Telix Pharmaceuticals Limited
ACN 616 620 369
Suite 401, 55 Flemington Road
North Melbourne
Victoria, 3051
Australia

ASX RELEASE

For personal use only

FDA Approves Telix's Prostate Cancer Imaging Product, Illuccix®

Melbourne (Australia) and Indianapolis, IN (U.S.A.) – 20 December 2021. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company), a global biopharmaceutical company focused on the development of diagnostic and therapeutic products based on molecularly targeted radiation (MTR), today announces that the United States Food and Drug Administration (FDA) has approved Telix's lead prostate cancer imaging product, Illuccix®.

Illuccix is a kit for the preparation of gallium-68 (^{68}Ga) gozetotide (also known as PSMA-11) injection, a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in patients with prostate cancer with:

- suspected metastasis who are candidates for initial definitive therapy;
- suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

"The approval of Illuccix will give patients considerably improved access to PSMA-PET imaging, an advanced diagnostic tool that was recently included in the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)[1] for Prostate Cancer," said Dr. Oliver Sartor, Medical Director at Tulane Cancer Center. "With patient doses able to be prepared on-site or via commercial radiopharmacy networks, either via generator or cyclotron, Illuccix delivers flexible patient scheduling and on-demand access throughout the day."

Illuccix is the first commercially available FDA-approved product to enable wide accessibility to ^{68}Ga-based PSMA-PET imaging for physicians and eligible patients across the United States. Illuccix can be prepared with ^{68}Ga via either GE's FASTlab™ cyclotrons or in nuclear pharmacies and healthcare centers across the country using Eckert & Ziegler's GalliaPharm® generator or IRE ELIT's Galli Eo® generator. This optionality along with a four-hour shelf life after radiolabeling with ^{68}Ga, enables Illuccix to flexibly extend the reach of advanced PSMA-PET imaging to patients across the country.

"This product offers a level of flexibility and accessibility to healthcare professionals we really haven't seen before in this class of products and may help us provide better patient experiences as a result," said Dr. Sartor.

With a distribution network encompassing more than 140 nuclear pharmacies through its agreements with Cardinal Health and PharmaLogic, Telix will be able to provide Illuccix to more than 85% of eligible PET imaging sites throughout the United States.

"This heralds a new era of patient and physician access to gallium-based PSMA-PET imaging and marks an important new stage for Telix as we bring our first commercial product to market in the United States," said Dr. Christian Behrenbruch, Managing Director and CEO at Telix. "Improved imaging can provide physicians with the insights to determine the most appropriate treatment pathway and give patients in the U.S. access to a specific and sensitive imaging tool for the detection of prostate cancer throughout the body."

About Illuccix®

Illuccix is a kit for the preparation of gallium-68 (^{68}Ga) gozetotide (also known as PSMA-11) injection.

[1] https://www.nccn.org/guidelines/category_1 - Pg. 24J.

^{68}Ga gozetotide Injection is used for imaging prostate cancer with positron emission tomography (PET), and targets prostate specific membrane antigen (PSMA), a protein that is overexpressed on the surface of more than 90% of primary and metastatic prostate cancer cells. Illuccix enables gozetotide (PSMA-11) to be labelled with the radionuclide ^{68}Ga directly before injection by medical professionals. After preparing the radiopharmaceutical and injecting it into the patient, PSMA positive lesions are localized by PET imaging.

Illuccix has been approved by the U.S. Food and Drug Administration (FDA), and by the Australian Therapeutic Goods Administration (TGA).[2] Telix is also progressing marketing authorization applications for Illuccix in the European Union[3], Canada[4], and other jurisdictions around the globe.

Important Safety Information

WARNINGS AND PRECAUTIONS

Risk for Misdiagnosis
Image interpretation errors can occur with gallium Ga 68 gozetotide 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. The performance of gallium Ga 68 gozetotide for imaging of biochemically recurrent prostate cancer seems to be affected by serum PSA levels and by site of disease. The performance of gallium Ga 68 gozetotide for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by Gleason score. 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.

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 health care workers. 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, each receiving one dose of gallium Ga 68 gozetotide. The average injected activity was 188.7 ± 40.7 MBq (5.1 ± 1.1 mCi). No serious adverse reactions were attributed to gallium Ga 68 gozetotide. 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 see full Prescribing Information at http://illuccixhcp.com/s/illuccix-prescribing-information.pdf

[2] ASX disclosure 2 November 2021.
[3] ASX disclosure 1 May 2020.
[4] ASX disclosure 16 December 2020.

For personal use only

For personal use only

About Prostate Cancer in the United States

Prostate cancer is the second leading cancer in men in the United States after skin cancer, with nearly 250,000 cases estimated in 2021, a significantly higher incidence than either lung cancer (119,000 new cases) or bowel cancer (80,000 new cases). Prostate cancer was also the second leading cause of cancer death in U.S. men in 2020, and it is estimated that more than 34,000 men will die from their disease in 2021.[5] More than 812,000 U.S. men were estimated to be living with prostate cancer in 2020.[6] In 2021 the National Comprehensive Cancer Network Guidelines® for prostate cancer were updated to include PSMA-PET imaging to be considered as an alternative to standard imaging of bone and soft tissue and for detection of unfavorable intermediate, high and very high risk as well as recurrent prostate cancer.

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development of diagnostic and therapeutic products using Molecularly Targeted Radiation (MTR). Telix is headquartered in Melbourne, Australia with international operations in Belgium, Japan, Switzerland and the United States. Telix is developing a portfolio of clinical-stage products that address significant unmet medical need in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com and follow Telix on Twitter (@TelixPharma) and LinkedIn.

Telix Investor Relations

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

Important Information

This announcement does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States, or in any other jurisdiction in which such an offer would be illegal. The securities referred to herein have not been and will not be registered under the United States Securities Act of 1933 (the "U.S. Securities Act"), or under the securities laws of any state or other jurisdiction of the United States and may not be offered or sold within the United States, unless the securities have been registered under the U.S. Securities Act or an exemption from the registration requirements of the U.S. Securities Act is available. None of the technologies or products described in this document have received a marketing authorisation in any jurisdiction. This announcement has been authorised for release by Dr Christian Behrenbruch, Managing Director and Chief Executive Officer. The Telix Pharmaceuticals name and logo are trademarks of Telix Pharmaceuticals Limited and its affiliates (all rights reserved).

[5] American Cancer Society, 2021.
[6] Globocan, 2021.