Prescient Secures EU Authorisation to Commence PTX-100 Clinical Trial for CTCL Patients

Highlights:

- European CTIS grants authorisation for PTX-100 trial in relapsed/refractory Cutaneous T-cell Lymphoma (r/r CTCL)
- Approval enables activation of trial sites in Italy
- PTX-100: a first-in-class therapy targeting cancer growth pathways advancing in Phase 2a trials with recruitment to begin in Europe

MELBOURNE, Australia – 15 December 2025 – Prescient Therapeutics Limited (ASX: PTX), a clinical-stage oncology company developing targeted cancer therapies today announced that the European Clinical Trials Information System (CTIS), has granted authorisation to initiate its PTX-100 clinical trial in patients with relapsed/refractory Cutaneous T-cell Lymphoma (CTCL) in Italy. This approval allows Prescient to activate trial sites and commence patient recruitment for the Phase 2a study in Europe.

Prescient CEO, James McDonnell commented: "This authorisation marks a significant milestone for Prescient and for patients living with CTCL. It reflects months of dedicated work by our clinical team and brings us closer to delivering a new treatment option for a disease with high unmet need."

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The Disclosure Committee of the Board of Prescient Therapeutics Limited has approved the release of this announcement.

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About Prescient Therapeutics Limited (Prescient)

Prescient Therapeutics (ASX: PTX) is a clinical-stage oncology company focused on personalised cancer treatments through advanced targeted and cellular therapies.

Targeted Therapy

PTX-100: is a first in class compound with the ability to block an important cancer growth enzyme known as geranylgeranyl transferase-1 (GGT-1). It disrupts oncogenic Ras pathways by inhibiting the activation of Rho, Rac and Ral circuits in cancer cells, leading to apoptosis (death) of cancer cells. PTX- 100 is believed to be the only GGT-1 inhibitor in the world in clinical development. PTX-100 demonstrated safety and early clinical activity in a previous Phase 1 study and recent PK/PD basket study of hematological and solid malignancies. PTX-100 has recently completed a Phase 1b expansion cohort study in T cell lymphomas, where it showed encouraging efficacy and safety. The US FDA has granted PTX-100 Orphan Drug Designation for all T Cell Lymphomas and Fast Track Designation for the treatment of adults with relapsed or refractory (r/r) mycosis fungoides, the most common subtype of CTCL. A Phase 2 study in Cutaneous T cell lymphoma (CTCL) is recruiting globally and expects to enrol up to 40 patients in the phase 2a part of the trial.

Cell Therapy Platforms

CellPryme-M: Prescient's novel, ready-for-the-clinic, CellPryme-M technology enhances adoptive cell therapy performance by shifting T cells towards a central memory phenotype, improving persistence, and increasing the ability to find and penetrate tumours. CellPryme-M is a 24-hour, non-disruptive process during cell manufacturing. Cell therapies that could benefit from additional productivity in manufacturing or increased potency and durability in-vivo, would be good candidates for CellPryme-M.

CellPryme-A: CellPryme-A is an adjuvant therapy designed to be administered to patients alongside cellular immunotherapy to help them overcome a suppressive tumour microenvironment. CellPryme-A significantly decreases suppressive regulatory T cells; increases expansion of CAR-T cells in vivo; increases tumour penetration of CAR-T cells. CellPryme-A improves tumour killing and host survival of CAR-T cell therapies, and these benefits are even greater when used in conjunction with CellPryme-M pre-treated CAR-T cells.

OmniCAR: is a universal immune receptor platform enabling controllable T-cell activity and multi- antigen targeting with a single cell product. OmniCAR's modular CAR system decouples antigen recognition from the T-cell signalling domain. It is the first universal immune receptor allowing post- translational covalent loading of binders to T-cells. OmniCAR is based on technology licensed from Penn; the SpyTag/SpyCatcher binding system licensed from Oxford University; and other assets. OmniCAR is in pre-clinical development.

The targeting ligand can be administered separately to CAR-T cells, creating on-demand T-cell activity post infusion and enables the CAR-T to be directed to an array of different tumour antigens. OmniCAR provides a method for single-vector, single cell product targeting of multiple antigens simultaneous or sequentially, whilst allowing continual re-arming to generate, regulate and diversify a sustained T-cell response over time.

Find out more at www.ptxtherapeutics.com or connect with us via LinkedIn.

Forward-Looking Statements

This announcement contains forward-looking statements based on current expectations, estimates, and assumptions. These statements are subject to risks and uncertainties that may cause actual results to differ materially. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this announcement. The Company undertakes no obligation to update these statements except as required by law.