
Drug Master File for Prostate Imaging Product Filed with the FDA

Melbourne (Australia) and Indianapolis, IN (USA) – 26th March 2018. Telix Pharmaceuticals Limited (ASX:TLX) (“Telix Group”, “Company”), a clinical-stage biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or “molecularly-targeted radiation” (MTR), has today announced the submission of a Drug Master File (**DMF**) for a sterile kit used in the preparation of ⁶⁸Ga-PSMA-11 (**PSMA Kit**), to the US Food and Drug Administration (FDA DMF ID: 032631).

Dr. Bernard Lambert, President of Telix USA noted “The filing of this DMF marks an important step toward offering a commercial PSMA prostate imaging solution for the US market, and we are the first to have achieved this accomplishment in collaboration with our partner, ANMI. There is considerable demand for effective prostate imaging in the United States and we already have several leading cancer hospitals preparing to use the PSMA Kit. We’d also like to acknowledge the excellent work of our colleagues at NukeMed and the team at Indiana University, who worked tirelessly over the past six months to complete the validation work.”

The PSMA Kit has been validated for use with all major vendors of ⁶⁸Ga generators, including Eckert & Ziegler¹, ITM² and IRE ELiT³. The PSMA Kit is expected to be commercially available by mid-2018, subject to FDA review of the manufacturing package. The DMF is held by Kyzeo Imaging LLC (**Kyzeo**), a joint-venture company between Telix Pharmaceuticals (US) Inc. and ANMI SA.

About the US Prostate Cancer Imaging Market

Prostate cancer has emerged as the #1 cancer killer in the United States, with approximately 160,000 new cases annually and three million men living with prostate cancer.⁴ There remains a major unmet need to better diagnose and stage men with prostate cancer, from initial diagnosis all the way to therapeutic monitoring in patients with late-stage metastatic disease. The prostate imaging market in the US is estimated to be a USD \$500m market opportunity, likely to be dominated by the use of Positron Emission Tomography (PET) and imaging agents targeting prostate-specific membrane antigen (PSMA) in particular.⁵

About Telix Pharmaceuticals Limited

Telix Pharmaceuticals Limited (Telix Group, Telix) is a global biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or “molecularly-targeted radiation” (MTR). The company is headquartered in Melbourne with international operations in Brussels (EU), Kyoto (JP) and Indianapolis (US). Telix is developing a portfolio of clinical-stage oncology products that address significant unmet medical need in renal, prostate and brain (glioblastoma) cancer. Telix is listed on the Australian Securities Exchange (ASX:TLX). For more information visit www.telixpharma.com.

¹ <http://www.ezag.com>

² <http://www.isotope-technologies-munich.com>

³ <http://www.ire.eu/>

⁴ American Cancer Society : <https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html>

⁵ Jadvar et al. J Nucl Med February 1, 2018 vol. 59 no. 2 228-229



About ANMI SA

ANMI SA is a precursor supplier for radiometal labelled radiopharmaceuticals and a global service provider in the nuclear medicine field, located in Liège, Belgium. ANMI has developed innovative solutions to facilitate the scalable synthesis of “theranostic” radiopharmaceuticals and to ease their daily production in hospitals. ANMI's vision is focused on increasing patient access to new high-performance radiopharmaceuticals through streamlined and cost-effective production processes. For more information visit www.anmi.be.

About Kyzeo Imaging, LLC

Kyzeo Imaging, LLC is US-based JV between ANMI and Telix USA (the US operating entity of Telix Group) to commercialize a sterile cold kit for the preparation of ⁶⁸Ga-PSMA-11 for the imaging of prostate cancer with Positron Emission Tomography (PET). The commercial partnership is structured as a JV to support a profit-sharing arrangement between Telix USA and ANMI, and to support the use of the PSMA Kit in 3rd party clinical trials of novel prostate cancer therapeutics in a commercially arms-length manner from Telix Group. Telix USA is the exclusive distribution partner for the PSMA Kit in the US market.

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None of the products described in this release have obtained a marketing authorization from the US Food and Drug Administration.