PTX-200 AML Trial Progresses to Next Dose Level

MELBOURNE Australia, 3 August 2020: Prescient Therapeutics Limited (ASX: PTX) ("Prescient"), a clinical stage company developing personalised medicine approaches to cancer, today announced that its Phase 1b study of PTX-200 and cytarabine in patients with acute myeloid leukemia (AML) successfully completed the first cohort at 25 mg/m^2 PTX-200 under the modified study protocol. No dose limiting toxicities were observed, and therapy was better tolerated than under the previous dosing schedule. The study has now progressed to the next dose level of 35 mg/m^2 PTX-200.

As previously reported, three of 15 patients experienced complete responses in the study in relapsed or refractory AML patients, which is a difficult to treat cancer population.

The study modification was made by Prescient in consultation with the study investigators to change the dosing schedule of PTX-200 in relation to the administration of chemotherapy agent cytarabine, with the aim of minimising the potential for overlapping drug interactions that potentially could lead to side effects. The modification entailed maintaining the day 1 PTX-200 dose and removal of days 8 and 15, whilst delaying the start of the cytarabine 5-day continuous infusion to days 3-7 (of a 21-day cycle).

The first cohort of three patients with this modified protocol was enrolled and completed with no dose limiting toxicities reported. Upon review of the safety data from this cohort with the study investigators, Prescient has opened the next cohort for enrolment at 35 mg/m^2 PTX-200. This cohort is actively screening.

Prescient's Chief Medical Officer, Dr Terrence Chew said, "It is pleasing to see the AML study continue to advance despite the COVID-19 pandemic. No significant safety issues were seen. We look forward to escalating the dose in this next cohort as we seek to expand on the encouraging responses previously observed in this study, in a patient population that is difficult to treat and has limited treatment options."

The AML study is led by world-renowned leukemia expert Professor Jeffrey Lancet at the H. Lee Moffitt Cancer Center in Florida. Associate Professor Tara Lin at the University of Kansas Medical Center is also participating in the study.

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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.

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 ptxtherapeutics.com, or connect with us via Twitter @PTX_AUS and LinkedIn.

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

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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 forward-looking 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 "believes," "plans," "expects," "anticipates," and words of similar import, constitute "forward-looking statements." Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of Prescient to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following: the risk that our clinical trials will be delayed and not completed on a timely basis; the risk that the results from the clinical trials are not as favourable as we anticipate; the risk that our clinical trials will be more costly than anticipated; and the risk that applicable regulatory authorities may ask for additional data, information or studies to be completed or provided prior to their approval of our products. Given these uncertainties, undue reliance should not be placed on such forward-looking statements. The Company disclaims any obligation to update any such factors or to publicly announce the results of any revisions to any of the forward-looking statements contained herein to reflect future events or developments except as required by law.

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Supplemental COVID-19 Risk Factors

Please see our website : Supplemental COVID-19 Risk Factors