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The Company Announcements Platform

ASX Limited

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US FDA Reactivates Prescient's IND for PTX-100 Breast Cancer Trial

10 June 2015, Melbourne, Australia: Prescient Therapeutics (ASX:PTX), a clinical stage oncology company, has been advised that the US Food and Drug Administration (FDA) has reactivated the Investigational New Drug (IND) for its novel drug candidate PTX-100 (formerly known as GGTI-2418) in a Phase Ib trial for the treatment of metastatic breast cancer. This follows the acquisition of the drug from Pathway Oncology in mid 2014.

This follows a submission to the FDA of a detailed and complete protocol for the proposed study in patients with Stage IV metastatic breast cancer. The objective of the study will be to determine the optimal dosing schedule and dose of PTX-100 in combination with chemotherapy drug docetaxel, which is approved for the treatment of patients with metastatic breast cancer.

Prescient Managing Director, Dr Rob Crombie, commented: "Despite decades of research and use of chemotherapy regimens, resistance to cancer chemotherapy is a common phenomenon, resulting in rapid disease progression and treatment failure in up to 90% of metastatic breast cancer patients. Metastatic breast cancer is one of the leading causes of cancer mortality, accounting for more than 400,000 deaths annually worldwide. Prescient is focused on advancing clinical development of novel oncology candidates that may provide improved options over existing therapies in this area of high unmet medical need."

"The reactivation of the IND for PTX-100 is an important development for Prescient and opens the way to commence additional clinical trials at some of the world's leading cancer centers. Prescient's lead drug candidate PTX-200 has already commenced Phase Ib/II trials with a breast cancer trial underway at Albert Einstein University in New York and an ovarian cancer trial underway at the Moffitt Cancer Center in Florida. Very few ASX companies have two open INDs with the FDA that cover two novel approaches to treating cancer."

PTX-100 is a potent and selective inhibitor of an important cancer growth enzyme called geranylgeranyltransferase-1 (GGT-1), part of the well validated Ras signaling pathway known to contribute to many forms of cancer. In preclinical studies, PTX-100 has been shown to synergize with standard chemotherapeutic regimes, making them more effective. Furthermore, in a first-in-human single-agent, dose ranging clinical study, PTX-100 was shown to be well tolerated in patients with refractory solid tumors. In the study carried out at University of Pennsylvania and Indiana University, four of 13 evaluable patients experienced stabilization of their disease, in spite of the fact that their cancers were late stage and resistant to prior treatments of chemotherapy.

The proposed PTX-100 study is on track to commence early 2016. This will be conducted as a Phase Ib open label dose escalation safety study to select an optimal dose and treatment regimen of PTX-100 in combination with docetaxel. It is expected that follow on studies will be conducted in order to precisely target and determine the cancers, combinations of drugs, and patients that will most clearly benefit from this drug.

About Prescient Therapeutics

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

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 leukaemia. This highly promising compound is now the focus of two current clinical trials. The first is a Phase 1b/2 study examining PTX-200 in breast cancer patients at the prestigious Montefiore Cancer Center in New York. A Phase 1b/2 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 Florida's Lee Moffitt Cancer Center. These trials are funded by grants from the U.S. Department of Defense and U.S. National Cancer Institute. In addition, Prescient is planning a Phase 1b/2 trial evaluating PTX-200 as a new therapy for acute myeloid leukemia in 2015.

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 (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. Prescient expects to commence Phase 1b/2 clinical trials in breast cancer and multiple myeloma in 2015. At the same time, Prescient plans to develop its novel p27 cancer biomarker as a companion diagnostic that will potentially identify those patients that are most likely to respond to PTX-100 therapy.

Prescient has licensed access to its Co-X-Gene™ platform technology to French biotechnology company Transgene for use in two immunotherapeutic products.

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