or other similar terms or expressions. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements are based on Telix's good-faith 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] Imaging of prostate-specific membrane antigen with positron emission tomography.

[2] ClinicalTrials.gov ID: NCT07052214.

[3] Magnetic resonance imaging.

[4] Imaging of prostate-specific membrane antigen with positron emission tomography/computed tomography.

[5] Hu et al. *JAMA Oncol.* 2024.

[6] Vickers et al. *J Clin Oncol.* 2010.

[7] Schaufler C et al. *Urologic Oncology: Seminars and Original Investigations*. 2022.

[8] Durkan G et al. *Prostate Cancer Prostatic Dis.* 2000.

[9] Emmett et al., *Eur Urol.* 2021.

[10] Buteau et al. *Lancet Oncol.* 2026. ClinicalTrials.gov ID: NCT05154162.

Source: Telix Pharmaceuticals Limited