



Title: Fractionated Prostate Cancer Therapy Data Published, Significant Treatment Benefit to Patients

Date: 26th April, 2019

Program relevance: TLX591 (Prostate Therapy), TLX591-CDx (Prostate Imaging)

Synopsis:

The development of TLX591 is underpinned by clinical data obtained for ¹⁷⁷Lu-huJ591 by prostate cancer researchers at Weill Cornell Medical College (WCMC) and collaborators. This most recent Phase II data demonstrates that fractionated (low dose, repeat dose) administration of ¹⁷⁷Lu-huJ591 significantly reduces hematologic toxicity while delivering demonstrable anti-tumour response and survival benefit to men with advanced castrate-resistant metastatic prostate cancer (mCRPC).

Key points for investors:

- This data set is an important part of the clinical rationale for developing TLX591, which is based on the ¹⁷⁷Lu-huJ591 anti-PSMA technology developed at WCMC.
- The side effect profile is significantly improved through low dose, repeat dosing with the most significant adverse event (AE) being transient, reversible neutropenia (white blood cell reduction) and thrombocytopenia (low platelet count). Unlike competitive approaches, there is no irradiation of salivary and lacrimal glands.
- Significant anti-tumour response is observed, particularly at the higher dosing levels.
- The highest dose delivered a significant median survival of 42.3 months in a patient population that typically demonstrates survival of <2 years.
- This is a significantly more robust treatment response than reported by competitive therapeutic approaches targeting prostate-specific membrane antigen (PSMA) with a smaller number of dose administrations.
- Patients with high PSMA expression from imaging responded the best, reinforcing the importance of “companion” PSMA imaging for this type of therapy (i.e. TLX591-CDx / illumet™ PET imaging program).



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Melbourne (Australia) – 26th April 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) announces that the fractionated therapy data for ¹⁷⁷Lu-huJ591 has been published in the peer-reviewed journal *Cancer*.

The fractionated (repeat dose) data for ¹⁷⁷Lu-huJ591 has been published by Telix’s academic collaborators at Weill Cornell Medical College (WCMC, New York) and Dana Farber Cancer Institute (Boston). The data is summarized as follows:

- Forty-nine (49) men with metastatic castrate-resistant prostate cancer (mCRPC) received fractionated (repeat) doses of ¹⁷⁷Lu-J591 ranging from 20 to 45 mCi/m² ×2, two weeks apart.
- The therapy was well-tolerated. At the highest dose of 45 mCi/m² ×2, the major toxicity was reversible (transient) neutropenia and thrombocytopenia. No exocrine gland (salivary/lacrimal) targeting was observed.
- The highest dose demonstrated the greatest decrease in prostate-specific antigen (PSA) levels and the longest survival (87.5% with any PSA decrease, 58.8% with >30% decrease, 29.4% with >50% decrease).
- 80% of patients had positive imaging of prostate-specific membrane antigen (PSMA); those with less intense PSMA imaging tended to have a poorer response, demonstrating the importance of PSMA imaging to select patients for therapy.
- Fractionated administration of ¹⁷⁷Lu-J591 enabled higher cumulative radiation dosing with fewer side-effects compared with previously reported single-dose escalation data.¹
- The highest dose delivered significant anti-tumour effect with a median survival of 42.3 months (95% confidence).

The results of the Phase I and Phase II fractionated data published by WCMC is an important patient subset of approximately 200 patients that have been treated to date. The use of a fractionated (lower repeat dose) approach considerably reduces toxicity while delivering durable treatment response in patients with mCRPC. This published data further supports the development of Telix’s prostate therapy program (TLX591).

The publication can be obtained at: <https://onlinelibrary.wiley.com/doi/abs/10.1002/cncr.32072>

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.

¹ *Clin Cancer Res.* 2013 Sep 15;19(18):5182-91



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