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**ASX RELEASE** 

# **Telix and RefleXion Expand Partnership for Prostate Cancer Treatment**

*Melbourne (Australia) and Indianapolis, IN (U.S.)* – 10 June 2022. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) and RefleXion Medical, Inc. (Hayward, California, U.S.) (RefleXion) today announced the signing of a co-development and commercialisation agreement, to expand the use of Telix's prostate cancer imaging agent, Illuccix<sup>®</sup> (kit for preparation of gallium (<sup>68</sup>Ga) gozetotide) with the RefleXion® biology-guided radiotherapy (BgRT)\* platform to guide external-beam radiotherapy in real-time.

BgRT is the first and only cancer treatment designed to integrate PET technology as part of external-beam radiotherapy delivery. It uses PET tracers as biological guides to signal the location of cancer and guide the delivery of radiotherapy to tumours in real-time. BgRT has the potential to offer significant advantages over conventional radiotherapy as it may one day enable treatment of multiple tumors per session for metastatic disease, increase the conformality of radiotherapy delivery, and reduce toxicity to healthy tissue. This approach may facilitate treatment of later stage cancers than is currently practical for hospitals or tolerable by patients.

Under the agreement, which builds on an existing strategic collaboration between the companies, Telix and RefleXion will conduct and co-fund a BgRT clinical program using Illuccix as a biological guide, seek regulatory approval and jointly pursue commercialization, initially in the United States. The parties will share in any upside generated if successfully commercialized. The clinical program is expected to commence in 2023. RefleXion is exclusively partnering with Telix for <sup>68</sup>Ga PSMA-PET imaging agents for use with BgRT. The agreement also includes the potential to expand the exclusive relationship beyond the U.S., in countries where both Illuccix and BgRT are intending to be commercialised.

If approved, Illuccix for BgRT could potentially open a broad new market opportunity for Illuccix as a therapy guidance agent. More than 60,000 men undergo external-beam radiotherapy for prostate cancer every year in the U.S. alone<sup>2</sup>. Illuccix for BgRT would require up to five doses per patient (one for each session of external-beam radiotherapy), potentially expanding the volume of Illuccix used in the U.S. significantly. The scheduling flexibility of Gallium-based compounds such as Illuccix may provide additional advantages for patients and caregivers using BgRT technology.

Dr. Christian Behrenbruch, Group CEO of Telix Pharmaceuticals said, "Following a successful evaluation period, we are pleased to expand our relationship with RefleXion and move ahead with a clinical program with the objective of regulatory approval of Illuccix for BgRT. This partnership demonstrates the potential for Illuccix and other molecularly-targeted imaging agents in our pipeline to be used as a tool to both detect the presence of metastatic disease and guide treatment using innovative complementary technologies such as BgRT."

Dr. Thorsten Melcher, Chief Business Officer at RefleXion added, "With PSMA-PET quickly being established as a standard of care in prostate cancer imaging, the clinical program aims to determine whether Telix's gallium-based tracer can provide a complete and robust signal to guide BgRT to treat all stages of prostate cancer, eventually including metastatic disease. Illuccix offers great accessibility and scheduling flexibility, factors which we believe will be well-suited to the treatment regimen with our BgRT system."

<sup>&</sup>lt;sup>1</sup> ASX release 8 July 2020

<sup>&</sup>lt;sup>2</sup> https://www.pcf.org/c/treatment-for-prostate-cancer-external-beam-radiation-therapy/

Reflexion has received marketing clearance from the United States Food and Drug Administration (FDA) for its X1 machine that combines high quality computed tomography (CT) imaging with stereotactic body radiotherapy (SBRT), stereotactic radiosurgery (SRS) and intensity modulated radiotherapy (IMRT).

### **About Reflexion Medical**

RefleXion is a privately-held company developing the first biology-guided radiotherapy system, a significant change in strategy from single tumor therapy to the ability to one day treat multiple tumors in the same treatment session in cancers that have metastasized. Currently, the RefleXion X1 machine is cleared for the delivery of stereotactic body radiotherapy (SBRT), stereotactic radiosurgery (SRS) and intensity modulated radiotherapy (IMRT). The company is also developing BgRT, which incorporates positron-emission tomography (PET) imaging data to enable tumors to continuously signal their location. The BgRT technology will synchronize these data with the linear accelerator to direct radiotherapy to tumors with sub-second latency. For more information, visit <a href="https://www.reflexion.com">www.reflexion.com</a> and follow RefleXion on <a href="https://www.reflexion.com">Twitter</a> (@reflexionmed) and <a href="https://www.linkedln">Linkedln</a>.

\*The RefleXion® X1 is cleared for SBRT/SRS/IMRT. BgRT is pending regulatory review and is not commercially available.

### **About Telix Pharmaceuticals Limited**

Telix is a biopharmaceutical company focused on the development and commercialisation 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 <a href="www.telixpharma.com">www.telixpharma.com</a> and follow Telix on <a href="twww.telixpharma.com">Twitter</a> (@TelixPharma) and <a href="LinkedIn.">LinkedIn.</a>

Telix's lead product, gallium-68 (<sup>68</sup>Ga) gozetotide (also known as <sup>68</sup>Ga PSMA-11) injection, has been approved by the U.S. Food and Drug Administration (FDA),<sup>3</sup> and by the Australian Therapeutic Goods Administration (TGA).<sup>4</sup> Telix is also progressing marketing authorisation applications for this investigational candidate in Europe<sup>5</sup> and Canada.<sup>6</sup>

Important Safety Information: <a href="https://www.illuccixhcp.com/important-safety-information">https://www.illuccixhcp.com/important-safety-information</a>

Please see full U.S. Prescribing Information at: <a href="https://illuccixhcp.com/wp-content/uploads/illuccixprescribing-information.pdf">https://illuccixhcp.com/wp-content/uploads/illuccixprescribing-information.pdf</a>

## **Telix Investor Relations**

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This announcement has been authorised for release by Dr. Christian Behrenbruch, Managing Director and Group Chief Executive Officer.

<sup>&</sup>lt;sup>3</sup> ASX disclosure 20 December 2021.

<sup>&</sup>lt;sup>4</sup> ASX disclosure 2 November 2021.

<sup>&</sup>lt;sup>5</sup> ASX disclosure 10 December 2021.

<sup>&</sup>lt;sup>6</sup> ASX disclosure 16 December 2020.

#### Legal Notices

This announcement may include forward-looking statements 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", "outlook", "forecast" and "guidance", or other similar words. 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 the Company's good-faith assumptions as to the financial, market, regulatory and other considerations that exist and affect the Company'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 studies, 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, manufacturing activities and product marketing activities; the commercialisation of Telix's product candidates, if or when they have been approved; 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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