Telix and Varian Announce Strategic Theranostics-EBRT Clinical Collaboration

10 Dec 2025

MELBOURNE, Australia and PALO ALTO, Calif., Dec. 10, 2025 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, "Telix") today announces a strategic clinical collaboration with Varian, a Siemens Healthineers company and global leader in radiation oncology, to develop novel clinical applications that combine Telix's theranostic products and external beam radiation therapy (EBRT).

EBRT is a widely used and validated treatment suitable for most solid malignant tumors. This treatment is typically delivered by radiation oncologists who play a central role in managing cancer across multiple stages of the patient journey. The role of EBRT and radiation oncology in treating cancer could potentially be enhanced by integrating with therapeutic radiopharmaceuticals and precision diagnostics. Working with Varian, a key player in EBRT, Telix will explore how theranostics can be used more effectively by radiation oncologists to enhance patient selection and deliver targeted treatment.

The first area of investigational focus is PSMA-PET[1] imaging for prostate cancer radiotherapy patients. Telix and Varian aim to identify opportunities to utilize Gozellix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection) and Illuccix® (kit for the preparation of gallium-68 (^{68}Ga) gozetotide injection)[2] in selecting patients for EBRT, developing personalized treatment plans (particularly in the context of Varian's Ethos adaptive radiotherapy), and monitoring responses to treatment. The agreement supports both company-sponsored and investigator-led clinical studies, enabling robust clinical exploration of novel approaches.

While the initial focus is on PSMA imaging, the collaboration has been implemented as a general framework for future co-development opportunities, with broad clinical applicability. This includes other PET imaging candidates in Telix's pipeline, such as TLX250-CDx (Zircaix® [3]) and TLX101-CDx (Pixclara®[3]), as well as potential future therapeutic radiopharmaceuticals. By combining radiopharmaceutical theranostics with Varian's EBRT technology, the companies believe radiation oncologists are uniquely positioned to lead both definitive and palliative treatment strategies.

Dr. Arthur Kaindl, Head of Varian, said, "Collaborating with Telix opens a powerful pathway to embed precision imaging and theranostics into the radiation therapy workflow, advancing how we personalize and optimize treatment decisions. By combining Telix's strength in molecular imaging and radiopharmaceuticals with Varian's leadership in radiation therapy and treatment planning, we are shaping a future of more targeted, patient-focused cancer care."

Dr. Christian Behrenbruch, Group CEO and Managing Director, Telix, said, "This strategic partnership with Varian represents a transformative opportunity to bring precision imaging into the heart of radiation oncology. Integrating theranostics into EBRT has the potential to improve patient outcomes. And by combining Telix's innovation in molecular imaging with Varian's global leadership in cancer treatment technologies, we are building alliances to explore new frontiers in personalized cancer care."

IMPORTANT SAFETY INFORMATION (GOZELLIX)

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.

IMPORTANT SAFETY INFORMATION (ILLUCCIX)
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
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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.

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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.

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 United States Food and Drug Administration (FDA)[4].

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

About Varian

At Varian, a Siemens Healthineers company, we envision a world without fear of cancer. For more than 75 years, Varian has developed, built, and delivered innovative technologies and solutions that help care providers around the globe treat millions of patients each year. Today, as a Siemens Healthineers company, we support every step of the cancer care journey – from screening to survivorship. From advanced imaging and radiation therapy to comprehensive software and services, to interventional radiology, we are harnessing the power of our perspective while also pursuing clinical research to create a more efficient, and more personalized care pathway. Because, for cancer patients everywhere, their fight is our fight. For more information, visit http://www.varian.com

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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] Imaging of prostate-specific membrane antigen with positron emission tomography.

[2] Combined usage is not currently approved in any jurisdiction globally.

[3] Products and brand names subject to final regulatory approval.

[4] Telix ASX disclosure 21 March 2025.