ASX Release

Clinical Trial Update

Melbourne, Australia (29 May, 2017): Clinical-stage oncology company Prescient Therapeutics Ltd (ASX: PTX) provides the following update on its clinical trials with PTX-200 following a serious adverse event (SAE) in a late-stage patient on its breast cancer trial.

The Phase 1b breast cancer trial with PTX-200 plus paclitaxel and has completed enrollment. However, subsequent to the preliminary safety and efficacy analyses, the last patient of 29 patients enrolled in the trial experienced a SAE and passed away.

The SAE occurred in a female patient with stage IV metastatic triple negative (advanced poor prognosis) breast cancer who experienced hepatic (liver) failure whilst also being treated with paclitaxel, which can impact liver metabolism. In his submission to the FDA, the Principal Investigator assessed that the cause of the SAE was possibly related to paclitaxel, possibly related to PTX-200, and possibly related to pioglitazone.

As per the Company's operating procedures, PTX has temporarily paused recruitment to each of its PTX-200 trials to further investigate the SAE with its consultants; to review the protocols and to update its risk mitigation plan, in order to maximize patient safety as well as ensuring maximum efficacy. The U.S. Food and Drug Administration (FDA) has been notified, and in early interactions has concurred with this approach; and in accordance with its policies, placed the trials on clinical hold whilst it requests further information and assists PTX in updating its risk mitigation plan. Once this process is completed, the Company intends to re-commence enrollment following formal lifting of the clinical holds by the FDA.

PTX's CEO and Managing Director, Steven Yatomi-Clarke said "We are in close dialogue with the FDA and expect to incorporate its recommendations and modifications into the trial protocols so that recruitment can re-commence at the earliest opportunity."

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About PTX-200

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 binding to the PH domain of Akt and 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 typical kinase inhibitors.

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

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. 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 relapse 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

PTX 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.

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 1 trial in advanced solid tumors and will be the focus of studies in rare hematological malignancies.

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