

# Prescient Signs Manufacturing Agreement for Next Generation CAR-T Therapy OmniCAR Ahead of Clinical Trials

**MELBOURNE Australia, 16 August 2022** – Prescient Therapeutics (ASX: PTX), a clinical stage oncology company developing personalised cancer therapies, has entered a manufacturing services agreement with specialist cell therapy manufacturer, Q-Gen Cell Therapeutics (Q-Gen), to produce its OmniCAR cell lines for upcoming clinical trials, with initial work now commenced.

As Prescient advances the development of its next-generation OmniCAR programs for acute myeloid leukemia (AML); Her2 positive solid cancers and glioblastoma multiforme, the encouraging progress of the OmniCAR AML program makes it likely be the first OmniCAR program to enter clinical studies.

Manufacturing will take place at Q-Gen's dedicated Brisbane facility, which produces autologous and allogeneic cell therapies for local and international pharmaceutical companies and academic research groups. Q-Gen is the cell therapy manufacturing arm of the QIMR Berghofer Medical Research Institute and is one of Australia's leading producers of cell-based medicines. Prescient has commenced the technology transfer process for OmniCAR-T cell manufacturing.

CAR-T therapies involve isolating T cells from a cancer patient and inserting new genetic material into them so that they express a new chimeric antigen receptor capable of recognising cancer cells, before being re-infused into the patient. By contrast, OmniCAR T cells will express a universal immune receptor (SpyCatcher), which can bind with any separate SpyTagged targeting ligand. Thus, OmniCAR cells can potentially address any cancer by incorporating binders to any cancer antigen. This modularity also enables other important and novel characteristics to overcome limitations faced by conventional CAR-T therapies, including post-infusion control of T cell activity and antigen re-direction.

This agreement with Q-Gen covers production and delivery of autologous OmniCAR-T cells for clinical trials. Material conditions of the contract include transduction of T cells with SpyCatcher lentivirus; arming of OmniCAR T cells with SpyTagged binders; and associated quality measures. This agreement will also incorporate CellPryme-M into the manufacturing process of OmniCAR T cells. The agreement lasts up to 5 years, with provision for earlier cessation or extension as per typical commercial terms.

**Q-Gen's General Manager, Andrew Masel**, commented "We are excited to be working with Prescient Therapeutics on what we see as a unique cell therapy platform. The team at Q-Gen is looking forward to working closely with Prescient to produce the product for clinical trials here at the QIMR Berghofer Medical Research Institute."



Prescient's CEO and Managing Director Steven Yatomi-Clarke said, "Prescient is working steadily towards our first in human studies of OmniCAR, which will be an important milestone for the Company. This important agreement secures Prescient's crucial supply of OmniCAR cells for our clinical trials and ensures we are producing the best possible cell therapy products for doctors and patients living with hard-to-treat cancers."

In January Prescient received accreditation by the Office of the Gene Regulator enabling the company to conduct clinical trials in Australia involving gene-edited cells such as OmniCAR.

- Ends -

## Join an investor briefing

Join Managing Director and CEO Steven Yatomi-Clarke for an investor briefing on Tuesday 23<sup>rd</sup> August at 12pm (AEST). Register for the session here.

## **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).

**CellPryme-M:** Prescient's novel, ready-for-the-clinic, CellPryme-M technology enhances adoptive cell therapy performance by shifting T and NK cells towards a central memory phenotype, improving persistence, and increasing the ability to find and penetrate tumours. CellPryme-M is a 24-hour, non-disruptive process during cell manufacturing. Cell therapies that could benefit from additional productivity in manufacturing or increased potency and durability in-vivo, would be good candidates for CellPryme-M.

## **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 GGT-1 inhibitor in the world in clinical development. PTX-100 demonstrated safety and early clinical activity in a previous Phase 1 study and recent PK/PD basket study of hematological and solid malignancies. PTX-100 is now in a Phase 1b expansion cohort study in T cell lymphomas, where it has shown encouraging efficacy signals and safety.

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, PTX-200 has a novel mechanism of action that specifically inhibits Akt without non-specific kinase inhibition effects. This highly promising compound is currently in a Phase 1b/2 trial in relapsed and refractory AML, where it has resulted in 4 complete remissions so far. PTX-200 previously generated encouraging Phase 2a data in HER2-negative breast cancer and Phase 1b in recurrent or persistent platinum resistant ovarian cancer.

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

Find out more at www.ptxtherapeutics.com or connect with us via Twitter @PTX\_AUS and LinkedIn.

Steven Yatomi-Clarke
CEO & Managing Director
Prescient Therapeutics
steven@ptxtherapeutics.com

Investor enquiries:
Sophie Bradley – Reach Markets
+61 450 423 331
ir@reachmarkets.com.au

Media enquiries:
Andrew Geddes – CityPR
+61 2 9267 4511
ageddes@citypublicrelations.com.au

#### **Disclaimer and Safe Harbor Statement**

Certain statements made in this document are forward-looking statements within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These forward-looking statements are not historical facts but rather are based on the current expectations of Prescient Therapeutics Limited ("Prescient" or the "Company"), their estimates, assumptions, and projections about the industry in which Prescient operates. Material referred to in this document that use the words 'estimate', 'project', 'intend', 'expect', 'plan', 'believe', 'guidance', and similar expressions are intended to identify forward-looking statements and should be considered an at-risk statement. These forward-looking statements are not a guarantee of future performance and involve known and unknown risks and uncertainties, some of which are beyond the control of Prescient or which are difficult to predict, which could cause the actual results, performance, or achievements of Prescient to be materially different from those which may be expressed or implied by these statements. These statements are based on our management's current expectations and are subject to a number of uncertainties and risks that could change the results described in the forward-looking statements. Risks and uncertainties include, but are not limited to, general industry conditions and competition, general economic factors, global pandemics and related disruptions, the impact of pharmaceutical industry development and health care legislation in the United States and internationally, and challenges inherent in new product development. In particular, there are substantial risks in drug development including risks that studies fail to achieve an acceptable level of safety and/or efficacy. Investors should be aware that there are no assurances that results will not differ from those projected and Prescient cautions shareholders and prospective shareholders not to place undue reliance on these forward-looking statements, which reflect the view of Prescient only as of the date of this announcement. Prescient is not under a duty to update any forwardlooking statement as a result of new information, future events or otherwise, except as required by law or by any appropriate regulatory authority.

Certain statements contained in this document, including, without limitation, statements containing the words "believes," "plans," "expects," "anticipates," and words of similar import, constitute "forward-looking statements." Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results, performance or achievements of Prescient to be materially different



from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among others, the following: the risk that our clinical trials will be delayed and not completed on a timely basis; the risk that the results from the clinical trials are not as favourable as we anticipate; the risk that our clinical trials will be more costly than anticipated; and the risk that applicable regulatory authorities may ask for additional data, information or studies to be completed or provided prior to their approval of our products. Given these uncertainties, undue reliance should not be placed on such forward-looking statements. The Company disclaims any obligation to update any such factors or to publicly announce the results of any revisions to any of the forward-looking statements contained herein to reflect future events or developments except as required by law.

This document may not contain all the details and information necessary for you to make a decision or evaluation. Neither this document nor any of its contents may be used for any other purpose without the prior written consent of the Company.

## **Supplemental COVID-19 Risk Factors**

Please see our website: Supplemental COVID-19 Risk Factors