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Czech Republic Grants National Authorisation for the Use of Telix's Prostate Cancer Imaging Product

Melbourne (Australia) and Liège (Belgium) – 16th February 2021. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') announces today that the Ministry of Health of the Czech Republic is the first European health authority to grant a national authorisation allowing the use of TLX591-CDx (Kit for the preparation of ^{68}Ga-PSMA-11), a radiopharmaceutical targeting Prostate-Specific Membrane Antigen (PSMA) for the imaging of prostate cancer using Positron Emission Tomography (PET).

The national authorisation, which is specific to Telix's prostate cancer imaging product, enables Czech physicians to use TLX591-CDx under a Specific Therapeutic Programme (STP), which allows medical products intended for the treatment, prevention or diagnosis of conditions severely affecting human health to be used prior to being granted a full European marketing authorisation.[1] Telix is collaboratively pursuing such temporary approvals in a number of European countries, concurrent with marketing authorisation applications.

Under the STP authorisation, which is valid until 31st December 2022 TLX591-CDx is indicated for the diagnostic imaging of prostate cancer using PET/CT or PET/MRI for the purposes of:

1. Primary staging of high-risk disease with a view to early identification of metastases
2. Localisation of prostate cancer in patients with PSA progression following radical treatment[2]
3. Identification of patients with extensive generalised prostate cancer for who radical life-saving treatment is not indicated

President of the Czech Society of Nuclear Medicine, Dr. David Zogala stated, "The Czech Society of Nuclear Medicine considers this temporary approval of PSMA PET in the Czech Republic to be a very important milestone, with an immense impact on the quality of prostate cancer care. Accessibility to this valuable examination will increase across the Czech Republic, as previously it was limited to one single pioneer hospital in Pilsen. The Society would like to acknowledge all the specialists who have taken part in the preparation of the Programme documentation, the supporting societies, the distributor, and the manufacturer."

Telix CEO, Dr. Christian Behrenbruch added, "We wish to acknowledge the outstanding leadership of the Czech Society of Nuclear Medicine, the Nuclear Medicine Institute at General University Hospital Prague, and the First Faculty of Medicine at Charles University Prague, in preparing and submitting the application for the Specific Therapeutic Programme use of TLX591-CDx, to the Czech Ministry of Health. The Czech Republic is the first European country to grant broad patient access to PSMA imaging, and we look forward to working with our distribution partner THP Medical Products to ensure this state-of-the-art imaging modality is available to all men in the Czech Republic living with prostate cancer."

About Prostate Cancer

Prostate cancer is the second most common cancer in men following skin cancer, with approximately 1.4 million men diagnosed with prostate cancer annually worldwide.[3] While meaningful advances in the treatment of prostate cancer have occurred in recent years, more than 375,000 men still die from

[1] https://www.sukl.eu/pharmaceutical-industry/related-information.
[2] Clinical indication also known as biochemical recurrence (BCR).
[3] GLOBOCAN 2020.

prostate cancer each year. The incidence of prostate cancer continues to increase, with the highest rates of the disease occurring in the United States, Canada, Europe and Australia and New Zealand.

About Telix Pharmaceuticals Limited

Telix is a clinical-stage 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, and the United States. Telix is developing a portfolio of clinical-stage products that address significant unmet medical needs in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com and follow us on Twitter (@TelixPharma) and LinkedIn.

Telix's lead product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been accepted for filing by the U.S. FDA[4], and has been granted Priority Review status by the Therapeutic Goods Administration (TGA) in Australia.[5] Telix is also progressing marketing authorisation applications for Illuccix® in the European Union[6] and Canada.[7] None of Telix's products have currently received a marketing authorisation in any jurisdiction.

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[4] ASX disclosure 24/11/2020.
[5] ASX disclosure 7/12/2020.
[6] ASX disclosure 1/05/2020.
[7] ASX disclosure 16/12/2020.