Recruitment Open for Expansion Cohort of Phase 1B Study of PTX-100 in Patients with T Cell Lymphomas

Key points:

- **Expansion cohort open for PTX-100 study in T cell lymphomas, an area of high unmet medical need**
- **Reaffirming aim to complete expansion cohort enrolment by end of 2022**
- **PTCL patient in previous escalation cohort remains on PTX-100 with durable partial response for 24 months to date (versus expected ≤ 4 months with standard of care[1])**
- **Potential for shorter path to registration**

MELBOURNE Australia, 5 April 2022: Prescient Therapeutics Limited ("Prescient"; ASX: PTX), a clinical stage oncology company developing personalised therapies to treat cancer, today announced the opening of enrolment in the expansion cohort of the Phase 1b trial of PTX-100 to treat T-cell lymphomas, a group of aggressive and rare blood cancers with significant unmet clinical need.

The expansion cohort is an open-label, non-randomised study that will enrol eight to 12 patients with relapsed and refractory T-cell lymphoma. It will be led by world-renowned hematologist, Professor H. Miles Prince at Epworth Hospital in Melbourne, Australia. Excellent safety data and encouraging preliminary evidence of clinical efficacy in patients with T-cell lymphomas in the Phase 1b study prompted clinical investigators to recommend expanding the study and to focus on enrolling patients with peripheral T-cell lymphomas (PTCL). PTCL is a blood cancer with substantial unmet need for new therapies and represents an exciting clinical and commercial opportunity for PTX-100. Prescient plans to include several patients with cutaneous T-cell lymphoma (CTCL) as well. CTCL clinical samples will bolster insights on drug activity in T-cell lymphomas overall.

Prescient is pleased to report that drug shipment has arrived in Australia to support the trials. As previously reported, there were unforeseen delays in manufacturing of additional PTX-100 due to worldwide supply chain and logistics challenges that impacted so many sectors, including drug manufacturers and their suppliers. This drug supply is sufficient for the dosing of the planned expansion cohort. Despite the delayed start, Prescient is still aiming to complete recruitment of the expansion cohort by the end of 2022.

One PTCL patient from the Phase 1b escalation cohort has now undergone 37 cycles of therapy and continues to receive PTX-100. This patient had particularly aggressive disease that had failed five prior therapies, none of which were able to control the disease for more than a few months before the

[1] Barta SK, *et al*. *Clin Lymphoma Myeloma Leuk*. 2019 Jun;19(6):356-364

disease progressed further. When treated with PTX-100, this patient experienced a partial response (reduction in cancer burden), and this response has endured for 24 months so far.

Another patient with cutaneous T cell lymphoma (CTCL) also had aggressive disease and had failed three prior treatments. This patient had a partial response on the study, with reduced cancerous lesions and symptomatic relief. The patient was on therapy for 12 months, receiving 19 cycles of therapy.

In both cases, such patients with refractory T-cell lymphomas on standard treatments would typically be expected to have disease progression within 4 months[2]. This highlights the encouraging nature of the responses to PTX-100.

Principle Investigator of the study, Professor Miles H Prince, AM said, "We continue to be encouraged by the safety and clinical activity of PTX-100 in patients with T-cell lymphomas. We look forward to expanding the investigations of PTX-100 in T-cell lymphomas, where we have already seen two unexpected and stunning responses in the prior cohort. It would be very exciting to see further responses to PTX-100 in this expansion cohort, particularly in PTCL, which is an aggressive cancer with few effective treatment options."

Prescient CEO and Managing Director, Steven Yatomi-Clarke said, "PTCL is not a common malignancy, but the nature of the disease and lack of effective treatment options may provide a shorter regulatory path, and the fastest route to market for PTX-100 in a high value area of unmet clinical need. Subject to efficacy observed in this expansion cohort, it may be possible to conduct a subsequent registration study that is smaller and shorter than large Phase III studies typically seen in other cancer trials."

"We are encouraged by the data produced to date with PTX-100. The excellent safety profile of PTX-100 is significant for two reasons. Firstly, the drug may have utility in fragile patients that are unable to tolerate other therapies with high toxicities. Secondly, PTX-100's low toxicity profile and wide therapeutic window opens up possibilities to combine PTX-100 with various other cancer therapies, depending on the cancer and line of treatment. We are currently exploring the potential for synergistic combination studies in parallel with this current study."

"We look forward to continuing to support the patients who remain on the therapy and supporting the dedicated and talented researchers working on the expansion cohort study as we pursue the quickest route to market for PTX-100 in areas of unmet clinical need," Mr Yatomi-Clarke said.

Peripheral T-Cell Lymphoma (PTCL)

PTCL encompasses a group of uncommon and aggressive cancers resulting from a patient's T-cells becoming cancerous. T-cells are an important part of the immune system which help the body fight infection. In cases when some T-cells start to grow too quickly and out of control, they can accumulate in the body. There are several sub-types of PTCL, but usually present in a similar way.

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[2] Barta SK, *et al*. *Clin Lymphoma Myeloma Leuk*. 2019 Jun;19(6):356-364

PTCL generally affects people aged 60 years and older, although it can occur at any time throughout adulthood. Current treatments for PTCL include combination chemotherapy regimens, localised radiotherapy, stem cell transplants and steroid therapy.

PTX-100

PTX-100 is a first-in-class targeted therapy that blocks an important cancer growth enzyme called GGT-1. It was co-invented by Prescient's Scientific Founder, Professor Said Sebti, and is exclusively licensed by Prescient from Yale University.

In the prior Phase 1b basket study, a total of 10 patients were enrolled - five with solid tumours (pancreatic and colorectal cancers) and five with haematological malignancies (multiple myeloma and T-cell lymphomas). Patients had received a median of three prior lines of therapy and up to five prior lines of therapy. PTX-100 was administered at doses ranging from 500 mg/m^2 to 2,000 mg/m^2. No serious adverse events related to PTX-100 were observed, and a clinical signal was seen in T-cell lymphomas.

- Ends -

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About Prescient Therapeutics Limited (Prescient)

Prescient Therapeutics is a clinical stage oncology company developing personalised medicine approaches to cancer, including targeted and cellular therapies.

Cell Therapies

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.

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.

Prescient is developing OmniCAR programs for next-generation CAR-T therapies for Acute Myeloid Leukemia (AML); Her2+ solid tumours, including breast, ovarian and gastric cancers; and glioblastoma multiforme (GBM).

Cell Therapy Enhancements: Prescient has several other initiatives underway to develop new cell therapy approaches.

Targeted Therapies

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 is now in a Phase 1b expansion cohort study in T cell lymphomas.

PTX-200 is a novel PH domain inhibitor that inhibits an important tumour survival pathway known as Akt, which plays a key role in the development of many cancers, including breast and ovarian cancer, as well as leukemia. Unlike other drug candidates that target Akt inhibition, PTX-200 has a novel mechanism of action that specifically inhibits Akt without non-specific kinase inhibition effects. This highly promising compound has previously generated encouraging Phase 2a data in HER2-negative breast cancer and Phase 1b in recurrent or persistent platinum resistant ovarian cancer, with a Phase 1b/2 trial currently underway in relapsed and refractory AML.

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

Find out more at www.ptxtherapeutics.com or connect with us via Twitter @PTX_AUS and LinkedIn.

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Supplemental COVID-19 Risk Factors

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