ASX Release

Clinical Hold Lifted on PTX-200 Breast Cancer Trial

- US FDA lifted the clinical hold on Prescient's PTX-200 breast cancer trial
- Phase 2 breast cancer trial allowed to resume
- All PTX-200 trials now unencumbered by clinical holds and free to recommence recruitment

Melbourne, Australia (11 December 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 trial of PTX-200 in patients with HER2 negative breast cancer. Prescient is now able to resume recruitment of patients in this trial, which is now in Phase 2. This was the last remaining PTX-200 trial on clinical hold.

As with the responses to the AML and ovarian cancer trials, Prescient has met the FDA's requests for the breast cancer trial to the FDA's satisfaction, which included updating the risk mitigation plan, to minimize risks around hepatotoxicity.

Prior to the clinical hold, the breast cancer trial had successfully completed Phase 1b study by meeting its pre-specified safety criteria. Furthermore, there were early encouraging signs of a positive effect from the preliminary efficacy analysis with five patients qualifying for Phase 2 analysis.

Prescient's CEO and Managing Director, Steven Yatomi-Clarke said, "This is a great result for Prescient, and we are very pleased to now have all these clinical holds behind us. Furthermore, it is very satisfying that we were able to successfully address three separate clinical holds in a timely manner. I am very proud of Prescient's team, who have all been working hard towards this successful outcome."

"There have been positive industry developments in the last several months that support our novel thesis of Akt inhibition in HER2 negative breast cancer. This reconciles with our encouraging preliminary results from our Phase 1b breast cancer trial. We look forward to sharing the final results soon."

"Prescient now has a very full work program, with many potentially transformative catalysts in the coming year across both our drugs".

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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 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. 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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