PTX-100 receives U.S. FDA Fast Track Designation

Announcement Highlights:

- **U.S FDA Fast Track designation received for PTX-100.**
- **Fast Track unlocks several benefits including increased access to FDA and rolling submissions of New Drug Application.**
- **It is also an important step towards Prescient's goal of Accelerated Approval – a key element of its PTX-100 commercialisation strategy.**
- **Join CEO, James McDonnell, for an online investor briefing on Thursday 17th April at 12pm (AEST). Register here: https://prescienttherapeutics.investorportal.com.au/investor-briefing/**

MELBOURNE Australia, 16th April 2025: Prescient Therapeutics Limited (ASX: PTX), a clinical stage oncology company developing personalised therapies for cancer, is delighted to announce the U.S. FDA has given PTX-100 Fast Track Designation for the treatment of adults with relapsed or refractory (r/r) mycosis fungoides, the most common subtype of CTCL. This marks another milestone for PTX-100 on the pathway to treating patients suffering with r/r Cutaneous T Cell Lymphoma (CTCL).

Fast Track is a process designed by the FDA to expedite the review of therapies that treat serious conditions with a high unmet need, with the aim of getting therapies to patients earlier. It provides several benefits including increased access to the FDA, the possibility of rolling submissions of New Drug Applications and a pathway to Accelerated Approvals – a key element of Prescient's PTX-100 strategy.

Granting Fast Track at this stage indicates that the FDA recognise that PTX-100 trial data already shows promise as a potential treatment option for an unmet medical need, despite other therapies being available in the US.

Prescient Therapeutics CEO, James McDonnell commented:

"Getting Fast-Track designation is a critical milestone towards our goal of advancing PTX-100 into a registration-enabling trial designed to support potential accelerated approval and, from there, commercialisation. As we progress our Phase 2 trials, we will be engaging closely with the FDA to ensure alignment on endpoints and study scope."

Join a briefing

CEO James McDonnell will be holding a live and online investor briefing on Thursday 17th April at 12pm (AEST). Register here:
https://prescienttherapeutics.investorportal.com.au/investor-briefing/

To stay updated with the latest company news and announcements, please update your details on our investor centre.

About Prescient Therapeutics Limited (Prescient)

Prescient Therapeutics (ASX: PTX) is a clinical stage oncology company developing personalised medicine approaches to cancer, including 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. A Phase 2 study in Cutaneous T cell lymphoma (CTCL) has completed the first study site enrolment and now expects the first patient in and dosed in the coming weeks.

Cell Therapy Platforms

CellPryme-M: Prescient's novel, ready-for-the-clinic, CellPryme-M technology enhances adoptive cell therapy performance by shifting T 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.

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

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Certain statements made in this document are forward-looking statements within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These forward-looking statements are not historical facts but rather are based on the current expectations of Prescient Therapeutics Limited ("Prescient" or the "Company"), their estimates, assumptions, and projections about the industry in which Prescient operates. Material referred to in this document that use the words 'estimate', 'project', 'intend', 'expect', 'plan', 'believe', 'guidance', and similar expressions are intended to identify forward-looking statements and should be considered an at-risk statement. These forward-looking statements are not a guarantee of future performance and involve known and unknown risks and uncertainties, some of which are beyond the control of Prescient or which are difficult to predict, which could cause the actual results, performance, or achievements of Prescient to be materially different from those which may be expressed or implied by these statements. These statements are based on our management's current expectations and are subject to a number of uncertainties and risks that could change the results described in the forward-looking statements. Risks and uncertainties include, but are not limited to, general industry conditions and competition, general economic factors, global pandemics and related disruptions, the impact of pharmaceutical industry development and health care legislation in the United States and internationally, and challenges inherent in new product development. In particular, there are substantial risks in drug development including risks that studies fail to achieve an acceptable level of safety and/or efficacy. Investors should be aware that there are no assurances that results will not differ from those projected and Prescient cautions shareholders and prospective shareholders not to place undue reliance on these forward- looking statements, which reflect the view of Prescient only as of the date of this announcement. Prescient is not under a duty to update any forward-looking statement as a result of new information, future events or otherwise, except as required by law or by any appropriate regulatory authority.

Certain statements contained in this document, including, without limitation, statements containing the words "believes," "plans," "expects," "anticipates," and words of similar import, constitute "forward- looking statements." Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of Prescient to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following: the risk that our clinical trials will be delayed and not completed on a timely basis; the risk that the results from the clinical trials are not as favourable as we anticipate; the risk that our clinical trials will be more costly than anticipated; and the risk that applicable regulatory authorities may ask for additional data, information or studies to be completed or provided prior to their approval of our products. Given these uncertainties, undue reliance should not be placed on such forward-looking statements. The Company disclaims any obligation to update any such factors or to publicly announce the results of any revisions to any of the forward-looking statements contained herein to reflect future events or developments except as required by law.

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Supplemental COVID-19 Risk Factors

Please see our website: Supplemental COVID-19 Risk Factors