Telix Announces Cardinal Health for Gozellix Commercial Distribution

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MELBOURNE, Australia and INDIANAPOLIS, April 08, 2025 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, Telix, the Company) today announces that it has selected Cardinal Health, Inc. (NYSE: CAH, Cardinal Health) as one of its commercial radiopharmaceutical distributors to supply finished unit doses of Gozellix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection), Telix's next-generation PSMA-PET imaging[1] agent for prostate cancer in the United States (U.S.).

Following recent U.S. Food and Drug Administration (FDA) approval[2], and in preparation for commercial launch in H1 2025, Telix has contracted with Cardinal Health to enable availability across a wide range of U.S. locations. To support the rollout, Cardinal Health has deployed Telix's ARTMS QUANTM Irradiation System® (QIS®) cyclotron technology, enabling standardized, high-efficiency and cost-effective production of cyclotron-produced gallium-68 for use with Gozellix®. These installations will facilitate multi-Curie local production of gallium-68.

Kevin Richardson, Chief Executive Officer, Telix Precision Medicine, said, "Cardinal Health is a highly valued radiopharmacy distributor and its broad geographic reach and excellence in service delivery has been a key factor in the commercial success of Illuccix®. We are pleased to be building upon our successful relationship to bring the accuracy and clinical utility of gallium-based imaging to even more patients across the country with Gozellix®."

Mike Pintek, President of Cardinal Health Nuclear & Precision Health Solutions, added, "We are pleased to continue to build on our relationship with Telix, which now includes the distribution of Illuccix®, Zircaix®[3] and Gozellix®. The combination of our extensive commercial distribution structure and the innovative ARTMS production technology enables us to broaden patient reach and scheduling flexibility for gallium-based PSMA imaging. We look forward to bringing this novel precision medicine diagnostic to patients and their healthcare providers."

Cardinal Health will operate as a strategic radiopharmacy distributor for Gozellix alongside Telix's in-house radiopharmacy network.

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, 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. 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[4], by the Australian Therapeutic Goods Administration (TGA)[5], by Health Canada[6], by the United Kingdom (UK) Medicines and Healthcare Products Regulatory Agency (MHRA)[7], by the Brazilian Health Regulatory Agency (ANVISA)[8], and in multiple countries within the European Economic Area (EEA)[9] following a positive decentralized procedure (DCP) opinion by the German medical regulator, BfArM[10]. Gozellix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection) has been approved by the U.S. FDA[11].

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.

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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] Telix ASX disclosure 21 March 2025.

[3] Subject to regulatory approval, Telix media release 17 September 2024.

[4] Telix ASX disclosure 20 December 2021.

[5] Telix ASX disclosure 2 November 2021.

[6] Telix ASX disclosure 14 October 2022.

[7] Telix ASX disclosure 13 February 2025.

[8] Telix ASX disclosure 18 March 2025.

[9] Denmark, Ireland, Luxembourg, Malta, the Netherlands and Norway at time of release.

[10] Telix ASX disclosure 17 January 2025.

[11] Telix ASX disclosure 21 March 2025.