
Telix Granted FDA Breakthrough Therapy Designation for Renal Cancer Imaging Product

Melbourne (Australia) – 1st July 2020. Telix Pharmaceuticals Limited (ASX: TLX, ‘Telix’, the ‘Company’) today announces that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy (BT) designation for Telix’s renal cancer imaging product TLX250-CDx (⁸⁹Zr-girentuximab). Under BT status, the FDA will work closely with Telix to provide guidance to the Company on the development of TLX250-CDx for the diagnosis of “indeterminate renal masses” that have been identified on CT or MRI imaging. TLX250-CDx is being developed for the purpose of determining whether such “indeterminate renal masses” are either clear cell renal cell cancer (ccRCC) or non-ccRCC, using Positron Emission Tomography (PET) imaging.

BT designation offers a number of significant benefits to Telix, including eligibility for Fast Track designation, more frequent and intensive interactions with the FDA, and the opportunity to submit a “rolling” Biological Licence Application (BLA) for TLX250-CDx, where the application can be submitted in separate modules to streamline the FDA review process for approval. The criteria for BT designation require preliminary clinical evidence that demonstrates the product may have substantial improvement on at least one clinically significant endpoint over available care.

Telix CEO Dr Christian Behrenbruch said, “The granting of Breakthrough designation by the FDA for our kidney cancer imaging product provides Telix with the opportunity to interact closely with the FDA to expedite the registration process of TLX250-CDx, a particularly important consideration given the current Phase III development status of the asset. There is a significant unmet medical need to improve diagnosis and staging of clear cell renal cell carcinoma (ccRCC), which is the most common and aggressive form of kidney cancer. It’s encouraging that the Agency recognizes this.”

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

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