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ASX RELEASE

Telix Withdraws Marketing Authorisation Application for Illuccix® in Europe

Melbourne (Australia) – 28 September 2022. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today provides an update regarding its marketing authorisation application (MAA) in Europe for its investigational product Illuccix® (TLX591-CDx, Kit for the preparation of ⁶⁸Ga-PSMA-11 injection).

The Company advises that, in the late stages of review, the Danish Medicines Agency (DKMA), in consultation with other European regulatory authorities, has requested additional Chemistry, Manufacturing and Control (CMC) data. These requests cannot be reasonably delivered within the prescribed review timeframe and therefore Telix has elected to withdraw the application.

This is an unexpected and extremely disappointing result considering that Illuccix has been approved by other major global regulators and given the Company's track record of delivering PSMA PET imaging reliably and safely to tens of thousands of European men with prostate cancer under compassionate and "magisterial" use availability. Ultimately, this is a poor outcome for patients.

Dr Christian Behrenbruch, Group Chief Executive Officer and Managing Director said, "This is not the outcome we expected, despite our best efforts to meet all regulator information requests. The outcome is reflective of the novelty of our submission approach ('full mixed' application) and the specific nuances of European product approval requirements (EU Pharmacopoeia). We are confident that the additional data can be provided, but the prescribed timeframes of the review process mean that the most efficient process is to withdraw the application and then resubmit.

"We note that the financial impact for FY2023 is minimal as full commercial sales were not expected to commence until mid-2023, following completion of the national approval phase and securing individual country reimbursement. We are in the fortunate position of having commercial sales underway in the United States and Australia, where we expect to see the growth trajectory continue. We remain committed to bringing an approved ⁶⁸Ga-PSMA-11 product to market in Europe."

Telix intends to resubmit for a marketing authorisation for Illuccix in Europe. The Company is also assessing alternative regulatory options available for the most streamlined route to approval with a revised submission. This includes pathways that were not available to the Company at the time of the original filing. The decision to enact a voluntary withdrawal maximises the regulatory resubmission options available for Illuccix in Europe.

Investor Conference Call

An investor conference call will be held at 9.15am AEST today, 28 September 2022 (7.15pm ET, 27 September 2022). Participants may register for the call at this link: <https://s1.c-conf.com/diamondpass/10025704-xd2g9k.html>

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),¹ and by the Australian Therapeutic Goods Administration (TGA).² Telix is also progressing marketing authorisation applications for this investigational candidate in Canada.³

Telix Investor Relations

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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 20 December 2021.

² ASX disclosure 2 November 2021.

³ ASX disclosure 16 December 2020.