Telix Pharmaceuticals Limited
ACN 616 620 369
Suite 401, 55 Flemington Road
North Melbourne
Victoria, 3051
Australia

Telix Granted TGA Priority Review for Prostate Cancer Imaging

Melbourne (Australia) – 7th December 2020. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') announces today that its application for a Therapeutic Goods Administration (TGA) determination for its prostate cancer imaging product TLX591-CDx (^{68}Ga-PSMA-11), a radiopharmaceutical for the imaging of prostate cancer using Positron Emission Tomography (PET), has been granted Priority Review status. This important outcome grants Telix a significantly accelerated timeframe of 150 working days for product dossier review and approval.

The Company's preliminary application to the TGA for TLX591-CDx was made at the same time as Telix's New Drug Application (NDA) submission to the United States Food and Drug Administration (FDA), the first successful commercial NDA submission for PSMA imaging in the United States. This represented a major commercial milestone for the Company and followed Telix's European submission in April 2020. In addition, a Medical Services Advisory Committee (MSAC) application is already in progress[1] and Telix expects that MSAC approval and commercial availability of TLX591-CDx should coincide around May-June of 2021, subject to TGA review and approval.

Telix CEO, Dr. Chris Behrenbruch stated "As an Australian headquartered company, we are especially delighted that the TGA has granted Priority Review for TLX591-CDx, bringing us one step closer to providing a commercially available prostate imaging agent to patients in our own backyard. This is an important development for urologic oncology in Australia as a properly validated and commercially available product will ensure far greater patient access and confidence in the technology, currently only available on a limited basis under "special access" use from a relatively small number of academic nuclear medicine departments around the country."

About Prostate Cancer in Australia

Prostate cancer is the most commonly diagnosed cancer (>19,000 cases annually) and second most common cause of cancer death (>3,000 annually) in Australian men. More than 90,000 Australians are estimated to be living with prostate cancer.[2]

About TLX591-CDx

Telix's prostate cancer imaging product TLX591-CDx (^{68}Ga-PSMA-11) is currently used under investigational (IND), clinical trial and special access use in the United States, Europe, Australia, and many other countries around the globe. The 'cold kit' format of TLX591-CDx enables rapid radiolabelling at room temperature with high radiochemical purity and production consistency, ideally suited to the commercial and hospital radiopharmacy setting. TLX591-CDx has not received a marketing authorisation in any jurisdiction.

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 and brain cancer. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com.

[1] http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1632-public
[2] Source: Cancer Australia

Telix Corporate Contact
Dr Christian Behrenbruch
Telix Pharmaceuticals Limited
CEO
Email: chris@telixpharma.com

Telix Investor Relations
Dr David N. Cade
Telix Pharmaceuticals Limited
CBO and Head of Investor Relations
Email: david.cade@telixpharma.com