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Prescient secures EU Orphan Drug Designation for PTX-100 in Cutaneous T-cell Lymphomas

Announcement Highlights:

- Prescient secures EMA Orphan Drug Designation for PTX-100 in CTCL
- EMA designation provides major benefits:
  - 10 years of EU market exclusivity upon approval
  - Protocol assistance and reduced fees
  - Centralized marketing authorization access
- PTX-100 is a first-in-class therapy designed to disrupt cancer growth pathways, now in Phase 2a trials for relapsed/refractory CTCL.
- Complements existing U.S. FDA Orphan Drug and Fast Track status
- Join CEO, James McDonnell, for an online investor briefing on Tuesday, 25th November at 3pm (AEDT). Register here: https://prescienttherapeutics.investorportal.com.au/investor-briefing/

MELBOURNE, Australia – 19th November 2025 – Prescient Therapeutics Limited (ASX: PTX) today announced that the European Medicines Agency (EMA) has granted Orphan Drug Designation (ODD) to PTX-100 for treating cutaneous T-cell lymphoma (CTCL) for both mycosis fungoides and sezary syndrome subtypes. This designation highlights the urgent need for new CTCL treatments and PTX-100's potential to deliver meaningful benefit to patients across Europe.

James McDonnell, CEO of Prescient said: "Securing EMA Orphan Drug Designation is a major milestone in our mission to bring innovative therapies to patients with limited options. This recognition validates our science and strengthens our commercial pathway in key markets."

Prescient is advancing PTX-100 through clinical development and is actively preparing for EMA discussions to accelerate the pathway toward marketing authorisation.

JOIN A BRIEFING

CEO James McDonnell will be holding a live and online investor briefing on Tuesday, 25th November at 3pm (AEDT). Register here: https://prescienttherapeutics.investorportal.com.au/investor-briefing/

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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.

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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.