ASX Release

Prescient Therapeutics Initiates Phase 1b Clinical Trial for First-in -Class Anti-Cancer Drug PTX-100 in Patients with Multiple Cancers

Highlights:

- **Innovative 'basket' study design will assess drug in multiple cancers**
- **Precision medicine approach offers a potentially faster development route**
- **International cancer expert Prof Miles H. Prince, AM is lead investigator**
- **Growing oncology industry interest in Ras pathways**

MELBOURNE Australia, 11 July 2019: Prescient Therapeutics Limited (ASX: PTX), a clinical stage oncology company, today announced the start of a Phase 1b trial of its second targeted anti-cancer drug PTX-100 in Australia. The new study is designed to rapidly identify the optimal dose and treatment schedule of PTX-100 in a variety of malignancies including myeloma, T-cell lymphomas, gastric and pancreatic cancers with Ras and RhoA mutations. Researchers will monitor the mutational status of patients' malignancies and, using a small sample size, seek to correlate this status with clinical activity. They will also study several cancer biomarkers to identify patients most likely to respond to PTX-100 therapy.

One of the world's leading cancer researchers, Melbourne-based Professor H. Miles Prince AM, will be the lead investigator. Professor Prince is an internationally renowned oncologist, with a highly respected reputation in cancer research, and has worked successfully on the development of many cancer drugs.

An earlier clinical study conducted at Pennsylvania State University and Indiana State University in patients with advanced solid tumors showed that PTX-100 was well tolerated and achieved stable disease in patients.

Unlike conventional clinical trials, the new study will take a 'basket' approach to assess the drug on multiple cancers with a view to addressing specific mutations, rather than tumor origin. This strategy has been successfully pioneered by several US companies like Loxo Oncology, Inc (acquired by Eli Lilly and Company for US$8 Billion in January 2019) as a faster way to identify cancer patients who will potentially benefit from the therapy.

Professor Prince said, "Molecularly targeted therapy is the way forward in treating cancers. We know the pathway that is targeted by PTX-100 is critical to the survival of the cancers included in this study. As a cancer specialist I want to see PTX-100 added to the tool-box of targeted treatments." Professor Prince and his team will treat patients at the Epworth Hospital in Melbourne.

Prescient Therapeutics Managing Director and CEO Steven Yatomi-Clarke said, "Commencing this novel study is a significant milestone for Prescient. Not many companies can boast a drug that is first-in-class entering the clinic. PTX-100 is a truly differentiated and unique inhibitor, and this further demonstrates Prescient's ability to progress important new therapies for cancer

patients. It is another big step forward in our goal of building a robust pipeline of personalized therapies against cancer."

"Furthermore, it is a significant coup for Prescient to have an outstanding authority in Professor Miles Prince lead this study, and speaks to the quality of the clinical faculty leading Prescient's trials."

PTX-100 a targeted cancer therapy

PTX-100 is a first-in-class drug candidate that works by blocking a common cancer growth enzyme which plays a key role in malignant cell transformation. It disrupts the oncogenic Ras pathways by inhibiting the activation of Rho, Rac and Ral circuits in cancer cells, leading to the death of cancer cells.

The open-label, non-randomized trial will enrol up to 24 participants to evaluate the pharmacokinetics and pharmacodynamics of the drug as well as safety and efficacy of two different doses in patients with advanced malignancies. Patients will receive the drug by intravenous infusion over 60 minutes on days one to five of a 14-day cycle for four cycles unless toxicity is observed. The aim is to identify the optimal time and dose-dependent effect of multiple doses of PTX-100.

Professor Miles H Prince AM

Professor Prince is involved in major clinical research programs ranging from the use of stem cells to the mechanism of the immune systems control of blood and cancer growth. He holds major Australian, American and European research grants and has published over 300 journal articles. He is a member of Australian, American and European Societies of Haematology and Oncology, and is on the boards of International Society of cutaneous lymphoma, International Waldenstrom's Macroglobulinemia Foundation and chairman of the Medical Scientific Advisory Group of Myeloma Australia. Professor Prince has recently been appointed Director of Molecular Oncology and Cancer Immunology at the Epworth Hospital.

Industry focus on Ras pathways

Although Ras has long been identified as an important target driving cancer, successful inhibition of Ras has proven elusive, due to a lack of binding sites on the molecule. In May 2019, multinational biopharmaceutical company Amgen announced encouraging Phase 1 studies with its Ras inhibitor AMG-510, which targets a small proportion of Ras with a particular mutation. This has led to a surge in industry interest in Ras.

Unlike other attempts at direct Ras inhibition, PTX-100 disrupts the Ras pathway downstream. It blocks the cancer growth enzyme known as geranylgeranyl transferase-1 (GGT-1) which inactivates Rho, Rac and Ral circuits in cancer cells downstream of Ras. PTX-100 is able to target not only cancers with Ras mutations, but also cancers with Rho mutations. PTX-100 is the only Rho inhibitor in clinical development worldwide.

PTX-100 is licensed by Prescient from Yale University, and was invented by Prescient Chief Scientific Officer, Professor Said Sebti, and Professor Andrew Hamilton, now President of New York University.

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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.

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 was well tolerated and achieved stable disease in a Phase 1 trial in advanced solid tumors.

PTX-100 is believed to be the only RhoA inhibitor in the world in clinical development. PTX-100 will soon commence a PK/PD basket study of hematological and solid malignancies, focusing on cancers with Ras and RhoA mutations.

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. Responses have demonstrated durability in the study so far.
- 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.

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