
Japanese Prostate Cancer Imaging Study Completes Enrolment

Melbourne (Australia) and Kyoto (Japan) – 9 September 2021. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that the last patient has been imaged in a Phase I clinical study of Telix’s investigational prostate cancer imaging product TLX591-CDx (Illuccix[®], Kit for the preparation of ⁶⁸Ga-PSMA-11 injection) in collaboration with Kanazawa University.

This study, which reached target enrolment of ten patients, is the first clinical evaluation of a Gallium-68-labeled prostate cancer diagnostic imaging agent in Japan. The objective is to obtain safety data in a representative Japanese patient population and to confirm that the targeting and biodistribution of TLX591-CDx in Japanese patients are consistent with international experience. Subject to positive outcomes, clinical data obtained from this study will facilitate development planning with Japan’s Pharmaceuticals and Medical Devices Agency (PMDA) and potentially other Asian regulators.

Professor Atsushi Mizokami from the Department of Integrative Cancer Therapy and Urology, Kanazawa University, Graduate School of Medical Science said, "I am pleased that we have successfully completed enrolment of the first Japanese clinical study of ⁶⁸Ga-PSMA-11 for men with advanced prostate cancer, despite severe ongoing disruption caused by the COVID-19 pandemic. This state-of-the-art PET imaging agent is currently under regulatory review in 17 countries worldwide and we are excited to play our role in bringing this important new diagnostic tool to market in Japan as efficiently as possible."

Shintaro Nishimura, President of Telix Pharmaceuticals Japan, added, "We are grateful to Professor Mizokami and his colleagues for their efforts in recruiting this trial in a timely fashion, as well as study participants for their commitment to delivering innovative benefits to Japanese men living with prostate cancer. I believe that this will become a cornerstone moment for future prostate cancer theranostics in Japan and the Asia-Pacific region and provides a pathway for Telix to engage with regulators for approval of our lead product, in Japan."

About Telix Pharmaceuticals Limited

Telix is a 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 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](https://twitter.com/TelixPharma) (@TelixPharma) and [LinkedIn](https://www.linkedin.com/company/telix-pharmaceuticals).

Telix’s lead investigational product, Illuccix[®] (TLX591-CDx) for prostate cancer imaging, has been accepted for filing by the U.S. FDA,¹ and is under priority evaluation by the Australian Therapeutic Goods Administration (TGA).² Telix is also progressing marketing authorisation applications for Illuccix[®] in the European Union³ and Canada.⁴ None of Telix’s products have received a marketing authorisation in any jurisdiction.

¹ ASX disclosure 24/11/20.

² ASX disclosure 14/04/21.

³ ASX disclosure 1/05/20.

⁴ ASX disclosure 16/12/20.

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