
Telix and Kanazawa University Commence Japanese Clinical Study for Prostate Cancer Imaging

Melbourne (Australia) – 14th December 2020. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today announces its subsidiary, Telix Pharmaceuticals Japan KK ('Telix Japan'), has entered a clinical study collaboration with Kanazawa University (Japan) for the conduct of a Phase I trial of TLX591-CDx (⁶⁸Ga-PSMA-11), a radiopharmaceutical for the imaging of prostate cancer using Positron Emission Tomography (PET).

The Phase I trial, which will enroll 10 patients with advanced prostate cancer, will be the first clinical trial involving the use of gallium-based PSMA imaging in Japan. Telix has developed TLX591-CDx as a next-generation PET imaging agent that targets prostate-specific membrane antigen (PSMA), which is expressed on the surface of prostate cancer cells. PSMA imaging has emerged as a new standard of care in prostate cancer imaging globally and is already included in clinical practice guidelines in the United States¹ and Europe.² The purpose of the study is to obtain preliminary Japanese ethnicity data in order to demonstrate to the Japanese Pharmaceutical and Medical Devices Agency (PMDA) that the targeting and biodistribution of TLX591-CDx is comparable to the rest of the world in order to facilitate planning discussions for product approval in Japan.

Dr. Shintaro Nishimura, President of Telix Japan, stated "It is a great pleasure to work with Kanazawa University, which is the oldest Department of Nuclear Medicine in Japan. Through this collaboration, we take a first critical step toward providing PSMA imaging to Japanese men with prostate cancer. The annual incidence of prostate cancer in Japan is 70,000 patients³ with this figure expected to rise over coming years. As such, there is an urgent need to deliver this break-through imaging modality to Japanese patients without delay. We wish to thank Kanazawa University's Departments of Nuclear Medicine and Urology, the Innovative Clinical Research Center (iCREK), and the Kanazawa Advanced Medical Center (KadMedic) for their support in bringing this important clinical study to realisation."

Prof. Seigo Kinuya, Professor of Nuclear Medicine at the Kanazawa University Hospital, Department of Nuclear Medicine, Chair of the Japanese Society of Nuclear Medicine, and Chair of the National Conference for Nuclear Medicine Theranostics, added, "The Third-Term Comprehensive 10-year Strategy for Cancer Control, a nation-wide initiative advocating the promotion of radiation therapy, has been in place since 2004. In order to deliver on this initiative, concrete development of new diagnostic and therapeutic agents in Japan is essential. Our collaboration with Telix Japan and this first clinical trial of ⁶⁸Ga-PSMA-11 prostate imaging in Japan are important milestones in the progress of Japanese nuclear medicine. We look forward to providing new diagnostics to patients in Japan as early as possible in collaboration with Telix."

About Kanazawa University

Kanazawa University is one of the leading national universities in Japan with approximately 10,000 students in Ishikawa Prefecture. Kanazawa University aims to contribute to world peace and the sustainable growth and development of humankind. Kanazawa University is committed to the real-world application of its research, and to contributing to local and international communities as the education and research focused university open to the region and the world. Kanazawa University

¹ <https://ascopubs.org/doi/full/10.1200/JCO.19.02757>.

² <https://uroweb.org/guideline/prostate-cancer/#5>.

³ GLOBOCAN 2018.

established the first Department of Nuclear Medicine in Japan. For more information, please visit <https://www.kanazawa-u.ac.jp/>.

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 oncology products that address significant unmet medical needs in prostate, kidney, brain and hematological cancers. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information, please visit www.telixpharma.com.

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