ASX Release

Improved manufacturing route for PTX-100

Melbourne, Australia (3 September 2018): Clinical-stage oncology company Prescient Therapeutics Ltd (ASX: PTX; Prescient) is pleased to advise that it has identified an improved manufacturing route for PTX-100 for use in its upcoming pharmacokinetic (PK) and pharmacodynamic (PD) clinical trial.

The new route confers several advantages over the previous method:

- Yielding twice as much drug product;
- Enabling a more meaningful number of patients to be treated in the upcoming study;
- Similar cost to the old method; and
- Regulatory compliance for all phases of study (whereas the old method was suitable only for phase 1).

The manufacture of PTX-100 is a complex process and the Prescient team, led by Dr Mike Preigh, VP - Chemistry, Manufacturing & Controls, has worked hard to achieve this outcome whilst keeping down the extensive costs that would otherwise be incurred.

A planned program for PTX-100 is rapidly advancing towards initiating an important PK and PD study in several malignancies. It is anticipated that the PK/PD trial will initiate in early 2019 with a more meaningful number of patients and will therefore be a more informative and productive study, and conducted to a higher regulatory standard.

In addition, Prescient is currently manufacturing a new batch of active pharmaceutical ingredient (API) as a precursor to manufacturing additional PTX-200 drug product in order to meet the demands of ongoing clinical trials. The manufacturing program is comprehensive and remains on track.

Prescient CEO and Managing Director, Steven Yatomi-Clarke said, “Chemistry, Manufacturing and Controls (CMC) are a crucial part of drug development and clinical trials, although often unseen and under-appreciated. Prescient has invested in robust CMC programs for both assets which will hold it in good stead going forward.”

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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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