ASX Release

PTX-200 Phase 1b Breast Cancer Trial Results
Prescient's Most Significant Clinical Milestone to Date

- Achieved overall response rate (ORR) of 50% against an expected industry average ORR of 25%
- In the five patients with locally advanced disease, two had pathologic complete responses (40%), with an ORR 100%
- Particularly encouraging results in women with ER+ breast cancer

Melbourne, Australia (10 April 2018): Clinical-stage oncology company Prescient Therapeutics Ltd (ASX: PTX) is delighted to announce that the patients evaluable for efficacy in the PTX-200 Phase 1b breast cancer trial exhibited an overall response rate of 50%, against an expected industry average response rate of 25% with paclitaxel alone. In patients with locally advanced disease, two patients had pathologic complete responses (40%), meaning a complete eradication of cancer.

The Phase 1b trial evaluated PTX-200 in combination with paclitaxel in women with HER2-negative breast cancer, including ER-/PR- (triple negative) and ER+ breast cancer[1]. The trial was conducted at the Montefiore Medical Center, Albert Einstein College of Medicine in New York (Montefiore Cancer Center) under the leadership of renowned breast cancer specialist Professor Joseph Sparano, MD, and the H. Lee Moffitt Cancer Center in Tampa (Moffitt). This study of PTX-200 is currently in Phase 2 in women with HER2 negative locally advanced breast cancer.

The Phase 1b dosed 28 patients in total, with 16 patients in the dose escalation stage. The expansion cohort comprised a further 12 patients with locally advanced or metastatic HER2-negative breast cancer, who received the recommended Phase 2 dose of 35 mg/m^2 of PTX-200, together with 80mg/m^2/week of paclitaxel, followed by standard doxorubicin-cyclophosphamide and surgery for locally advanced disease. Ten patients were evaluable for clinical response, of which five patients had locally advanced disease and five had metastatic disease.

Assessment Criteria for Breast Cancer

Assessment of disease falls into several different categories according to a patient's response to therapy:

- Pathological Complete Response (or Complete Response) (pCR or CR): meaning complete eradication of cancer from the patient;
- Partial Response (PR): partial but not complete eradication of cancer;
- Stable Disease (SD): cancer has not progressed, but neither has it diminished; and
- Progressive Disease (PD): cancer has progressed.

[1] Triple negative breast cancer is a type of breast cancer that does not have any of the three receptors commonly found on breast cancer cells: estrogen, progesterone and HER2 receptors. ER+ breast cancer does have estrogen receptors. The treatment of triple negative and ER+/HER2 negative breast cancers is characterized by a high level of unmet clinical need (GlobalData 2016).

Studies often quote an Overall Response Rate (ORR), which combines Complete and Partial Responses.

Studies on all sub-types of locally advanced breast cancer receiving weekly chemo reports a wide range of pCR rates, from 8-28%. For women with locally advanced ER+ HER2 negative breast cancer, typical expectations are pCR rates of 16% (11-22%) and ORR of 25%[2].

PTX-200 Phase 1b Efficacy Results

Ten breast cancer patients were evaluable for efficacy. The ORR across all patients was 50%.

By receptor status, responses were particularly encouraging in women with ER+ disease with pCR of 50% and ORR of 75%.

Table 1: Summary of Efficacy Results from Phase 1b Study – Metastatic and Locally Advanced Breast Cancer

	ER+	Triple negative	Total
pCR/CR	2	0	2
PR	1	2	3
SD	1	2	3
PD	0	2	2
ORR	**75%**	**33%**	**50%**

Of patients with locally advanced disease, which is the focus of the Phase 2 study, there were two pCRs (40%) and three PRs (60%) for an ORR of 100%.

Table 2: Summary of Efficacy Results from Phase 1b Study – Locally Advanced Breast Cancer

	ER+	Triple negative	Total
pCR/CR	2	0	2
PR	1	2	3
SD	0	0	0
PD	0	0	0
ORR	**60%**	**40%**	**100%**

[2] Hortobagyi, G, et al; *J Clin Oncol* 23:5983-5992; 2005; Sparano, J, et al ; *Breast Cancer Res Treat*; June 2014; Sparano, J, et al ; *Breast Cancer Res Treat*; June 2013

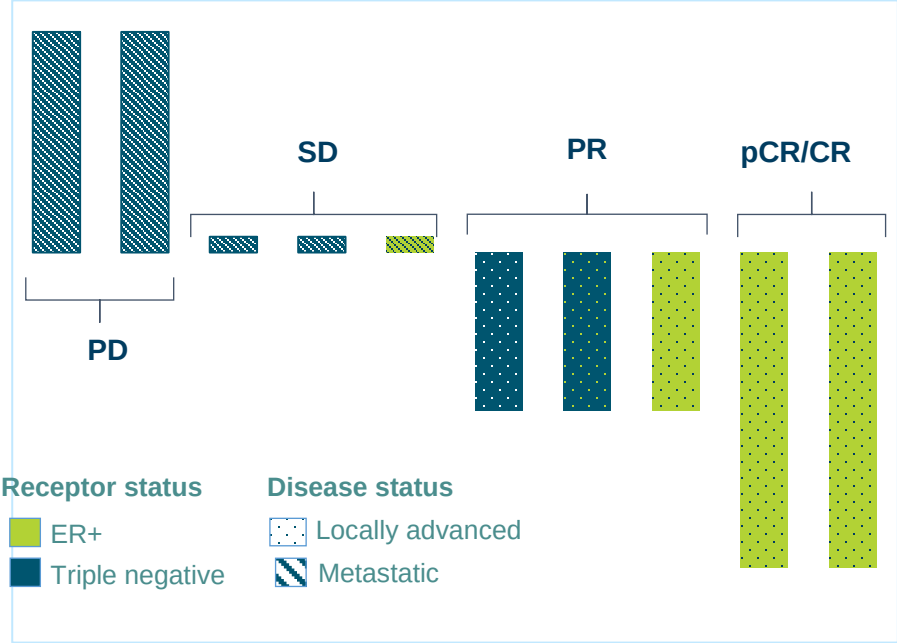

Figure 1: Visual representation of response by breast cancer receptor and disease status

This study is currently in a Phase 2 trial in women with HER2 negative locally advanced breast cancer, and five of the patients in the Phase 1b study qualify for assessment of Phase 2 data. The Phase 2 trial will be in 26 patients using a two stage Simons MinMax Design. If at least three pCRs are observed in the first 11 patients, then the Phase 2 trial expands to another 15 patients. For the purposes of this analysis, two pCRs have already been observed in the first five patients.

Market Dynamics for HER2 Negative Breast Cancer Drugs

The market for HER2 negative breast cancer was US$5.4 billion in 2015 of which 41% was comprised of generic chemotherapy. This market is expected to grow to US$10.6 billion by 2025, with particularly strong growth in China. The launch of new drugs in the neoadjuvant (pre-operative) setting is expected to be a major driver[3]. This is where PTX-200 is positioned.

In particular, large market opportunities remain for new drugs to treat patients who are resistant to endocrine therapy and to complement chemotherapy. Market observers have identified a lack of novel pipeline agents from pharmaceutical and biotechnology companies to address this opportunity[3]. Once again, PTX-200 is seeking to address this poorly met need.

Prescient Therapeutics' CEO, Steven Yatomi-Clarke said "This result is Prescient's most significant clinical milestone to date. We are very encouraged with the results from the Phase 1b study, albeit from a relatively small number of patients. Whilst the overall results were pleasing, it was particularly encouraging to see our best responses in women with ER+ disease, which is an especially difficult disease to treat, and with poor expected outcomes from current chemotherapy regimes alone.

Prescient is delighted to have a diversified clinical pipeline, headed by an asset with early clinical activity that is now in a Phase 2 trial."

[3] HER2-Negative/HR+ and Triple Negative Breast Cancer – Global Drug Forecast and Market Analysis to 2025

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:

- Phase 2 study examining PTX-200 in breast cancer patients at the prestigious Montefiore Cancer Center in New York and the Moffitt.
- 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.
- 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, namely RhoA mutant lymphomas.

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