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Telix Pharmaceuticals submits European marketing authorisation application for prostate cancer imaging product

Melbourne (Australia) and Liège (Belgium) – 1st May 2020. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today announces that it has submitted a marketing authorisation application (MAA) in Europe for TLX591-CDx (^{68}Ga-PSMA-11 Injection) for the imaging of prostate cancer with Positron Emission Tomography (PET).

The submission has been made to the Danish Medicines Agency (DKMA) in its capacity as a reference Competent Authority of a European member state. The DKMA will coordinate and lead the evaluation of Telix's MAA for TLX591-CDx on behalf of Denmark as well as a selection of European countries, nominated by Telix. These countries reflect the major European markets for Telix's prostate cancer imaging product.

In accordance with the current European Association of Urology (EAU) guidelines on prostate cancer imaging, Telix is seeking a product approval in Europe for TLX591-CDx for the indication of imaging patients with elevated prostate-specific antigen (PSA) after radical prostatectomy or radiation therapy. This indication, which is broadly termed biochemical recurrence (BCR), is reported to occur in 20-40% and 30-50% of men who have undergone prostatectomy or radiation therapy with curative intent, respectively.[1]

Telix EU President and co-founder of Telix's wholly owned subsidiary Advanced Nuclear Medicine Ingredients (ANMI) Mr Ludovic Wouters said "We are delighted to have submitted our first marketing authorisation application for a commercially significant market. We approached the DKMA as our reference Competent Authority due to their extensive experience in reviewing medical imaging and radiopharmaceutical product submissions. We've consulted with the DKMA since early 2019 and have gained valuable feedback based on a clear understanding of the clinical need for this technology."

Telix's European MAA for TLX591-CDx is the result of an extensive pan-European collaboration and includes clinical data obtained in over 2,000 patients from both prospective and retrospective studies at leading European nuclear medicine centres. Institutions contributing clinical data include Ospedale Sant'Orsola (Bologna, Italy), Ordensklinikum, St Vincent's Hospital (Linz, Austria), University Hospital of RWTH University (Aachen, Germany), Cliniques Universitaires Saint-Luc UCL (Brussels, Belgium) and Nuclear Medicine Biophysics Paris Hôpital Tenon (Paris, France).

Telix CEO Dr Christian Behrenbruch said that "Getting to the point of submitting a marketing authorisation based on extensive clinical data and a robust manufacturing package, is the rarely achieved goal of every small biopharmaceutical company. We have the added advantage that use of our technology has also now been written into clinical practice guidelines in Europe and the United States, so we expect rapid adoption post-approval. In addition to recognizing the clinical partners that have contributed to this submission, I'd like to acknowledge the outstanding pioneering work by scientists and clinicians at Heidelberg University in Germany and the Deutsches Krebsforschungszentrum (German Cancer Research Centre), whom we have to thank for the opportunity to bring this exciting technology to market for the benefit of patients."

[1] Kolodziej M. Management of Biochemically Recurrent Prostate Cancer Following Local Therapy. Am J Manag Care. 2014; 20:S273-S281.

About TLX591-CDx

TLX591-CDx (kit for the preparation of ^{68}Ga-PSMA-11 injection) is a proprietary formulation of PSMA-HBED-CC (PSMA-11), a novel small molecule agent targeting prostate-specific membrane antigen (PSMA), originally developed by the Heidelberg group of the Deutsches Krebsforschungszentrum (German Cancer Research Centre, DKFZ).[2] The "cold kit" format of TLX591-CDx enables rapid radiolabelling at room temperature with high radiochemical purity and production consistency, ideally suited for the radiopharmacy setting. Currently, TLX591-CDx is available for investigational use only. TLX591-CDx is not currently approved in any regulatory jurisdiction including the United States and European Union.

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 with international operations in Belgium, Japan and the United States. Telix is developing a portfolio of clinical-stage oncology products that address significant unmet medical need in renal, prostate and brain cancer. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telix.com.

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[2] Eder, et al. Bioconjugate Chem Apr 18, 2012; 23(4): 688-97.