Telix Partnership Expands GE Healthcare Immuno-Diagnostics Offering to the Global Clinical Research Market

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- New agreement adds two Telix investigational PET imaging radiotracers to GE Healthcare's immuno-diagnostic portfolio, to enable patient selection and monitoring in immunotherapy trials
- Telix tracers evaluate levels of carbonic anhydrase IX and lactate in tumours to inform and improve therapy selection
- GE Healthcare's Pharmaceutical Diagnostics business is an established global supplier of PET imaging tracers to the global clinical research market

Melbourne (Australia) – 17 October 2022. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) has today announced a collaborative development and reseller agreement with GE Healthcare to supply its investigational positron emission tomography (PET) imaging radiotracers, TLX250-CDx (89Zr-DFO-girentuximab), and [18F]-FLac (18F-3-fluoro-2-hydroxypropionate) for use in third party clinical research and development activities. These novel tracers offer the potential to provide key information about the metabolic environment of tumours, which could help to inform and improve therapy selection. The agreement was announced during the European Association of Nuclear Medicine (EANM) Congress in Barcelona, Spain.

TLX250-CDx - the subject of Telix's recently completed Phase III ZIRCON study in clear cell renal cell carcinoma [1] - targets the antigen, carbonic anhydrase IX (CAIX). Expressed in many solid tumour types, CAIX can be used to identify hypoxic tumours,[2] cells that have been deprived of oxygen, which can correlate with disease progression and resistance to therapy, including immunotherapy. Identifying such tumours may guide changes in care, from immune checkpoint inhibitor (ICI) monotherapy to combination treatments that overcome the hypoxic barrier.

[18F]-FLac, which Telix in-licensed in 2021,[3] has shown promise in imaging lactate metabolism in oxygenated tumours. High lactate in tumours could prevent ICI responses and additionally be harmful in patients receiving ICI therapies.[4] Understanding tumour lactate metabolic status could guide treatment decisions towards immunotherapy combinations that overcome this barrier.

TLX250-CDx and [18F]-FLac complement GE Healthcare Pharmaceutical Diagnostics' pipeline of investigational non-invasive [18F]-CD8 and [18F]-Granzyme-B imaging tracers for use by pharmaceutical companies in clinical trials, with the potential to predict and monitor response to immunotherapy. Currently an average of only 20-40 percent of patients respond to immunotherapies, and patient suitability is typically determined by taking tumour biopsies.[5]

Jonathan Barlow, SVP Global Business Development & Alliance Management, Telix, said, "This partnership will see our investigational imaging agents used more widely in third-party clinical trials. Excitingly, it will also help to expedite the development of 18F-FLac, while expanding the utility of our TLX250-CDx imaging candidate."

Sanka Thiru, Global Business Leader, Immuno-Oncology, at GE Healthcare's Pharmaceutical Diagnostics business, said: "This partnership expands our pharmaceutical services offering, including our toolbox of investigational PET imaging diagnostics. These aim to enrich clinical trials for pharmaceutical companies with the possibility of determining the metabolic environment and immune status of tumours, and if successful, help to improve speed to market for potential therapies. Ultimately, these PET imaging diagnostics could assist in delivering effective oncology therapies to patients."

Under the agreement, GE Healthcare will be responsible for the directed marketing and sales of Telix's imaging agents to pharmaceutical companies, with the close support of Telix, whilst Telix will be responsible for manufacturing and ongoing development of each product. Telix and GE Healthcare will explore validation of 18F-FLac for use in GE Healthcare's FASTlab TM, an automated PET radiochemistry synthesizer, widely used for onsite production of FDG[6] and other PET tracers.

The agreement has an initial term of five years, subject to review and termination rights based on performance after three years.

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development and commercialisation of diagnostic and therapeutic radiopharmaceuticals. Telix is headquartered in Melbourne, Australia with international operations in the United States, Europe (Belgium and Switzerland), and Japan. Telix is developing a portfolio of clinical-stage products that aims to 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's lead product, gallium-68 (68Ga) gozetotide (also known as 68Ga PSMA-11) injection, has been approved by the U.S. Food and Drug Administration (FDA),[7] and by the Australian Therapeutic Goods Administration (TGA).[8] Telix is also progressing a marketing authorisation application for this investigational candidate in Canada.[9]

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About GE Healthcare:

GE Healthcare is the $17.7 billion healthcare business of GE (NYSE: GE). As a leading global medical technology, pharmaceutical diagnostics and digital solutions innovator, GE Healthcare enables clinicians to make faster, more informed decisions through intelligent devices, data analytics, applications and services, supported by its Edison intelligence platform. With over 100 years of healthcare industry experience and around 48,000 employees globally, the company operates at the center of an ecosystem working toward precision health, digitizing healthcare, helping drive productivity and improve outcomes for patients, providers, health systems and researchers around the world.

This announcement has been authorised for release by the disclosure committee of Telix Pharmaceuticals Limited.

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To the maximum extent permitted by law, Telix disclaims any obligation or undertaking to publicly update or revise any forward-looking statements contained in this announcement, whether as a result of new information, future developments or a change in expectations or assumptions.

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[1] ASX disclosure 11 July 2022

[2] Huizing, F.J., Garousi, J., Lok, J. *et al.* CAIX-targeting radiotracers for hypoxia imaging in head and neck cancer models. *Sci Rep* 9, 18898 (2019). https://doi.org/10.1038/s41598-019-54824-5

[3] Media release 9 September 2021

[4] Johnson, *et al*. Dangerous dynamic duo: Lactic acid and PD-1 blockade. Cancer Cell 40(2) 127-130 (2022). https://doi.org/10.1016/j.ccell.2022.01.008

[5] Haslam A, Prasad V. Estimation of the Percentage of US Patients With Cancer Who Are Eligible for and Respond to Checkpoint Inhibitor Immunotherapy Drugs. JAMA Netw Open. 2019;2(5):e192535. doi:10.1001/jamanetworkopen.2019.2535

[6] 18F-FDG (2-deoxy-2-18F-fluoro-*D*-glucose)

[7] ASX disclosure 20 December 2021.

[8] ASX disclosure 2 November 2021.

[9] ASX disclosure 16 December 2020.