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## ASX ANNOUNCEMENT

### **Illuccix® Approved for Prostate Cancer Imaging in Brazil: First Marketing Authorization in Latin America**

Melbourne (Australia) and Porto Alegre (Brazil) – 18 March 2025. Telix Pharmaceuticals Limited (ASX: TLX, Nasdaq: TLX, Telix, the Company) today announces that the Brazilian Health Regulatory Agency (Agencia Nacional de Vigilância Sanitária or 'ANVISA') has approved Illuccix® (kit for the preparation of gallium-68 (<sup>68</sup>Ga) gozetotide injection) the Company's lead prostate cancer imaging agent. Illuccix® is the first and only PSMA-PET<sup>1</sup> prostate cancer imaging agent to receive full regulatory approval in Brazil.

Illuccix®, after radiolabeling with <sup>68</sup>Ga, is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- With suspected metastasis who are candidates for definitive initial therapy treatment, and
- With suspected recurrence based on an elevated specific antigen (PSA) level in the serum.

The marketing authorization is granted to Telix's partner R2PHARMA, Brazil's leading cold kit manufacturer, nuclear pharmacy and cyclotron network, and a subsidiary of GSH Corp Participações S.A. (Grupo GSH). Telix has provided Grupo GSH with an exclusive license to manufacture, distribute and market Illuccix® in Brazil<sup>2</sup>.

PSMA-PET is a diagnostic technology demonstrated to detect advanced prostate cancer. ANVISA becomes the latest regulatory body worldwide to approve Illuccix®<sup>3</sup>, which is already commercially available in Australia, Canada, New Zealand and the United States, and has recently been approved in the United Kingdom and in multiple countries within the European Economic Area (EEA).

Dr. Sérgio Altino de Almeida, nuclear medicine specialist, at Rede D'Or, the largest integrated healthcare network in Brazil said, "The ANVISA approval of Illuccix provides access to advanced prostate cancer imaging for men across Brazil, a large and rapidly growing market for gallium-68 based radiopharmaceuticals. The 'cold kit' format with generator-produced gallium will facilitate broad equity of access for men living with prostate cancer, regardless of whether they are based in regional, rural or metropolitan areas."

#### **JV to manufacture and distribute radiopharmaceuticals for clinical and commercial use in Brazil**

Telix also announces a joint venture (JV) with R2PHARMA to commercialize and distribute Telix's therapeutic and diagnostic radiopharmaceutical products in Brazil, building on the existing partnership established in 2019. The JV further strengthens this relationship with a commitment to jointly bring to market innovative and first-in-class therapeutic radiopharmaceuticals and imaging agents in Brazil.

The market for radiopharmaceuticals in Brazil is experiencing significant growth driven by the increasing prevalence of chronic diseases such as cancer, advancements in imaging technologies, and a growing senior population. Over the next decade, the Brazilian radiopharmaceuticals market

<sup>1</sup> Imaging of prostate-specific membrane antigen (PSMA) via a positron emission tomography (PET) scan (known as PSMA-PET).

<sup>2</sup> Telix ASX disclosure 3 July 2019. The license for Illuccix® in Brazil was granted by Telix to MJM Produtos Farmacêuticos e de Radioproteção S.A., a subsidiary of Grupo R2PHARMA.

<sup>3</sup> Illuccix® has been previously available in Brazil under an exceptional authorisation granted in December 2021 (Telix ASX disclosure 1 December 2021).

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is projected to reach US\$330 million<sup>4</sup>, with this growth supported by rising investments in the healthcare industry, public health awareness, and the introduction of new and advanced radiopharmaceuticals.

Under the agreement, Telix and R2PHARMA will establish a JV company in Brazil (Telix Innovations Brazil, Ltda.). Telix Innovations Brazil will hold the exclusive licence to commercialize and distribute Illuccix® as well as future product candidates from Telix's industry-leading theranostic pipeline. Telix Innovations Brazil will leverage the local knowledge and expertise of R2PHARMA to obtain the necessary licenses and governmental authorizations in Brazil<sup>5</sup>.

Raphaël Ortiz, CEO Telix International, added, "Telix is pleased to bring Illuccix to Brazil and Latin America, with this new imaging modality now recognized in leading clinical practice guidelines and already being adopted in other parts of the world. We would like to acknowledge our partner R2PHARMA for their commitment to gallium-based PSMA-PET and the hope this brings for men living with prostate cancer in Brazil. The JV takes our collaboration to the next stage with the aim to address unmet need for therapeutic and diagnostic radiopharmaceuticals across a range of disease areas."

R2PHARMA Nuclear Medicine & Innovation Vice-President, Rafael Madke, continued, "We are delighted to have been granted this marketing authorization for Illuccix in Brazil. The combination of Telix's innovative theranostic pipeline and R2PHARMA's manufacturing and distribution capabilities will support widespread access for patients and physicians to Illuccix and future additional products that until now have not been available in Latin America."

### **About Prostate Cancer in Brazil**

Prostate cancer is the most commonly diagnosed male cancer in Brazil with an estimated 71,730 new cases in 2023<sup>6</sup>. Prostate cancer was also the second most common cause of cancer death in men (after lung cancer), with approximately 20,000 men dying from their disease in 2022. More than 250,000 men in Brazil were estimated to be living with prostate cancer in 2022<sup>7</sup>.

### **About Illuccix®**

Illuccix® is a kit for the preparation of gallium-68 (<sup>68</sup>Ga) gozetotide (also known as PSMA-11) injection, a radioactive diagnostic agent indicated for PET imaging combined with computerized tomography (CT) scan in case of suspicion of prostate cancer relapse in adult males to detect and localize recurrent cancerous lesions. <sup>68</sup>Ga gozetotide injection targets 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 <sup>68</sup>Ga directly before injection by medical professionals.

Illuccix® has been approved by the U.S. Food and Drug Administration (FDA)<sup>8</sup>, by the Australian Therapeutic Goods Administration (TGA)<sup>9</sup>, by Health Canada<sup>10</sup>, by the United Kingdom (UK) Medicines and Healthcare Products Regulatory Agency (MHRA)<sup>11</sup>, by the Brazilian Health Regulatory Agency (ANVISA)<sup>12</sup> and in multiple countries within the EEA<sup>13</sup> following a positive decentralized procedure (DCP) opinion by the German medical regulator, BfArM<sup>14</sup>.

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<sup>4</sup> Allied Market Research 2022.

<sup>5</sup> Marketing authorizations in Brazil will be held by Telix Innovations Brazil, Ltda., returned to Telix on expiry or termination of the relevant license agreement.

<sup>6</sup> Brazilian Cancer Institute.

<sup>7</sup> Global Cancer Statistics 2022: GLOBOCAN survey. Published August 2024.

<sup>8</sup> Telix ASX disclosure 20 December 2021.

<sup>9</sup> Telix ASX disclosure 2 November 2021.

<sup>10</sup> Telix ASX disclosure 14 October 2022.

<sup>11</sup> Telix ASX disclosure 13 February 2025.

<sup>12</sup> Resolution-RE No. 954, of 13 March 2025, published at D.O.U. No. 51, page 75, 17 March 2025.

<sup>13</sup> Denmark, Luxembourg, Malta, and Norway at time of release.

<sup>14</sup> Telix ASX disclosure 17 January 2025.

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## About R2PHARMA

Operating since 2002, R2PHARMA commercially delivers Cold Kits for  $^{99m}\text{Tc}$  and  $^{68}\text{Ga}$  preparation for the Brazilian market. R2PHARMA is also the owner of the only private fully Good Manufacturing Practice (GMP) production facility in Brazil for nuclear medicine products. R2PHARMA products are sold throughout Brazil, serving more than 420 customers on a daily basis, and exports their products to more than 10 countries around the world. R2PHARMA is also a pioneer of the nuclear pharmacy model in Brazil with two operating centers in São Paulo and Rio de Janeiro. The company also operates the largest production network of cyclotrons in South America, with five sites distributed in the states of Paraná, São Paulo, Rio de Janeiro and Pernambuco. The last installed facility will include, in addition to the production of  $^{18}\text{F}$  radiopharmaceuticals, a solid target for the production of  $^{89}\text{Zr}$ ,  $^{68}\text{Ga}$  and  $^{64}\text{Cu}$ , as well as a laboratory dedicated to the production of molecules labeled with  $^{177}\text{Lu}$ . For more information visit: <http://r2pharma.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. Telix is listed on the Australian Securities Exchange (ASX: TLX) and the Nasdaq Global Select Market (Nasdaq: TLX).

Visit [www.telixpharma.com](http://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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*This announcement has been authorised for release by the Telix Pharmaceuticals Limited Disclosure Committee on behalf of the Board.*

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