



**ASX Release**

## **Clinical Trial Updates**

**Melbourne, Australia (29 January 2018):** Clinical-stage oncology company Prescient Therapeutics Limited (ASX: PTX; Prescient) is delighted to provide an update on its clinical trials following removal of all clinical holds on its PTX-200 clinical trials.

Prescient's CEO and Managing Director, Steven Yatomi-Clarke said, "The clinical holds naturally caused a delay in recruitment and required us to focus resources to address the holds. Pleasingly, these were met successfully and in a relatively timely manner. Fortunately, at the time of the clinical holds, Prescient was under budget and either ahead of schedule or on schedule in each of our trials. Accordingly, Prescient is well placed to minimize delays. 2018 is shaping up to be a year with many clinical milestones, which is exciting for shareholders."

### **PTX-200**

All PTX-200 trials are now off clinical hold and are either currently recruiting or in the process of obtaining requisite institutional-level approvals to recommence recruitment.

Prescient is currently undertaking another manufacturing run of PTX-200 to meet increased clinical needs.

#### *HER2-negative breast cancer*

An important near-term milestone is the release of the final Phase 1b results of PTX-200 with paclitaxel in locally advanced and metastatic HER2-negative breast cancer. Final results from the Phase 1b trial are expected Q1 2018.

The clinical hold was lifted without amendment to the dosing schedule, meaning that this trial can effectively recommence from where it stopped. The trial is currently in Phase 2, with 5 patients qualifying for Phase 2 data analysis.

Based on final Phase 1b results, Prescient will take the opportunity to modify the protocol with a view to strengthening Phase 2 analysis; in particular, stratifying patients based on their hormone receptor status to observe responses in these different breast cancer sub-types. Recruitment for Phase 2 will then recommence under this revised design, expected around the middle of 2018.

#### *Acute Myeloid Leukemia (AML)*

Recruitment in the trial of PTX-200 with cytarabine in relapsed or refractory AML has recommenced following the removal of the clinical hold. A total of five patients have now been recruited to the second dosing cohort of 35mg/m<sup>2</sup>.



Participating clinicians are pleased with the progress of the trial. The Phase 1b component is on track to complete recruitment around mid-2018 (although it may take slightly longer if the trial achieves the highest dose escalation of PTX-200).

### *Ovarian Cancer*

Following lifting of the hold of the trial of PTX-200 and carboplatin in platinum-resistant recurrent ovarian cancer, Prescient has taken the opportunity to make further amendments to the protocol (that are unrelated to PTX-200) to aid flexibility in carboplatin dosing. This has been submitted for FDA and internal review board approval to allow recommencement of recruitment.

Prescient has now treated six patients at the second dosing cohort of 25mg/m<sup>2</sup> and twelve patients in total. Prescient is aiming to complete this Phase 1b trial by the end of 2018.

### **PTX-100**

Preparations for the pilot study are underway. PTX-100 has previously completed a Phase 1 study in solid tumors, which demonstrated safety, tolerability and stable disease in some patients with advanced cancers. This next trial plans to understand pharmacokinetics and pharmacodynamics, particularly in the hematological setting, and correlating this against Rho and Ras mutant status of patients and if successful, will potentially enable further trials in RhoA mutant cancers. This trial is planned to commence mid-year.

The ultimate goal of this program, should the trials be successful, is to progress towards a registration study in mutant RhoA lymphomas.

Manufacturing PTX-100 is underway and scheduled to coincide with this the timeline. By utilizing existing starting product, Prescient has avoided the costs of a very expensive manufacturing run for this pilot study.

### **ENDS**

### **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. 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.

#### **Further enquiries:**

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