



**ASX Release**

## **Prescient to Resume Clinical Trial of PTX-200 in Ovarian Cancer**

- US FDA has lifted the clinical hold on PTX's Phase 1b trial in Ovarian Cancer
- Modifications have been made to trial inclusion criteria and protocols
- PTX to resume trial recruitment

**Melbourne, Australia (6 November 2017):** Clinical-stage oncology company Prescient Therapeutics Limited (ASX: PTX; Prescient) is pleased to announce the U.S. Food and Drug Administration (FDA) has lifted the clinical hold placed on the Company's Phase 1b trial of PTX-200 in patients with platinum resistant ovarian cancer. Prescient is now preparing to resume recruitment of patients in this trial.

As previously announced, 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. These severe adverse event are not unusual in oncology clinical studies where patients are very ill and where existing standard therapies can have potentially serious adverse effects.

Prescient has responded to the FDA's requests for the ovarian cancer trial, including an updated risk mitigation plan, to the FDA's satisfaction, and removal of the clinical hold allows the trial to resume. This development follows the FDA lifting the clinical hold on the Company's trial of PTX-200 in patients with refractory or relapsed Acute Myeloid Leukemia (AML), announced on September 4.

The remaining clinical hold is the PTX-200 trial in patients with metastatic and locally advanced HER2 negative breast cancer, which Prescient is addressing. This trial had successfully completed the Phase 1b study prior to it being placed on hold.

Prescient's CEO and Managing Director, Steven Yatomi-Clarke said, "We are pleased to resume our trial of PTX-200 in ovarian cancer, which represents a significant unmet medical need, particularly for women affected by platinum resistant forms of the disease. Our team is addressing our last remaining clinical hold, and will continue to work with the FDA in a similar process until it is resolved.

In the meantime, Prescient has a busy and exciting schedule of clinical activity with PTX-200 in AML and ovarian cancer, as well as activities for PTX-100 in RhoA mutant lymphomas."

**ENDS**



## 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 relapsed 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.

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 inhibits the activation of Rho, Rac and Rho 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 rare hematological malignancies, namely RhoA mutant lymphomas.

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