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Telix Granted FDA Orphan Drug Designation for Novel Multiple Myeloma Targeted Alpha Therapy (TAT)

Melbourne (Australia) – 31st August 2020. Telix Pharmaceuticals Limited (ASX: TLX, 'Telix', the 'Company') today announces that the United States Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for 4-[^{211}At] astato-l-phenylalanine (internally designated as TLX102), for the treatment of multiple myeloma. The granting of an ODD for TLX102 qualifies Telix for various drug development incentives which may include FDA-administered market exclusivity for seven years, waived FDA prescription drug user fees, and tax credits for R&D and clinical development costs.

Multiple myeloma is a haematologic malignancy (blood cancer) arising from plasma cells, the white blood cells responsible for antibody production, with an incidence of 32,000 cases and an estimated prevalence of 129,000 cases in the United States in 2020.[1]

Telix's TLX102 is an evolution of the Company's existing investigational glioblastoma treatment TLX101 (4-[1^{31}I]Iodo-l-Phenylalanine), incorporating new chemistry and rapid synthesis methods to replace ^{131}I (iodine-131) with ^{211}At (astatine-211). Astatine-211 is a high-energy, very short-range radiation emitting isotope known as an "alpha emitter". The short-range of alpha radiation may be ideally suited to blood cancers such as multiple myeloma, which are typically comprised of disseminated cancer cells that require highly targeted radiation to minimise damage to adjacent healthy tissues, particularly bone marrow.

Telix CEO Dr Christian Behrenbruch said, "The granting of an Orphan Drug Designation by the FDA for TLX102 will enable Telix to develop a unique targeted therapy product for multiple myeloma, a cancer that still has a poor prognosis with a 5-year survival of around 50%, despite recent advances in treatment. TLX102 is an example of "Targeted Alpha Therapy" or "TAT", which represents the vanguard of radiopharmaceutical development. Telix has one of the strongest R&D pipelines for TAT with isotopes such as astatine and actinium."

TLX102 has already shown promising efficacy in standard pre-clinical models of multiple myeloma and is expected to be evaluated in humans in H2, 2021. This internally-directed R&D program is the result of two years of collaboration with the University of Nantes and the ARRONAX cyclotron facility (France) and Osaka University (Japan), and has resulted in the in-licensing of significant new intellectual property to further augment Telix's potential future product development pipeline.

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 with international operations in Belgium, Japan and the United States. Telix is developing a portfolio of clinical-stage oncology products that address significant unmet medical needs in prostate, kidney and brain cancer. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com.

[1] Siegel RL, Miller KD et al. (2020). Cancer Statistics, CA Cancer J Clin 2020;70:7-30.

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