

ASX Release

PTX-200 AML Study Expanded

- Enrollment completed on schedule
- Two complete responses
- Optimizing PTX-200 dose along with modified chemo dose

Melbourne, Australia (30 August 2018): Clinical-stage oncology company Prescient Therapeutics Ltd (ASX: PTX; Prescient) is pleased to provide an update on its trial of PTX-200 with cytarabine in relapsed or refractory acute myeloid Leukemia (AML). Encouraging efficacy signals were seen as the Company looks to expand the study to optimize Akt inhibition in the combination therapy.

The trial completed its Phase 1b enrollment target on time, with 15 patients recruited and 13 treated in the study led by world-renowned AML expert Professor Jeff Lancet at the H. Lee Moffitt Cancer Center (Moffitt) in Florida and including the Yale Cancer Center and Kansas University Medical Center.

In a very difficult to treat patient population, Prescient is delighted to report that two patients had a complete response (CR) to treatment, meaning total eradication of disease. This is an improvement on the already encouraging single agent activity of PTX-200 in the Phase 1 monotherapy study.

Some peculiar toxicities were observed in three AML patients, including stomatitis, appendicitis and a small bowel obstruction, which were not seen in the Phase 1 study of PTX-200 as a monotherapy, nor in the other PTX-200 trials. Transaminase elevation was observed in three subjects, although only one was dose limiting.

Following liaison with investigators, Prescient will add an additional exploratory arm of the study to explore PTX-200 in combination with a lower dose of cytarabine in order to best optimize the dose of PTX-200 and best inhibit Akt. A similar modification was made to the PTX-200 study in ovarian cancer, which reduced the amount of chemotherapy (in that case, carboplatin).

Prescient aims to enroll 9-12 additional patients under this arm of the study to identify the optimal synergistic dose between PTX-200 and cytarabine. This will also bolster the number of samples for PK and PD analysis.

Prescient's Chief Medical officer, Dr Terrence Chew, said "In studies exploring combination therapies it is important to identify the synergistic dose between both drugs in a particular patient population. The two CRs are encouraging in patients with relapsed and refractory AML, where treatment outcomes are poor. We look forward to building on this as we optimize the synergistic dose between PTX-200 and cytarabine."

ENDS



About Prescient Therapeutics Limited (Prescient)

Prescient Therapeutics is a clinical stage oncology company developing targeted therapies that address specific mutations that drive cancer and contribute to resistance.

Prescient's lead drug candidate **PTX-200** 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 is now the focus of three current clinical trials:

- Phase 2 study examining PTX-200 in breast cancer patients at the prestigious Montefiore Cancer Center in New York and Florida's H. Lee Moffitt Cancer Center (Moffitt). PTX-200 showed encouraging efficacy signals in the Phase 1b study, with twice the expected response rate in subjects with locally advanced cancer.
- Phase 1b/2 trial evaluating PTX-200 as a new therapy for relapsed and refractory Acute Myeloid Leukemia, being conducted the Moffitt; Yale Cancer Center in New Haven, Connecticut (Yale) and Kansas University Medical Center (KUMC) under the leadership of Professor Jeffrey Lancet, MD.
- Phase 1b/2 trial of PTX-200 in combination with current standard of care is also underway in patients with recurrent or persistent platinum resistant ovarian cancer at the Moffitt.

Prescient's second novel drug candidate, **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 inhibits the activation of Rho, Rac and Ral circuits in cancer cells, which act as key oncogenic pathways, leading to apoptosis (death) of cancer cells. PTX-100 was well tolerated and achieved stable disease in a Phase 1 trial in advanced solid tumors and will be the focus of studies in Ras and RhoA mutant malignancies.

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