Title: Strategy Update – Acceleration of Prostate Cancer Therapy Program

Date: 8th January 2019

Program relevance: TLX591

Synopsis:

In conjunction with the completion of the acquisition of Atlab Pharma SAS (ASX release: 11/09/18) Telix instigated an audit of the historical academic data for huJ591 (the "parent" antibody to Telix's prostate therapy program). The high-level data from several academic Phase I and II studies has been previously published in a peer-reviewed setting, however much of the clinical detail remains undisclosed.

Analysis of the data and independent monitoring by a third-party Clinical Research Organization (CRO) is strongly supportive of taking huJ591 into a Phase III study under certain dosing conditions (fractionated dosing), subject to regulatory approval. In doing so, Telix is potentially able to accelerate its antibody-directed prostate cancer radiotherapy program by approximately two years. Certain commercial opportunities underpin this decision.

Key points for investors:

- The complete and detailed analysis of existing huJ591 data clearly informs the basis of a Phase III trial design in a well-defined patient population and is an opportunity for Telix to accelerate an important commercial inflection point for the Company.
- In particular, the impressive durability of response in a clinically and commercially-important patient population (chemotherapy naïve metastatic castrate-resistant prostate cancer) is highly promising (n=54 patients). Initial results demonstrate a 48+ months median overall survival (OS) recorded in the highest dose cohort with a well-tolerated toxicity profile. This compares very favorably to competing programs.
- Recent commercial momentum in the metastatic prostate radiotherapy setting strongly underpins this decision, including the FDA's approval for Endocyte Inc. to commence the Phase III VISION trial (first patient enrolled in June '18) and the subsequent acquisition of Endocyte by Novartis for USD $2.1Bn (October '18).

Strategy Update – Acceleration of Prostate Cancer Therapy Program

Melbourne (Australia) – 8th January 2019. Telix Pharmaceuticals Limited (ASX:TLX) ("Telix", the "Company"), an Australian biopharmaceutical company focused on the development of diagnostic and therapeutic products based on targeted radiopharmaceuticals or "molecularly-targeted radiation" (MTR), today announced a strategy update for the TLX591 (prostate therapy) program.

Audit of Weill Cornell ^{177}Lu-huJ591 Data

Concurrent with the completion of the acquisition of Atlab Pharma SAS (ASX release: 11/09/18) Telix engaged a third-party Clinical Research Organization (CRO) to audit and monitor the clinical data acquired by Weill Cornell Medical Centre (WCMC)[1] for ^{177}Lu (lutetium)-huJ591. HuJ591 is a humanized anti-PSMA[2] monoclonal antibody (mAb) that has been extensively studied as a targeting agent in several hundred patients, including 217 patients for targeted radionuclide therapy in multiple Phase I and II studies. HuJ591 is one of the most widely studied targeting agents in radionuclide therapy for prostate cancer. Via the acquisition of Atlab, Telix has certain commercial radiotherapy rights to huJ591.

The focus of the audit was prior clinical experience with fractionated (repeat dosing) of ^{177}Lu-huJ591. Fractionated dosing enables the hematologic (blood/marrow) toxicity typically associated with antibody-directed radiotherapy to be ameliorated. A high-level summary of this data has been previously published in a peer-reviewed setting[3] but the clinical detail remains largely undisclosed.

HuJ591 Fractionated Data: Analysis

The analysis of the audited WCMC huJ591, which includes extensive patient follow-up (to Dec '18) and survival analysis, has confirmed several key findings. An interim analysis report has been issued to Telix with a fully monitored (quality assured) database due at the end of March '19.

The key findings are:

- ^{177}Lu-huJ591 is well tolerated, particularly with fractionated dosing at or below 45mCi/m^2.
- Other than manageable hematologic toxicities, no other off-target (i.e. salivary/lacrimal gland) effects were observed.
- The median OS of metastatic castrate-resistant prostate cancer patients with significant disease burden compares favorably to previously reported survival benefit of competing programs, such as the PSMA-617 program (Endocyte/Novartis)[4], In particular the highest dose cohorts (2x40mCi/m^2 and 2x45mCi/m^2) demonstrated a durable OS of over 40 months (n = 36 patients), reaching 48.4 months for the highest dose cohort (n = 16 patients).
- The survival benefit of ^{177}Lu-huJ591 in chemotherapy naïve (pre-chemo) patients is approximately twice that of patients that received end-stage chemotherapy (e.g. docetaxel).
- The data is sufficiently robust to inform target patient population inclusion/exclusion criteria, biomarker measures such as PSA level, tumor burden and PSMA expression levels determined from PET imaging and the dosing regimen for a Phase III trial.

[1] and collaborating institutions
[2] PSMA = Prostate-Specific Membrane Antigen, a target expressed by the majority of prostate cancers
[3] Tagawa et al. *Journal of Clinical Oncology* 2016 34:15_suppl, 5022-5022 (ASCO abstract)
[4] Data from the German multi-center trial for PSMA-617 - Rahbar et al. Clin Nucl Med. 2016 Jul;41(7):522-8

Impact on Program Decision-Making

Considering the highly promising analysis results for the fractionated huJ591 dose escalation data, Telix's management (in consultation with advisors) have formed the view that:

- The huJ591 fractionated data supports progressing to a Phase III study in an expedited fashion, particularly given the significant level of commercial interest in PSMA-based therapeutics. This decision accelerates the commencement of a Phase III trial by approximately 2 years, subject to regulatory approval.
- Telix's proprietary engineered huJ591 (previously denoted as TLX591) will continue to be developed as a "second generation" program for use with an alpha-emitting radionuclide (^{225}Ac – actinium). Actinium is a promising fit for the kinetics and product profile of this antibody and further extends the depth of Telix's therapeutic pipeline.

Manufacture of huJ591 and TLX591

Telix has previously disclosed that it is manufacturing both a proprietary huJ591 variant and the "original" huJ591 for clinical use (ASX Release: 02/07/18). Telix elected to manufacture clinical grade huJ591 to support comparability studies and several important ongoing collaborations, including with WCMC and BZL Biologics LLC (ASX Release 11/09/18). As such the Company has an existing manufacturing plan that is supportive of this strategic pivot.

Indicative Timelines

- March 19: submission of an information package to the US Food and Drug Administration (FDA), summarizing the entirety of the clinical data for ^{177}Lu-huJ591. Request for an "end of Phase II meeting" to formally review the existing data and establish a Phase III roadmap.
- May/June '19: FDA meeting request to obtain guidance on proposed Phase III clinical trial protocol (currently under development with Telix's medical advisors). The Company envisages also recruiting patients in Australia and therefore this trial will also require registration with the Therapeutic Goods Administration (TGA).
- August/September '19: Release of radiolabeled material suitable to potentially support early patient recruitment in Australia.
- Q4 '19: Filing of Phase III Investigational New Drug (IND) application based on FDA guidance.

Impact on Capital Requirements

The Company's budgeted activity includes completion of manufacturing of huJ591. The Company had also budgeted for a US-based Phase II study of the re-engineered huJ591 in approximately 120 patients (planned start mid-2019). This expenditure will be now deferred until the start of a Phase III trial in late 2019 / early 2020 in order to prioritize huJ591. Telix has adequate funding to prepare the necessary documentation to engage with the relevant regulatory authorities.

Telix does not currently have sufficient capital to execute a Phase III trial. However, further capital would not be sought for such a study until the Company had agreement from the FDA to proceed (late 2019 / early 2020). Potential commercial partnerships may also offset future capital needs.

Telix CEO Dr. Christian Behrenbruch stated, *"Given the considerable momentum around prostate radiotherapy, we feel it is prudent to pursue a strategy that enables us to get to Phase III as soon as possible. Based on the detailed data we believe that huJ591, with a fractionated dosing regimen, can potentially outperform our competition while Telix continues to develop a second-generation product aimed at alpha nuclide therapy."*

Impact on Pipeline Nomenclature

On a go-forward basis, the following pipeline nomenclature will be used by the Company:

- TLX591: ^{177}Lu-huJ591 (for consistency of reference to huJ591)
- TLX592: ^{225}Ac-labeled engineered huJ591 (Telix's kinetically-modified huJ591)

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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.

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