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PTX-100 Trial Progresses to Expansion Cohort Following Successful Phase 1b

Key Points:

- **PTX-100 exhibited excellent safety profile in Phase 1b with no serious adverse events related to PTX-100**
- **Clinical signal seen in T cell lymphoma (TCL) patients**
- **Two patients remained on therapy for 12 - 17 months (versus expected ≤4 months with standard of care[1])**
- **PTX-100 will now progress to an expansion cohort study focussing on TCL with potential for subsequent registration study**
- **Peripheral T-cell lymphoma (PTCL) is a hematological malignancy with considerable unmet need and potentially a shorter path to market**

MELBOURNE Australia 27 July 2021: Prescient Therapeutics Limited (ASX: PTX), the clinical stage oncology company developing personalised medicine approaches to cancer, including targeted therapies, cell therapy enhancements and next generation CAR-T therapies, is pleased to announce results from the PTX-100 Phase 1b basket trial in solid and hematological cancers. PTX-100 exhibited an excellent safety profile and demonstrated biological activity in two highly pre-treated T cell lymphoma (TCL) patients with aggressive disease. Prescient will now advance PTX-100 to an expansion cohort study focusing on TCL, which represents an area of significant unmet clinical need.

Phase 1b Enrolment

A total of 10 patients were enrolled in the Phase 1b basket trial: 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.

Safety

PTX-100 exhibited an excellent safety profile in the study, being well tolerated up to and including the highest dose of 2,000mg/m^2.

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

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Several Grade 3 or 4 adverse events were observed on the study, including a reduction in platelets (observed in three patients); reduction of neutrophils or neutropenia (observed in two patients). None of these were deemed serious, nor related to PTX-100.

Serious adverse events included nose bleeds (one patient); osteomyelitis (bone infection; one patient); hip fracture (one patient) and subarachnoid haemorrhage (one patient). None of these were determined to be related to PTX-100.

Clinical Activity

Although the primary goal of the basket trial was to evaluate safety, clinical benefit was observed in two patients with TCL with aggressive disease that had failed 3-5 prior therapies.

One patient with peripheral T cell lymphoma (PTCL) had particularly aggressive disease and had failed five prior treatments, each time being unable to control the disease for more than a few months before the disease progressed further. Treated with PTX-100, this patient experienced a partial response (reduction in cancer burden) with no disease progression for 17 months so far. This patient has undergone 24 cycles of therapy and continues to receive PTX-100.

Another patient with cutaneous T cell lymphoma (CTCL) with K-Ras mutation 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 TCL on standard of care therapies would typically be expected to have disease progression within 4 months[2], highlighting the encouraging nature of these responses.

Expansion Cohort Study

Following the encouraging results of the Phase 1b basket trial, Prescient will progress the development of PTX-100 as a monotherapy in an expansion cohort study in relapsed and refractory TCL, with a particular focus on PTCL.

It is currently anticipated that 8-12 patients will be enrolled in the expansion cohort, which will again be led by Professor H. Miles Prince at Epworth Hospital in Melbourne, Australia. It is expected that the expansion cohort study will be accommodated by Prescient's current manufacturing run of PTX-100 and within Prescient's current budget.

In the event that the expansion cohort is successful in demonstrating the benefit of PTX-100 in PTCL, it is possible that development could advance directly to a separate registration study. Precedent approval of drugs in this field indicate that relatively small trials may be sufficient for registration, compared with typical Phase 3 trials.

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

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PTCL is a disease of considerable unmet need. Survival following relapse is poor and has not significantly improved in the last 20 years[3,4]. Whilst PTCL is not a common malignancy, the nature of disease and the paucity of effective treatment options for refractory patients creates a potentially shorter regulatory path for PTX-100 in this setting, and the fastest route to market in a high value area of unmet clinical need.

Prescient looks forward to providing further details on the expansion cohort study in the coming quarter.

Principal Investigator of the study, Professor H. Miles Prince, said, "The safety profile of PTX-100 was impressive in the Phase 1b basket trial, with the drug very well tolerated at all dose levels. It was also very encouraging to see early clinical activity. The two TCL patients that responded had aggressive disease and had quickly progressed on previous therapies. Therefore, it was surprising to not only see clinical responses in these patients, but for these benefits to endure for a year or longer, together with symptomatic relief. It would be very exciting for the field if PTX-100 can continue to demonstrate similar benefits in more TCL patients in the expansion cohort."

Prescient's CEO and Managing Director, Steven Yatomi-Clarke said, "We are very pleased with the outcomes of the Phase 1b basket study from several perspectives. The safety profile of PTX-100 is significant for two reasons – firstly that this drug may have utility in fragile patients unable to tolerate therapies with high toxicities. Secondly because the low toxicity profile of PTX-100 opens up possibilities to add it as a combination agent with various other cancer therapies, depending on the cancer and line of therapy.

Additionally, we are encouraged by the biological activity demonstrated by PTX-100 in certain patients on the basket trial with T cell lymphomas. Whilst numbers are small, the observation is encouraging in that it indicates activity of PTX-100 as a monotherapy in patients where other therapies have failed. We look forward to exploring this in the expansion cohort study as we pursue the quickest route to market for PTX-100 in areas of unmet clinical need."

– Ends –

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[3] Mak V, et al. *J Clin Oncol* 2013; 31:1970-6.
[4] Chihara D, et al. *Br J Haematol* 2017; 176:750-8.

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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

Please see our website : Supplemental COVID-19 Risk Factors