

# First-in class Ras pathway inhibitor PTX-100 Proceeds to Next Dose Level in Basket Study

- First-in-class Ras pathway inhibitor PTX-100 acceptable safety in second cohort at 1,000 mg/m<sup>2</sup>
- Proceeding to next dose level of 2,000 mg/m<sup>2</sup>
- Two of three patients from first cohort continue on therapy, with stable disease or better

**MELBOURNE Australia, 12 August 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 second cohort of patients and demonstrating acceptable safety. Furthermore, follow-up analyses on patients in the first cohort at 500 mg/m<sup>2</sup> has revealed two patients with partial response and stable disease.

The Phase 1b basket study seeks to determine the safety, dose regimen and treatment schedule of PTX100 as a single agent, in several cancers where Ras and RhoA mutations are prevalent. These mutations are present in many cancer types, but there are still no approved therapies against either Ras or RhoA mutant cancers. The study is being conducted at Melbourne's Epworth Healthcare and Peninsula & South Eastern Haematology and Oncology Group.

The three patients enrolled and treated in the second study cohort were heavily pre-treated patients suffering from advanced pancreatic cancer; peripheral T cell lymphoma (PTCL) and Angioimmunoblastic T-cell lymphoma (AITL). The patients in this cohort received 1,000 mg/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 approved the trial to proceed to the next dose of 2,000 mg/m<sup>2</sup> of PTX-100.

In addition, two patients from the first 500 mg/m<sup>2</sup> cohort had reported with stable disease or better at the end of 4 cycles of PTX-100 and meet criteria for continued treatment under the protocol. One patient in 500mg/m<sup>2</sup> cohort has multi-chemorefractory PTCL and is stable while and the other patient, who has cutaneous T cell lymphoma (CTCL) and achieved a partial response (PR). Both of these patients have received 9 cycles of PTX-100 treatment.



Principal Investigator, Professor H. Miles Prince AM, said, "We are encouraged by the good safety results to date and excited to proceed to the third cohort of this important cancer study."

Prescient CEO and Managing Director Steven Yatomi-Clarke said, "We are very pleased to progress this unique study to the next dose level. We thank the patients involved and the dedication of the researcher teams for their work given the challenges and disruptions faced by everyone working in our healthcare system."

## 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.

– Ends –

## Share Purchase Plan

PTX is currently conducting a Share Purchase Plan (SPP) at 5.5c. The SPP closes on 17 August 2020 at 5pm AEST. To request your personalised SPP forms click here:

https://prescienttherapeutics.investorportal.com.au/request-forms/

## Investor briefing

PTX will host an investor briefing tonight at 7pm AEST to provide investors with an overview of recent news flow and progress by the company. To register for the briefing click here:

https://prescienttherapeutics.investorportal.com.au/shareholderbriefing/

Find out more at <u>ptxtherapeutics.com</u>, or connect with us via Twitter <u>@PTX\_AUS</u> and <u>LinkedIn</u>.

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

## 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.

**Cell Therapy:** 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 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 tumours, PTX-100 was well tolerated and achieved stable disease.

**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 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:

#### **COVID-19 Therapies**

Two assets are being assessed by the Doherty Institute for antiviral activity against SARS-CoV-2, the virus that causes COVID-19 disease.

Find out more at <u>ptxtherapeutics.com</u>, or connect with us via Twitter <u>@PTX\_AUS</u> and <u>LinkedIn</u>.

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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 forwardlooking 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



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This document may not contain all the details and information necessary for you to make a decision or evaluation. Neither this document nor any of its contents may be used for any other purpose without the prior written consent of the Company.

#### **Supplemental COVID-19 Risk Factors**

Please see our website : Supplemental COVID-19 Risk Factors