



Title: Telix and Cyclotek Complete Manufacturing of VisAct® ImmunoPET Tracer

Date: 21st March 2019

Program relevance: All programs but particularly TLX250 (therapy)

Synopsis:

VisAct® is an imaging agent (a “contrast agent”) used with Positron Emission Tomography (PET). VisAct® images the location of activated (killer) T-cells and can be essentially used to take a “snapshot” of how the immune system is responding to therapy. This is a potentially invaluable tool because we increasingly combine different anti-cancer drugs with immunotherapies, however determining how to best time / cycle between different drugs is challenging and often ad-hoc. By being able to image – quantitatively – immune cells trafficking to the tumour, we can optimize the delivery of combination treatments.

Key points for investors:

- MTR drugs are highly immunogenic. Irradiating a tumour causes immune cells to migrate to the cancer. Unleashing the potency of immune cells through combining targeted radiation with immuno-oncology drugs (for example, ‘checkpoint inhibitors’) is a potentially very potent strategy for treating metastatic cancer.
- Telix’s TLX250 therapeutic (¹⁷⁷Lu-girentuximab) for the treatment of clear cell renal cell (kidney) cancer has demonstrated potent anti-tumour effect, as well as evidence of immune system involvement. In order to optimize the combination of TLX250 with immuno-oncology drugs, Telix intends to use VisAct® to image immune response and determine when best to cycle between therapies.
- Cyclotek, Telix’s manufacturing partner in Australia/New Zealand, is an experienced manufacturer of PET tracers for clinical use. VisAct® is available from Cyclotek as an investigational imaging agent.
- There is considerable international interest in the use of VisAct® and there are currently multiple collaborative clinical trials running (NCT03684655, NCT03142204, NCT03129061, NCT03007719) demonstrating the potential of this technology in immuno-oncology.



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Melbourne (Australia) – 21st March 2019. Telix Pharmaceuticals Limited (ASX.TLX) (“Telix”, the “Company”), a clinical-stage biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or “molecularly-targeted radiation” (MTR) is pleased to announce that in conjunction with Cyclotek (Aust) Pty Ltd., a leading radiopharmaceutical contract manufacturing organisation (CMO), it has completed the manufacturing ¹⁸F-AraG (VisAct®) to a standard suitable for clinical use.

Telix obtained a research license and limited commercial rights for VisAct® from CellSight Technologies, Inc. in September 2017. Telix and Cyclotek have collaborated to establish a commercial-scale manufacturing process for VisAct® for use in Telix clinical trials as well as to enable access pharmaceutical companies and clinicians interested in using the product for research purposes. VisAct® is a novel positron emission tomography (PET) imaging tracer that enables quantitative images of the immune system to be captured using standard hospital imaging equipment. With the rise in importance of immuno-oncology, VisAct® is a potentially invaluable tool in the understanding of how to optimise the delivery of cancer immunotherapy”.

Telix Pharmaceuticals co-founder and CEO, Dr. Christian Behrenbruch stated, “We were keen to take a license to VisAct® because of our kidney cancer and glioblastoma (brain cancer) therapy programs. A vitally important part of the treatment response mechanism of targeted radiation relates to the mobilization of the immune system. In particular, Telix’s TLX250 program will be further developed as a combination therapy with ‘checkpoint inhibitor’ drugs such as Bristol-Myers Squibb’s Opdivo® (anti-PD-1 antibody) so we need to know when the immune system is properly “primed” to give the best combined treatment effect.”

About Telix Pharmaceuticals Limited

Telix Pharmaceuticals Limited (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.

Telix Corporate Contact

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

Telix Investor Relations

Lisa Wilson
In-Site Communications
Tel: +1 212 452 2793
Email: lwilson@insitecony.com

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