PTX-200 AML Trial Progresses to Higher Dose

MELBOURNE Australia, 23 April 2021: Prescient Therapeutics Limited (ASX: PTX) ("Prescient"), a clinical stage oncology company developing personalised medicine approaches to cancer, today announced that its Phase 1b clinical study of PTX-200 and cytarabine in patients with acute myeloid leukemia (AML) successfully completed the second cohort at 35 mg/m^2 PTX-200 under the modified study protocol, with no dose limiting toxicities observed. As planned, the study has now progressed to the next dose level of 45 mg/m^2 PTX-200. Approximately 158,000 patients globally suffer from AML[1], a cancer of the bone marrow that prevents formation of normal blood cells. AML progresses quickly and has poor survival rates. After initial chemotherapy, most patients relapse, leading to an ongoing unmet medical need.

Three patients were treated at 35 mg/m^2 PTX-200 with no dose limiting toxicities reported. No additional clinical responses were seen in this cohort. Under the revised study protocol PTX-200 is administered on day 1 and cytarabine administered by continuous infusion on days 3-7 (of a 21-day cycle). As previously reported, the three patients have achieved complete responses in the study so far.

Following review of the safety data from this cohort with the study investigators, Prescient has opened the next cohort for enrolment at 45 mg/m^2 PTX-200.

Prescient's Chief Medical Officer, Dr Terrence Chew said, "AML remains a very difficult disease to treat, especially in the relapsed and refractory setting, with patients often too sick to endure vigorous treatment. It is therefore pleasing to see the completion of this cohort without dose limiting toxicities, suggesting that AML patients are able to better tolerate the combination of PTX-200 and cytarabine under the modified protocol. This has allowed us to explore this higher dose of 45 mg/m^2 of PTX-200, which we hope will build upon the encouraging responses previously observed in this study."

The AML study is led by world-renowned leukemia expert Professor Jeffrey Lancet at the H. Lee Moffitt Cancer Center in Florida. Associate Professor Tara Lin at the University of Kansas Medical Center is also participating in the study.

– Ends –

[1] Research and Markets, 2020

About Prescient Therapeutics Limited (Prescient)

Prescient Therapeutics is a clinical stage oncology company developing personalised medicine approaches to cancer, including targeted and cellular therapies.

Cell Therapies

OmniCAR: is a universal immune receptor platform enabling controllable T-cell activity and multi-antigen targeting with a single cell product. OmniCAR's modular CAR system decouples antigen recognition from the T-cell signalling domain. It is the first universal immune receptor allowing post-translational covalent loading of binders to T-cells. OmniCAR is based on technology licensed from Penn; the SpyTag/SpyCatcher binding system licensed from Oxford University; and other assets.

The targeting ligand can be administered separately to CAR-T cells, creating on-demand T-cell activity post infusion and enables the CAR-T to be directed to an array of different tumour antigens.

OmniCAR provides a method for single-vector, single cell product targeting of multiple antigens simultaneous or sequentially, whilst allowing continual re-arming to generate, regulate and diversify a sustained T-cell response over time.

Prescient is developing OmniCAR programs for next-generation CAR-T therapies for Acute Myeloid Leukemia (AML); Her2+ solid tumours, including breast, ovarian and gastric cancers; and glioblastoma multiforme (GBM).

Cell Therapy Enhancements: Prescient has several other initiatives underway to develop new cell therapy approaches.

Targeted Therapies

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 is believed to be the only RhoA inhibitor in the world in clinical development. PTX-100 is currently in a PK/PD basket study of hematological and solid malignancies, focusing on cancers with Ras and RhoA mutations. In a previous Phase 1 trial in advanced solid tumours, PTX-100 was well tolerated and achieved stable disease.

PTX-200 is a novel PH domain inhibitor that inhibits an important tumour 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 has previously generated encouraging Phase 2a data in HER2-negative breast cancer and Phase 1b in recurrent or persistent platinum resistant ovarian cancer, with a Phase 1b/2 trial currently underway in relapsed and refractory AML.

Find out more at ptxtherapeutics.com, or connect with us via Twitter @PTX_AUS and LinkedIn.

The Board of Prescient Therapeutics Limited has approved the release of this announcement.

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Supplemental COVID-19 Risk Factors

Please see our website : Supplemental COVID-19 Risk Factors