ASX Release

Prescient to Resume Clinical Trial of PTX-200 in AML

- US FDA has lifted the clinical hold on Prescient's AML Phase 1b/2 trial
- Safety modifications have been made to trial inclusion criteria and protocols
- Prescient is responding to the US FDA with data on its two other studies of PTX-200 in patients with breast and ovarian cancer

Melbourne, Australia (4 September 2017): Clinical-stage oncology company Prescient Therapeutics Ltd (ASX: PTX; Prescient) is pleased to announce the U.S. Food and Drug Administration (FDA) has lifted the clinical hold on the Comp any's Phase 1b/2 clinical trial of PTX-200 in patients with refractory or relapsed Acute Myeloid Leukemia (AML). Prescient is now preparing to resume recruitment of patients in this trial. In parallel, the Company is in the process of responding to similar FDA requests on its breast and ovarian cancer studies which are currently on hold and will update the market accordingly.

As previously announced on 29 May, Prescient paused its three clinical trials of PTX-200 following a serious adverse event in a patient with late-stage breast cancer who experienced liver failure and passed away. The patient had metastatic disease, compromised liver function and was being administered several concomitant medications. Severe adverse events are not unusual in oncology clinical studies where patients are very ill and where existing standard therapies can have potentially serious adverse effects. Upon notification, the FDA placed a clinical hold on the three PTX-200 trials in order to review clinical study information and to enable Prescient to update its risk mitigation plan to FDA's satisfaction. In doing so, Prescient has now revised the trial inclusion criteria whereby anyone with a history of liver disease will no longer be eligible to participate in the trial. In addition, Prescient will conduct a liver function test prior to administering each dose of PTX-200 plus cytarabine.

Prescient's CEO and Managing Director, Steven Yatomi-Clarke said, "Prescient's team has worked hard to address and resolve this clinical hold in a timely manner, and the review of the data from our investigations was as expected."

"Importantly, the clinicians involved remain engaged and are enthusiastic to recommence recruitment for this exciting AML study, which we believe holds great potential. Furthermore, Prescient has continued to manage its cash prudently during this clinical hold period. We look forward to working with the FDA to resolve the clinical holds on our two other studies of PTX-200 following a similar process."

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About Prescient Therapeutics Limited (Prescient)

Prescient is a clinical stage oncology company developing novel compounds that show promise as potential new therapies to treat a range of cancers that have become resistant to front line chemotherapy.

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. The first is a Phase 1b/2 trial evaluating PTX-200 as a new therapy for relapse and refractory Acute Myeloid Leukemia, being conducted at Florida's H. Lee Moffitt Cancer Center (Moffitt); Yale Cancer Center in New Haven, Connecticut (Yale) and Kansas University Medical Center (KUMC) under the leadership of Professor Jeffrey Lancet, MD.

Prescient is also conducting a Phase 1b/2 study examining PTX-200 in breast cancer patients at the prestigious Montefiore Cancer Center in New York and the Moffitt, currently on clinical hold. The third trial is a 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, also currently under clinical hold.

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 (GGT). It also blocks the Ral and Rho circuits in cancer cells which act as key oncogenic survival 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 rare hematological malignancies.

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