

**ASX Release**

## **Interim Durability Analysis of PTX-200 in Breast Cancer Responders Demonstrates No Disease Progression**

- PFS and OS to date average 27 months
- Even partial responders remain free of disease progression

**Melbourne, Australia (10 December 2018):** Clinical-stage oncology company Prescient Therapeutics Limited (ASX: PTX; Prescient) is pleased to announce interim durability data on the PTX-200 study in HER2 negative, locally advanced breast cancer. Follow-up studies have determined that none of the five responders in the Phase 2 component of the trial have had disease progression to date.

Progression Free Survival (PFS), which is the time from the start of treatment until disease recurrence or progression, ranges from 22.8 months to 30.4 months so far, with an average of 27 months. All patients remain progression free to date.

Overall survival (OS), which is the time from start of treatment until patient death, exhibits the same average duration of 27 months as none of the patients have passed away.

To date, not only did patients with pathological complete responses (pCR) remain free of disease progression, but interestingly all patients that had partial responses (PRs) also remain free of disease progression after over two years.

Prescient's Chief Medical Officer, Terrence Chew, MD, said, "Typically, women with locally advanced breast cancer will have disease recurrence 5 years after successful treatment, but many of these women will progress within the first two years<sup>1</sup>. The observation that our patients have not experienced any cancer progression beyond two years on average is therefore encouraging and supports the response rates we have seen so far."

Whilst PFS and OS are not formal endpoints to this study, their analysis nevertheless fortifies the body of evidence for the study's endpoint of pathological complete response (pCR) rates, which the US FDA recognizes as an endpoint to accelerated approval<sup>2</sup>.

Prescient Managing Director and CEO Steven Yatomi-Clarke said, "Roche's Phase 3 Akt inhibitor, ipatasertib – being tested in a different subset of breast cancer, metastatic triple negative disease - recently demonstrated three things that are very relevant to Prescient. Firstly, the Akt pathway is activated in response to chemotherapy in breast cancer patients. Secondly, Akt

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<sup>1</sup> Jardines L, Oncology, June 2015; SEER data

<sup>2</sup> US FDA, (CDER). Guidance for industry: pathological complete response in neoadjuvant treatment of high-risk early-stage breast cancer: use as an end point to support accelerated approval. October 2014.

inhibitors enhance the killing of breast cancer cells. Thirdly and most significantly, this Akt inhibition results in clinical benefit for breast cancer patients<sup>3</sup>.”

“This demonstrates that Akt inhibition can make a clinical difference to breast cancer patients, which is what Prescient is seeking to demonstrate in these studies. Further, we believe that PTX-200’s unique mechanism of action as a PH domain inhibitor may have advantages over other Akt inhibitors.”

“It is worth noting that two of the people involved in the discovery and development of ipatasertib at Array BioPharma both now work in key roles with Prescient: our Vice President of Chemistry, Manufacturing and Controls, Dr Mike Preigh and our Vice President for Business Development Dr Jim Winkler. They both continue to provide significant insights that are very valuable in our own program,” Mr Yatomi-Clarke added.

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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** is a novel PH domain inhibitor that 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.
- 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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<sup>3</sup> Data presented at ASCO Annual Meeting June 2018 by Rebecca Dent

**Further enquiries:**

Steven Yatomi-Clarke  
CEO & Managing Director  
Prescient Therapeutics Limited  
+61 417 601 440

Andrew Geddes  
CityPR  
+61 2 9267 4511

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