ASX Announcement

Prescient's PTX-200 Phase 2a trial in HER2-Negative Breast Cancer Exhibits High Overall Response Rate

- Overall response rate of 91% in women with locally advanced HER2 negative breast cancer
- Two patients reported pathologic complete responses, another patient with clinical complete response
- Excellent ongoing durability, with 9 of 10 evaluable patients free of disease progression to date, with up to 40 months of disease-free progression
- New study to focus on ER+ breast cancer

Melbourne, Australia 23 December 2019: Prescient Therapeutics Limited (ASX: PTX) ("Prescient"), a clinical stage company developing personalised medicine approaches to cancer, is pleased to announce encouraging efficacy results from the Phase 2a trial of its lead candidate PTX-200 in women with HER2 (human epidermal growth factor receptor 2) negative, locally advanced breast cancer. The results from eleven women exhibited an overall response rate of 91%. Two patients had pathologic complete responses (complete eradication of disease), with another patient having a clinical complete response (which was unable to be confirmed surgically). Furthermore, patients continue to exhibit robust durability of response, with progression-free survival averaging 22 months so far, and up to 40 months, tracking favourably against expectations. Based on these encouraging results, the Company plans to initiate a new trial focusing specifically on patients with estrogen-receptor-positive (or ER positive) disease, which appears to be the most responsive patient population.

In this Phase 2a study, eleven patients were enrolled with locally advanced, HER2-negative breast cancer; nine with ER+ disease and two with triple negative disease[1]. Patients received 35 mg/m^2 of PTX-200, together with 80mg/m^2/week of paclitaxel, followed by standard doxorubicin-cyclophosphamide (AC therapy) and surgery.

[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).

The trial was conducted by researchers at the prestigious Montefiore Medical Center, Albert Einstein College of Medicine in New York under the leadership of world-leading breast cancer specialist Professor Joseph Sparano, and at the H. Lee Moffitt Cancer Center in Florida, under the guidance of Dr Heather Han.

Understanding the assessment criteria for breast cancer treatments

Assessment of locally advanced breast cancer falls into several different standard categories according to a patient's response. The following are universally recognized definitions to evaluate patient responses:

pCR	pathological Complete Response; a complete eradication of cancer, confirmed by surgery.
cCR	clinical Complete Response; total eradication of cancer; but has not been confirmed by surgery.
PR	Partial Response; partial but not complete eradication of the cancer.
SD	Stable Disease; the cancer has not progressed but has not diminished
PD	Progressive Disease; the cancer has progressed.
NE	Not Evaluable; patient was not able to be evaluated in accordance with the study protocol.
ORR	Overall Response Rate; combines complete and partial responses.

As previously reported, studies on all sub-types of locally advanced breast cancer receiving weekly chemotherapy reported a wide range of expected response rates. For women with locally advanced ER positive and HER2 negative breast cancer, typical expectations are pCR rates of approximately 16%[2].

Durability of response is measured as progression free survival (PFS), which is the time from the start of treatment until disease recurrence or progression, and ultimately overall survival (OS), which is the time from start of treatment until patient death. Typically, up to 60% of women with locally advanced HER2 negative breast cancer experience disease recurrence five years after successful treatment, but many of these women will progress within the first 24 months[3].

[2] Green, M., et al , et al; *J Clin Oncol* 23:5983-5992; 2005; Tu, Y. , et al ; *Breast Cancer Res Treat*; June 2014; Andreopolou, E., , et al ; *Breast Cancer Res Treat*; June 2013
[3] Jardines L, Oncology, June 2015; SEER data; Gianni, L., et al. *Lancet Oncol* 2014; 15: 640–47

PTX-200 Phase 2a Efficacy Results

Response rates

Ten of the eleven patients were evaluable for the study primary efficacy endpoint of pathologic response in the breast determined at surgery and all responded to therapy.

All ten evaluable patients responded to therapy. The ORR across all patients was 91%. Two patients had pathological complete responses, meaning complete eradication of disease, and all eight remaining patients experienced pathological partial responses.

One patient was not evaluable surgically as per protocol, having unfortunately passed away prior to scheduled surgery from adverse events considered related to doxorubicin, a chemotherapy agent, and unrelated to PTX-200. This patient entered the study with an particularly large ER positive breast tumor that was completely eradicated following treatment with PTX-200 and paclitaxel. Whilst undergoing subsequent therapy with Adriamycin and cyclophosphamide (AC), the patient passed away from cardiac complications prior to scheduled surgery. Whilst this patient's CR was therefore unable to be confirmed surgically as per protocol, it was nevertheless deemed a clinical complete response, which was confirmed by autopsy.

The Simons two-stage design was aiming to demonstrate three pCRs in the first eleven patients; Prescient believes that two pCRs and an additional cCR (confirmed by autopsy) demonstrates comparable proof of concept with respect to efficacy. Combined, the three complete responses (27%) compares favorably against an expected pCR rate of 16% with current standard of care and improves the ORR to 100%.

Table 1: Summary of Efficacy Results from Phase 2a Study in Locally Advanced Breast Cancer

	ER positive	Triple negative	Total
pCR	2	0	2
pPR	6	2	8
SD	0	0	0
PD	0	0	0
NE (cCR)*	1	0	
ORR			**90.9%**

*patient determined as Not Evaluable under the assessment criteria of the trial protocol, but nevertheless had a clinical Complete Response.

Durability of response

Patients are under ongoing evaluation for duration of treatment response.

PFS ranges from 6.7 months to 40 months so far, with an average of 22 months. Nine of ten evaluable patients remain progression free to date.

OS exhibits an average duration of 22.4 months so far, as one of the evaluable patients has passed away.

These durability observations are tracking favourably against the 24 month window during which many breast cancer patients typically relapse. Prescient considers that the robust durability of response bolsters the encouraging response rates observed in this study.

Prescient Therapeutics CEO and Managing Director, Steven Yatomi-Clarke said, "These promising results are an important clinical milestone in our work to find better treatments for breast cancer. Results indicate that the most responsive patient population to our therapy in breast cancer is patients with ER positive disease, and that we should focus on this sub set of patients for PTX-200. To this end, we will now seek to switch this study to a new trial combining PTX-200 and hormone therapy, which is the standard of care for locally advanced ER positive breast cancer. Furthermore, our investigators also expect this combination to have a superior safety profile to the current combination with chemotherapies paclitaxel and AC. To mitigate rising costs of conducting clinical studies in the US, Prescient will seek to conduct this study in Australia and/or as an investigator sponsored study backed by non-dilutive funding."

"The global market demand for HER2-negative breast cancer therapies was forecast to grow to US$10.6 billion by 2025. The launch of new breast cancer drugs in the pre-operative setting is expected to be a major driver of this growth; as is the strong demand for new drugs to treat ER+ patients who are resistant to endocrine therapy[4]. Market observers have identified a lack of novel pipeline agents from pharmaceutical and biotechnology companies to address this opportunity. Prescient is positioning PTX-200 to address this poorly met need," he said.

-Ends-

[4] GlobalData 2017

About Prescient Therapeutics Limited (Prescient)

Prescient Therapeutics is a clinical stage oncology company developing personalised medicine approaches to cancer, including targeted and cellular therapies.

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 disrupts oncogenic Ras pathways by inhibiting the activation of Rho, Rac and Ral circuits in cancer cells, leading to apoptosis (death) of cancer cells. PTX-100 is believed to be the only RhoA inhibitor in the world in clinical development. PTX-100 is currently in a PK/PD basket study of hematological and solid malignancies, focusing on cancers with Ras and RhoA mutations. In a previous Phase 1 trial in advanced solid tumors, PTX-100 was well tolerated and achieved stable disease.

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 has encouraging Phase 2a data in HER2-negative breast cancer; Phase 1b/2 in relapsed and refractory AML and Phase 1b in recurrent or persistent platinum resistant ovarian cancer:

Cell Therapy: Prescient has a collaboration with Carina Biotech developing new CAR-T therapy approaches.

Find out more at ptxtherapeutics.com, or connect with us via Twitter @PTX_AUS and LinkedIn.

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