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ASIA EDITION

Telix granted FDA Orphan Drug Designation for bone marrow conditioning treatment

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TLX66 has also previously been granted ODD status by the European Medicines Agency in Europe

Australia's Telix Pharmaceuticals announced that the United States Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for TLX66 (^{90}Y-besilesomab), for conditioning treatment prior to hematopoietic stem cell transplant (HSCT).

The granting of an ODD for TLX66 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.

Bone marrow conditioning is performed prior to HSCT, a procedure where the patient's bone marrow is cleared of cells and replaced by stem cells (cells that can develop into different types of cells), to encourage production of new bone marrow that produces healthy blood cells. Traditional conditioning regimens are associated with morbidity and mortality from chemotherapy, limiting their use particularly in pediatric and rare diseases.

TLX66 has the potential to add to the depth of conditioning, thereby removing additional disease-causing cells. In addition, TLX66's potential to reduce the toxicity of existing conditioning regimens could increase the number of patients that are eligible for transplant.