ptx

ASX Release

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PTX-200 Breast Cancer Trial Progresses

- Phase Ib breast cancer trial enters expansion cohort
- H. Lee Moffitt Cancer Center joins trial recruitment

Melbourne, Australia 17 February 2016: Clinical stage oncology company Prescient Therapeutics Ltd (PTX) is pleased to announce that the last patient (patient 17) has been dosed in the escalation stage of its Akt inhibition Phase Ib breast cancer trial at the Montefiore Cancer Center of Albert Einstein University in New York (Albert Einstein University) under the guidance of Professor Joseph Sparano. The trial is targeting women with metastatic and locally advanced HER2 negative breast cancer.

This last patient received treatment on the third dose level and had no dose limiting toxicity (DLT). As a result, the recommended Phase II dose (RPTD) for this trial has been determined as 35 mg/m² PTX-200, together with chemotherapy.

As part of this expansion stage, PTX is pleased to announce that the H. Lee Moffitt Cancer Center (Moffitt) in Tampa, Florida will shortly join Albert Einstein University in the Phase Ib expansion cohort and the Phase II trial, and is expected to soon commence recruitment.

Dr. Heather Han, a medical oncologist specializing in breast cancer in The Center for Women's Oncology at Moffitt, will conduct the study.

PTX's Chief Medical Officer, Terrence Chew, M.D. said "We are making good progress with this trial under Professor Sparano's guidance and I am delighted that a physician of Dr Han's caliber has agreed to join the trial."

Professor Sparano said "We have amended the protocol to expand the inclusion criteria to include patients with metastatic breast cancer and prior anthraycline exposure plus patients with stage IIB-IIIC disease. This is a major development that will enhance accrual and accelerate completion of the study."

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About PTX-200

Hyperactive Akt is a prominent feature of many human cancers and is correlated with resistance to chemotherapy.

PTX-200 is a novel and selective Akt activation inhibitor. It is both anti-proliferative and pro-apoptotic.

Most Akt inhibitors seek to work by mimicking ATP, a molecule used by all kinases in the cells; and therefore off target effects are likely to result in toxicities.

By contrast, the mechanism by which PTX-200 inactivates Akt is not by inhibiting its kinase, but rather by preventing its binding to the plasma membrane where it must be localized to be phosphorylated and activated. Therefore, by preventing Akt binding to the plasma membrane, PTX-200 inhibits Akt, but without the off target toxic effects of kinase inhibitors.



About Prescient Therapeutics Limited (PTX)

PTX is a clinical stage oncology company developing novel compounds that show promise as potential new therapies to treat a range of cancers that have become resistant to front line chemotherapy.

PTX'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. This compound is now the focus of three current clinical trials. The first is a Phase Ib/II study examining PTX-200 in breast cancer patients at the Montefiore Cancer Center in New York and at Florida's H. Lee Moffitt Cancer Center (Moffitt). A Phase Ib/II trial of the compound in combination with current standard of care is also underway in patients with recurrent or persistent platinum resistant ovarian cancer at the Moffitt. These trials are funded in part by grants from the U.S. National Cancer Institute. In addition, PTX has recently received IND allowance for a Phase Ib/II trial evaluating PTX-200 as a new therapy for Acute Myeloid Leukemia.

PTX'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 also blocks the Ral and Rho circuits in cancer cells which act as key oncogenic survival pathways, leading to apoptosis (death) of cancer cells. PTX-100 was well tolerated and achieved stable disease in a Phase I trial in advanced solid tumors.

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