

# Prescient expands PTX-200 AML Cohort Following Additional Complete Remission

# **Key points**

- Patient achieved CRi at 45mg/m<sup>2</sup> PTX-200 + cytarabine
- 4th complete remission on relapsed & refractory AML study
- No dose limiting toxicities reported at 45mg/m<sup>2</sup>
- Expanding cohort to three additional patients at same dose level

**MELBOURNE Australia, 9 May 2022:** Prescient Therapeutics Limited (ASX: PTX) ("Prescient"), a clinical stage oncology company developing personalised medicine approaches to cancer, today announced that its Phase 1b clinical study of PTX-200 and cytarabine in patients with relapsed and refractory acute myeloid leukemia (AML) will expand the cohort at 45 mg/m² PTX-200 following another complete remission and no dose limiting toxicities at this dose level.

Three patients were treated at 45 mg/m<sup>2</sup> PTX-200 together with cytarabine, with no dose limiting toxicities reported. One patient in the cohort achieved a CRi, meaning complete remission of disease, with neutrophils and/or platelets yet recover to normal levels. CR (complete remission) and CRi are typically ascribed the same predictive value of successful treatment outcome<sup>1</sup> This latest patient brings the total of complete remissions on this study to four patients.

Additionally, one patient in the prior cohort at 35mg/m<sup>2</sup> PTX-200 has been determined to have had a partial response (reduction in cancer burden).

Approximately 158,000 patients globally suffer from AML<sup>2,</sup> a cancer of the bone marrow that prevents formation of normal blood cells. AML progresses quickly and has poor survival rates. After initial chemotherapy, most patients relapse, leading to an ongoing unmet medical need.

The Principal Investigator of the AML study is world-renowned leukemia expert Professor Jeffrey Lancet at the H. Lee Moffitt Cancer Center (Moffitt) in Florida, US, where he is Chair of the Department of Malignant Hematology.

This latest data, together with data from the previous Phase 1 monotherapy study of PTX-200 in acute leukemias, has guided Prescient and Professor Lancet to expand enrolment at this dose level to another three patients, in order to further explore safety and efficacy at this dose level.

<sup>&</sup>lt;sup>1</sup> Innes et al., Blood, 2018

<sup>&</sup>lt;sup>2</sup> Research and Markets, 2020



The study's Principal Investigator, Professor Lancet, said, "It is encouraging to see a CRi at this dose level, which brings a total of four complete remissions on the study so far. It was also pleasing to see that this dose level was well tolerated by patients, with no reported dose-limiting toxicities. It is believed that 45mg/m² may be a biologically effective dose of PTX-200, therefore we will recruit an additional three patients at this dose level to further investigate safety and efficacy in this fragile patient population."

Prescient CEO and Managing Director, Steven Yatomi-Clarke, said, "It is very satisfying to see another patient with remission in a disease that is so aggressive and fatal. Despite recent advancements, AML remains a disease of unmet medical need, and we look forward to advancing this study with the aim of benefiting more AML patients."

- Ends -

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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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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