Continued promising results in PTX-100 T Cell Lymphoma Phase 1b Cohort

Key Points:

- **Positive response rates, with two new complete responses in patients with relapsed and refractory PTCL since last update**
- **7 of 10 evaluable patients had durations of response exceeding standard of care**
- **Excellent safety profile maintained**
- **Will modestly increase number of patients to create robust regulatory package for FDA meeting, following recent Orphan Drug Designation from FDA**

MELBOURNE Australia, 16 March 2023: Prescient Therapeutics Limited (ASX: PTX), a clinical stage oncology company developing personalised therapies to treat cancer, is pleased to provide an update on the PTX-100 Phase 1b expansion cohort in relapsed and refractory T cell lymphomas (TCL). PTX-100 continues to show encouraging clinical activity in this difficult-to-treat patient population, with several clinical responses that include two patients with relapsed and refractory peripheral TCL (PTCL) that have had complete responses (complete eradication of cancer) since the prior update in November 2022, which is not generally expected in this disease. PTX-100 also continues to exhibit an excellent safety profile at the highest dose of 2000 mg/m^2. The study is being led by globally renowned haematologist, Professor H. Miles Prince at Epworth Hospital in Melbourne, Australia.

Phase 1b Enrolment

A total of 13 TCL patients have been dosed with PTX-100: 8 patients with PTCL and 5 patients with cutaneous TCL (CTCL). Patients had received a median of 3 prior lines of therapy and up to 5 systemic prior lines of therapy. PTX-100 was administered at doses up to 2,000 mg/m^2. The expansion cohort has met its minimum enrolment schedule, and the study is ongoing as patients are responding for longer than expected (see Clinical Activity, below).

Four patients currently remain on therapy and additional patients are being recruited.

Safety

PTX-100 continues to exhibit an excellent safety profile on the study, with very few serious adverse events. Grade 3 (severe) adverse events observed as being possibly related to PTX-100 include cases of neutropenia, thrombocytopenia and anaemia. Several of these cases were observed in the same patient and the patients recovered/resolved these events. Prescient believes that such side effects are not uncommon in treating this patient population and are likely manageable.

Clinical activity

Although the primary goal of the study is to evaluate safety, PTX-100 continues to exhibit encouraging clinical activity in the difficult-to-treat patient population, especially when considered against responses expected from current standards of care. This is summarised in Table 1.

Table 1: Summary of TCL patients' responses so far in PTX-100 Phase 1b study

	Overall Response Rate		**Progression Free Survival (months)**	
	Target[1]	Actual[2]	Target[1]	Actual[2]
r/r TCL (n=10)	>30%	**40%**	5-6	**8.7**

1. Considered a target benchmark for a Phase 2 or registration study. S.M. Horowitz *et al*; Blood Dec 2021
2. Study ongoing; based on evaluable patients. Results as at 6 March 2023

Comments of note for this update:

- All 13 TCL patients were assessable for safety; 10 patients were assessable for efficacy. 5 patients had r/r PTCL and 5 patients had r/r CTCL.
- Targeted progression free survival (PFS) is median, however with small patient numbers in this study PTX is reporting mean PFS. In this update, PFS is impacted by newer patients on the study, whose treatments are in the earlier stages but remain ongoing. This results in a lowering of the overall PFS figures. PFS for r/r PTCL was 9.2 months and for r/r CTCL was 8.2 months.
- In CTCL, an additional measure of clinical utility is Clinical Benefit Rate (CBR), which includes those patients with complete and partial responses and those with durable

stable disease. Typically, CTCL therapies have a CBR of 50%[1], so far on this study the observed CBR is 60%.

Individual patient responses are summarised in the swimmer plot in Figure1.

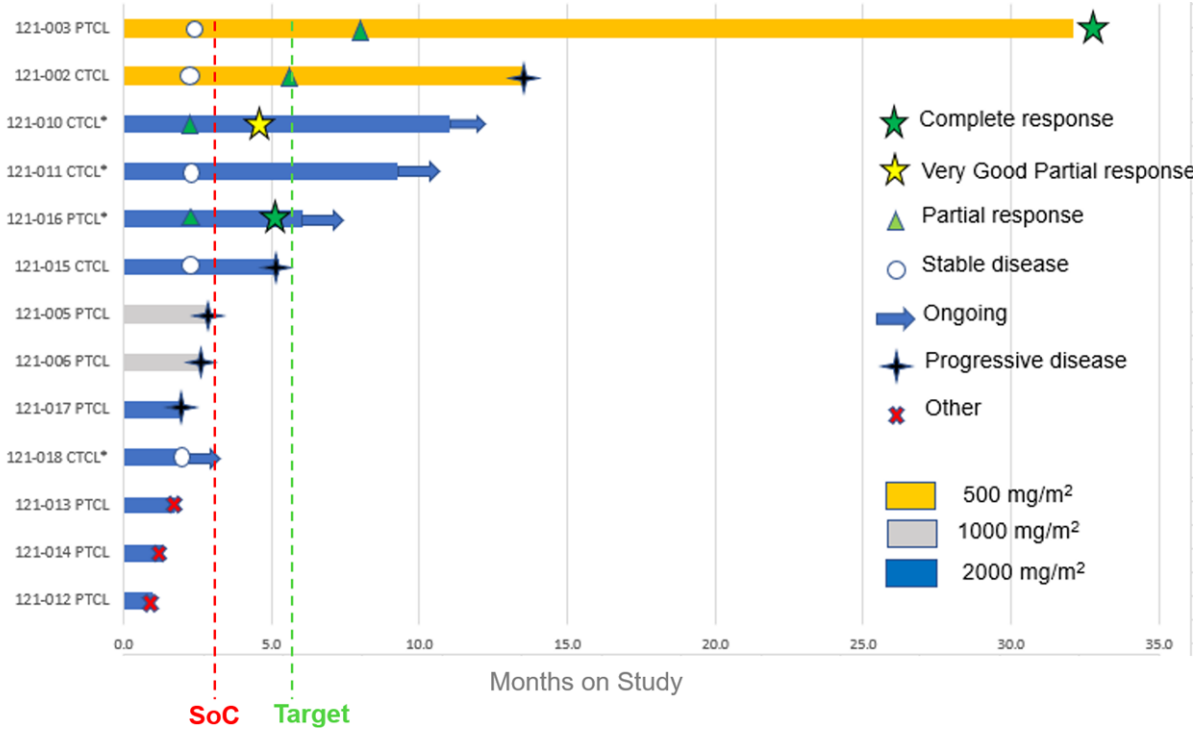

Figure 1: Swimmer plot of individual TCL patient responses and duration

Results as at 6 March 2023

SoC: duration of response (months) from current Standard of Care treatments

Target: Duration of response (months) that is considered a target benchmark for a Phase 2 or registration study (S.M. Horowitz *et al*; Blood; Dec 2021)

Next steps

Based on encouraging data so far, regulatory advisors have recommended enrolling seven additional patients in order to support a more robust data package for a meeting with the US FDA.

Prescient is planning a subsequent Phase 2 trial in TCL, which will be conducted subject to satisfactory Phase 1b outcomes. Prescient will seek to apply for this Phase 2 trial to be an Accelerated Approval trial with the FDA in an Orphan Indication. If this is granted, Accelerated Approval could pave the way for the Phase 2 trial to be the study enabling

[1] H.M. Prince; *et al*; J Clin Oncol; 2010

expedited regulatory approval of PTX-100. If Accelerated Approval is not granted, the Phase 2 trial will proceed as per conventional drug development pathways, with a subsequent study likely required for approval.

Prescient will also be seeking clarification on the dose optimisation and dose schedule considerations for the Phase 2 study pursuant to the FDA's Project Optimus, which seeks to maximizes not only the efficacy of a drug but also its the safety and tolerability.

Prescient will be applying for a meeting the FDA later this year. A favourable outcome would see the registrational Phase 2 study open within 12 months, subject to satisfactory results from the Phase 1b trial. A possible scenario may involve regulatory interactions taking place and/or a subsequent Phase 2 trial initiated before the current Phase 1b officially concludes, due to the long duration of responses being observed in this Phase 1b study.

To facilitate further studies, Prescient will conduct another manufacturing campaign of PTX-100, planning for this has already commenced. Manufacturing will be conducted and documented at higher levels of rigour required to support later stage trials and regulatory submissions.

Prescient's Chief Medical Officer, Dr Terrence Chew, said, "We are very pleased to see these promising efficacy and safety results in this difficult to treat patient population. With confirmation of these preliminary results, we expect to proceed expeditiously to a registration trial and to be able to provide PTX100 to these patients who desperately need more effective therapies."

Prescient's CEO and Managing Director, Steven Yatomi-Clarke, said, "It is very exciting to see this clinical data for PTX-100 continue to unfold so favourably, especially in these relapsed and refractory T cell lymphomas, which are particularly difficult to treat and where other therapies have failed. Unlike other TCL therapies, PTX-100 continues to exhibit an excellent safety profile, and the patient responses we are observing are very promising for a Phase 1b study.

Whilst Phase 1 trials necessarily focus on safety, we have a valuable opportunity to bolster our trial with a small number of additional patients to enable Prescient to have a more meaningful and productive dialogue with the FDA. This follows last week's decision by the FDA to grant PTX-100 Orphan Drug Designation for all TCLs, and presents an exciting and unique opportunity for Prescient and for TCL patients awaiting more effective therapies."

– 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.

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, where it is showing encouraging efficacy and safety. The US FDA has granted PTX-100 Orphan Drug Designation for all 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 is currently in a Phase 1b/2 trial in relapsed and refractory AML, where it has resulted in 4 complete remissions so far. PTX-200 previously generated encouraging Phase 2a data in HER2-negative breast cancer and Phase 1b in recurrent or persistent platinum resistant ovarian cancer.

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).

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

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

Please see our website : Supplemental COVID-19 Risk Factors