FDA Approves New Prostate Cancer Imaging Agent Gozellix®

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MELBOURNE, Australia and INDIANAPOLIS, March 21, 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 its New Drug Application (NDA) for Gozellix® (TLX007-CDx, kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection), Telix's next-generation PSMA-PET imaging [1] agent for prostate cancer.

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.

Gozellix® is a novel product which provides a longer shelf life of up to six hours and an extended distribution radius compared to existing gallium-based imaging products. The ability to reliably deliver the product much further from its point of production means Gozellix® can reach PET cameras that are currently not served by any PSMA imaging providers, bringing the accuracy and clinical utility of gallium-based imaging to more patients across the U.S. The innovative formulation, which allows for more scalable production, also has the potential to enhance the efficiency, scheduling flexibility and throughput of scanning clinics.

Gozellix® builds on the success of Telix's established PSMA-PET imaging agent, Illuccix ®, and will be available alongside the first-generation product, providing choice for customers and patients based on their individual needs.

In the U.S., the accuracy and sensitivity of PSMA-PET imaging means it has become the standard of care for prostate cancer imaging after initial diagnosis and biochemical recurrence[2]. However, only a relatively small fraction of the 3.4 million men living with prostate cancer in the U.S. have undergone this type of precision medicine scan[3,4]. Telix believes Gozellix® will help to address these access issues, as it is expected to be eligible for full reimbursement[5] with reduced or no patient co-insurance, meaning it can reach more patients, particularly in underserved populations.

Kevin Richardson, Chief Executive Officer, Telix Precision Medicine, said, "Securing FDA approval for Gozellix is a major win for prostate cancer patients, who gain enhanced access to state-of-the-art ^{68}Ga PSMA-PET imaging. Telix continues to invest in innovation across our portfolio, and Gozellix is a testament to this continuous improvement approach. With the launch of Gozellix, our team is excited to be bringing the new generation of prostate cancer scanning to more American men, delivered with the reliability, service and flexibility that customers have come to expect from Telix."

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.

ADVERSE REACTIONS
The safety of gallium Ga-68 gozetotide was evaluated in 960 patients in the PSMA-PreRP and PSMABCR 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%.

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 Pharmaceuticals (US) by calling 1-844-455-8638 or emailing pharmacovigilance@telixpharma.com.

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, 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. ARTMS, IsoTherapeutics, Lightpoint, Optimal Tracers and RLS are Telix Group companies. 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, has been approved by the U.S. FDA[6], by the Australian Therapeutic Goods Administration (TGA)[7], by Health Canada[8], by the United Kingdom (UK) Medicines and Healthcare Products Regulatory Agency (MHRA)[9], by the Brazilian Health Regulatory Agency (ANVISA)[10], and in multiple countries within the European Economic Area (EEA)[11] following a positive decentralized procedure (DCP) opinion by the German medical regulator, BfArM[12]. Gozellix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection) has been approved by the U.S. FDA[13].

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.

Telix Investor Relations

Ms. Kyahn Williamson
Telix Pharmaceuticals Limited
SVP Investor Relations and Corporate Communications
Email: kyahn.williamson@telixpharma.com

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

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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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 and results of Telix's preclinical and clinical trials, and Telix's research and development programs; Telix's ability to advance product candidates into, enrol 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 commercialisation 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; 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] NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.4.2024.
[3] NIH Common Cancer Sites — Cancer Stat Facts. Accessed May 2024.
[4] Company analysis based on proprietary and public domain data.
[5] Hospital Outpatient Prospective Payment System (OPPS) patients eligible for reimbursed PSMA-PET scanning.
[6] Telix ASX disclosure 20 December 2021.
[7] Telix ASX disclosure 2 November 2021
[8] Telix ASX disclosure 14 October 2022.
[9] Telix ASX disclosure 13 February 2025.
[10] Telix ASX disclosure 18 March 2025.
[11] Denmark, Luxembourg, Malta, the Netherlands and Norway at time of release.
[12] Telix ASX disclosure 17 January 2025.
[13] Telix ASX disclosure 21 March 2025.