

## **First-in class Ras pathway inhibitor PTX-100 Proceeds to Next Dose Level; Adds New Trial Site**

- **First-in-class Ras pathway inhibitor PTX-100 acceptable safety in first cohort at 500 mg/m<sup>2</sup>**
- **Symptomatic relief in patient with cutaneous T cell lymphoma (CTCL)**
- **Proceeding to next dose level of 1,000 mg/m<sup>2</sup>**
- **Additional Australian clinical trial site added to study**

**MELBOURNE Australia, 22 April 2020:** Prescient Therapeutics (ASX: PTX) ("Prescient"), a company developing personalised medicines for cancer, is pleased to announce that the Phase 1b study of PTX-100 will proceed to the next dose level following successful completion of the first cohort of patients and demonstrating acceptable safety. One patient with cutaneous T cell lymphoma (CTCL) has experienced symptomatic relief with an unconfirmed response and will continue on therapy with PTX-100. Furthermore, Peninsula & South Eastern Haematology and Oncology Group (PASO) has been added as a new site to the study to aid recruitment and diversity of cancer types.

The Phase 1b basket study seeks to determine the safety, dose regimen and treatment schedule of PTX100, a first-in-class drug, in several cancers where Ras and RhoA mutations are prevalent. These mutations are present in many cancer types, but there remains no approved therapy against either Ras or RhoA mutant cancers.

The three patients in the first study cohort were heavily pre-treated patients suffering from advanced multiple myeloma, cutaneous T cell lymphoma (CTCL) and peripheral T-cell lymphoma (PTCL), respectively, all of which are difficult diseases to treat. The patients in this cohort received 500mg/m<sup>2</sup> doses of PTX100 with no drug-related safety issues observed. Based on these safety observations, the study's safety monitoring committee has allowed the trial to proceed to the next dose of 1,000 mg/m<sup>2</sup> of PTX-100.

The clinical team at the Epworth Hospital reported that the patient with CTCL experienced symptomatic relief and has requested to continue PTX-100 therapy in line with the protocol. The clinical response status of this patient is yet to be confirmed.

Prescient also announces the expansion of the study to include PASO in South-Eastern Victoria under the guidance of Professor Vinod Ganju, an internationally trained oncologist with deep clinical research experience. It is anticipated that PASO's focus on solid tumours for this trial will complement the haematological cancer expertise of Epworth, and increase the diversity of cancer types recruited to this basket study.

The study's Principal Investigator, Professor H. Miles Prince AM, said, "We were able to enrol and treat heavily pre-treated patients in the initial cohort, with the regimen of PTX-100 being well tolerated with no drug related adverse events. We are encouraged and excited to be proceeding into the second cohort of this trial at a higher dose of PTX-100. It is also great to welcome Professor Ganju's centre in the next cohort to further progress this important study."

Prescient CEO and Managing Director Steven Yatomi-Clarke said, "We are delighted with the safety profile in the first cohort leading to a dose escalation of PTX-100, especially in heavily pre-treated patients with advanced cancers. We are especially pleased at the progress of this trial in the face of substantial global disruptions."

"The Ras pathway has been in focus over the last 12 months, receiving much attention from the medical and pharmaceutical communities, and we believe the outcomes of this PTX-100 study – especially as a unique, first-in-class inhibitor of this pathway - will warrant attention."

### **Further study details**

The PTX-100 basket study is an open-label, non-randomized trial that will enrol up to 24 participants to evaluate the pharmacokinetics and pharmacodynamics of PTX-100, as well as safety and efficacy of up to three different doses in patients with advanced malignancies.

The study takes a 'basket' approach to assess the drug on multiple cancers with a view to addressing specific mutations, rather than tumor origin. Basket studies pioneered by several US companies have quickly identified patient populations who could benefit from the investigational drug, sometimes leading to fast track approval.

Patients will receive the drug by intravenous infusion of PTX-100 over 60 minutes on days one to five of a 14-day cycle for four cycles unless toxicity is observed. The aim is to identify the optimal time and dose-dependent effect of multiple doses of PTX-100.

The Phase 1b basket study is led by Professor H. Miles Prince AM, an internationally renowned oncologist who has contributed to the successful development of several new breakthrough cancer therapies.

Prescient is seeking to identify the mutational status of each patients' malignancies and, within the constraints of a small sample size, seek to correlate this status with any clinical activity. Several cancer biomarkers will be investigated with the aim of identifying patients that may be most likely to respond to PTX-100 therapy.

### **About PTX-100**

PTX-100 is a first-in-class drug candidate that works by disrupting the oncogenic Ras pathway by inhibiting the activation of Rho, Rac and Ral, leading to the death of cancer cells.

An earlier study conducted in the US at Pennsylvania State University and Indiana State University in patients with advanced solid tumors showed PTX-100 was well tolerated and achieved stable disease in patients.

PTX-100 is licensed by Prescient from Yale University, and was invented by Prescient Chief Scientific Officer, Professor Said Sebti, recently appointed as Associate Director of Basic Research at Virginia Commonwealth University Massey Cancer Center, and Professor Andrew Hamilton, the President of New York University.

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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.

**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 RhoA inhibitor in the world in clinical development. PTX-100 is currently in a PK/PD basket study of hematological and solid malignancies, focusing on cancers with Ras and RhoA mutations. In a previous Phase 1 trial in advanced solid tumors, PTX-100 was well tolerated and achieved stable disease.

**PTX-200** is a novel PH domain inhibitor that inhibits an important tumor 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 which are non-specific kinase inhibitors that have toxicity problems, PTX-200 has a novel mechanism of action that specifically inhibits Akt whilst being comparatively safer. This highly promising compound has encouraging Phase 2a data in HER2-negative breast cancer; Phase 1b/2 in relapsed and refractory AML and Phase 1b in recurrent or persistent platinum resistant ovarian cancer:

**Cell Therapy:** Prescient has several initiatives underway to develop new CAR-T therapy approaches.

Find out more at [ptxtherapeutics.com](http://ptxtherapeutics.com), or connect with us via Twitter [@PTX\\_AUS](https://twitter.com/PTX_AUS) and [LinkedIn](https://www.linkedin.com/company/ptxtherapeutics).

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

**For more information please contact:**

Steven Yatomi-Clarke  
CEO & Managing Director  
Prescient Therapeutics Limited  
+61 417 601 440

Andrew Geddes  
CityPR  
+61 2 9267 4511

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