ASX Release

PTX-100 to Re-enter Trials in Hematology Niche

- RhoA-mutant lymphomas identified as a potentially transformative indication for PTX-100
- PTX-100 appears to be world's most clinically advanced RhoA inhibitor in oncology; giving it a unique positioning in this area of high unmet need
- New patent application for PTX-100 in RhoA mutant cancers
- Parallel work program of pre-clinical studies whilst preparing for clinical trial

Melbourne, Australia (3 October 2017): Clinical-stage oncology company Prescient Therapeutics Ltd (ASX: PTX; Prescient) is pleased to announce that it plans to re-enter the clinic with its small molecule geranylgeranyl transferase inhibitor (GGTI), known as PTX-100, in rare lymphomas - a group of related cancers that affect the lymphatic system, which forms part of the immune system. PTX-100 may have a particular advantage in treating lymphomas driven by a mutation of the molecular switch RhoA.

PTX-100 disrupts an important cancer signaling pathway, known as the Ras pathway. Ras mutations are observed in one-third of all cancers, and successfully addressing this aberrant pathway represents a large unmet need in many cancers. However, the development of drugs that target Ras directly has proven difficult[1]. By contrast, PTX-100 works downstream of Ras by preventing activation of downstream molecular "switches" Rho, Ral and Rac. These switches are involved in cell growth and survival.

Recent research has discovered that mutated RhoA (which is inactivated by PTX-100) is implicated in several types of lymphomas including:

- Angioimmunoblastic T-cell lymphoma (AITL);
- Peripheral T-cell lymphoma not other specified (PTCL-NOS);
- Adult T-cell leukemia/lymphoma (ATL);
- Burkitt lymphoma; and
- Diffuse large B-cell lymphoma (DLBCL).

In addition, RhoA mutations are in 25% of diffuse-type gastric cancer.[2]

Prescient has now filed a new patent application for PTX-100 in RhoA mutant cancers.

[1] Gysin S, et al. *Genes & Cancer 2011;* 2: 359–372

[2] Kataoka, K and Ogawa, S; *Experimental Hematology* 2016; 44:1123–1129;
Cortes, JR, et al; *Blood* 2016; 128:608;
Palomero, T, et al; *Blood* 2016; 122:846.

Many of these diseases have poor prognoses and are under-served by current treatments, thus representing a very attractive development path through to commercialization for PTX-100 in this niche.

As a case in point, AITL is a rare, aggressive (fast-growing) T-cell lymphoma. It accounts for between 1-2% of non-Hodgkin lymphomas[3], equating to about 1,000 new cases in the US per year. About 70% of AITL patients have RhoA mutations[4].

The prognosis of AITL patients is poor, with a median survival of 1-3 years[5]. There are no proven first line therapies for AITL. Recommended first-line therapy for treatment of AITL is either a clinical trial with experimental therapies or a multi-agent chemotherapy regimen. Effects are short term and associated with early relapse[6]. Patients may be treated with steroids to relieve symptoms, but this does not address the disease.[7]

Rare diseases can transform smaller companies where a drug with a novel approach finds an areas of unmet need. In certain circumstances they require smaller trials with shorter timeframes, meaning that smaller companies can potentially carry the program for longer, rather than licensing earlier than desired. Consistent with this strategy, the US Food and Drug Administration recently granted Orphan Drug Designation to PTX-200 in acute myeloid leukemic (AML).

Prescient is undertaking a parallel work program of pre-clinical studies whilst it undertakes the preparation required to commence a clinical trial. The Company looks forward to sharing updates on both these fronts.

PTX-100 has previously completed a Phase 1 clinical trial as a monotherapy in refractory, advanced solid tumors, (mostly gastrointestinal tumors) at Indiana and Penn Universities in 13 patients demonstrating safety, with 4 patients showing durable stable disease.

PTX's CEO and Managing Director, Steven Yatomi-Clarke said "PTX-100 has potential utility in a wide variety of cancers. The management team and Board undertook a strategic review of different development options for PTX-100 to determine the best next step for its development from scientific, clinical, regulatory and commercial perspectives.

We concluded that hematological diseases with mutated Ras and RhoA represent tremendous opportunities for Prescient. In particular, rare diseases like AITL have the

[3] "A clinical evaluation of the International Lymphoma Study Group classification of non-Hodgkin's lymphoma. The Non-Hodgkin's Lymphoma Classification Project". *Blood*. 89 (11): 3909–18. June 1997

[4] Kataoka, K and Ogawa, S; *Experimental Hematology* 2016; 44:1123–1129;

[5] Mosalpuria, K; *et al*; *Seminars in Hematology,* Jan 2014; 51 (1); 52-58
LaCasce, AS; *Blood*; 2014; 123: 1293-1296

[6] Mosalpuria, K; *et al*; *Seminars in Hematology,* Jan 2014; 51 (1); 52-58

[7] www.lymphoma.org

potential for expedited development and regulatory pathways, which can be a significant advantage for companies with access to this development route.

Our research has found that there are very few RhoA inhibitors in development, almost all of which are pre-clinical or earlier in their development[8]. PTX-100 seems to be the most clinically advanced drug in the world in this area and gives Prescient a significant head start and unique position in RhoA mutant lymphomas. We have also sought to protect this with a new patent application.

We look forward to laying down the groundwork necessary for commencing new patient studies in this area. We are tremendously excited about this program - it is potentially transformative for Prescient."

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About Prescient Therapeutics Limited (Prescient)

Prescient 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.

Prescient'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.

Prescient 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, currently on clinical hold. 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, also currently under clinical hold.

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 and will be the focus of studies in rare hematological malignancies.

[8] GlobalData 2017

Further enquiries:

Steven Yatomi-Clarke
CEO & Managing Director
Prescient Therapeutics Limited
+61 417 601 440

Kyahn Williamson
WE Buchan
kwilliamson@buchanwe.com.au
+61 9866 4722

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