Telix Pharmaceuticals Limited
ACN 616 620 369
Suite 401, 55 Flemington Road
North Melbourne
Victoria, 3051
Australia

TLX66 Meets Study Objectives in Patients with AL Amyloidosis

Melbourne (Australia) and Southampton (United Kingdom) – 25 May 2021. Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) today announces that the Company's bone marrow conditioning investigational candidate TLX66 (^{90}Y-besilesomab) has met study objectives, demonstrating the initial safety profile in patients with Systemic Amyloid Light Chain Amyloidosis (AL amyloidosis).

The TRALA trial (Targeted Radiotherapy for AL Amyloidosis) is a Phase I/IIa trial to evaluate the safety and toxicity of TLX66 as the sole bone marrow conditioning agent prior to autologous hematopoietic stem cell transplantation (HSCT) in patients with AL amyloidosis.[1] The TRALA trial was sponsored by University Hospital Southampton in Southampton U.K. and run across four centres: Southampton, University College Hospital London, Royal Free Hospital London, and Queen Elizabeth Hospital Birmingham. All study data were reviewed by the trial's Independent Data Monitoring Committee (IDMC).

In total, nine patients with AL amyloidosis were enrolled into the TRALA trial and received TLX66 as the sole bone marrow conditioning agent prior to undergoing autologous HSCT. TLX66 demonstrated a favourable safety profile and was well tolerated in all nine patients, each of whom completed the trial. All patients (100%) were successfully engrafted following bone marrow conditioning with TLX66 and autologous HSCT without any chemotherapy. Disease response as measured by fall in clonal free light chains (FLC) was seen in seven out of the nine patients, with two complete responses (CR) and five partial responses (PR) within the first 100 days post-transplant. In two of the patients achieving PR, the clonal FLC continued to fall, with one patient achieving CR subsequently with no further treatment. In addition, reduction in the measurable malignant plasma cells in the bone marrow was seen in six of eight evaluable patients. All patients remain alive at a median follow-up of 31 months (range 14 – 57 months).

Consultant Hematologist at University Hospital Southampton and TRALA principal investigator Dr. Kim Orchard stated, "We are highly encouraged by the safety and tolerability that ^{90}Y-besilesomab has demonstrated as a single agent bone marrow conditioning approach in patients with AL amyloidosis. Compared to the significant toxicity profile typically experienced with conventional chemotherapy-based regimens, molecularly targeted radiation with ^{90}Y-besilesomab demonstrated a very benign toxicity profile, which may in turn enable a considerably greater proportion of patients with AL amyloidosis to undergo life prolonging stem cell transplantation. The very low toxicity but with demonstrable responses is very encouraging."

Telix Chief Medical Officer Dr. Colin Hayward said, "The results from the TRALA trial indicate that TLX66 may offer a new approach to bone marrow conditioning in patients who could benefit from HSCT such as those with AL amyloidosis, providing new hope to patients with this rare disease and with few effective treatment options. TLX66 was well-tolerated, enabling successful engraftment of the patients' own transplanted stem cells without the need for toxic chemotherapy. With all patients remaining alive, and most not requiring further therapy, we believe these data support taking TLX66 forward into a pivotal registration program in this rare disease indication."

[1] EudraCT Number: 2015-002231-18.

About Amyloidosis

Amyloidosis is a rare disease in which faulty plasma cells in the bone marrow (that normally generate antibodies in response to infection) produce an abnormal protein called 'amyloid' which accumulates in the organs of the body. Progressive accumulation of amyloid in organs such as the heart and kidneys eventually lead to organ failure and death. Amyloidosis occurs at the rate of ~12 per 1,000,000 population, per annum, with an estimated prevalence of 30,000 to 45,000 in the United States and European Union, respectively.[2] While a rare disease, amyloidosis portends a poor prognosis, with a median survival from diagnosis of approximately 11 months if untreated.

Current standard of care typically requires bone marrow conditioning with multi-drug regimens comprising cyclophosphamide, bortezomib, dexamethasone and high dose melphalan, prior to HSCT. While long-term survival is achievable in patients undergoing HSCT, such bone marrow conditioning regimens are typically highly toxic and may be poorly tolerated in a significant proportion of patients and associated with high morbidity and mortality. Consequently, safer, more tolerable conditioning agents represent a significant unmet clinical need.

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, Australia with international operations in Belgium, Japan, and the United States. Telix is developing a portfolio of clinical-stage products that address significant unmet medical needs in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com and follow Telix on Twitter (@TelixPharma) and LinkedIn.

Telix's lead investigational product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been accepted for filing by the U.S. FDA,[3] and is under priority evaluation by the Australian Therapeutic Goods Administration (TGA).[4] Telix is also progressing marketing authorisation applications for Illuccix® in the European Union[5] and Canada.[6] None of Telix's products have received a marketing authorisation in any jurisdiction.

Telix Corporate Contact

Dr. Christian Behrenbruch
Telix Pharmaceuticals Limited
Managing Director and CEO

Email: chris.behrenbruch@telixpharma.com

Telix Corporate Communications

Dr. Stewart Holmstrom
Telix Pharmaceuticals Limited
Director of Corporate Communications

Email: stewart.holmstrom@telixpharma.com

[2] Quock TP et al. Blood Advances. 2018.
[3] ASX disclosure 24/11/20.
[4] ASX disclosure 14/04/21.
[5] ASX disclosure 1/05/20.
[6] ASX disclosure 16/12/20.