



ASX ANNOUNCEMENT

7 MARCH 2022

Final Results from the Phase 1 Trial of CORE NK Platform in Blood Cancers and Solid Tumors

- Durable Complete Response (CR) achieved with 15+ month ongoing response in one patient with high risk MDS (Myelodysplastic Syndrome)
- 100% Disease Control Rate (DCR) achieved in blood cancer patients (n=3) at day 28
 - 100+ day durability in 2 out of 3 patients
- CORE NK cell platform demonstrates safety, substantial efficacy and robust expansion and persistence of universal donor NK cells
- Positive safety profile established with no Graft versus Host Disease (GvHD), Cytokine Release Syndrome (CRS) or Dose Limiting Toxicities (DLT's)
- Universal donor NK cells were derived from a novel feeder cell line and found to persist in patients for at least 4 weeks without exogenous cytokine support
- Chimeric is advancing development of its CORE NK Platform as a combination therapy in blood cancers and as chimeric antigen receptor (CAR) NK therapies in solid tumors
- Webinar to be held at 11am AEDT today. [Click here to register.](#)

Chimeric Therapeutics (ASX:CHM, "Chimeric"), a clinical-stage cell therapy company and an Australian leader in cell therapy, is pleased to announce the results of the phase 1 clinical trial of its CORE NK platform, a **Clinically validated, Off the shelf, Robust, Enhanced Natural Killer** cell platform completed at Case Comprehensive Cancer Center.

Over the course of the phase 1 clinical trial 9 heavily pretreated patients with blood cancers (n=3) and solid tumors (n=6) were administered two infusions (day 0 and day 14) at one of three different CORE NK dose levels, 10×10^6 (n=3), 25×10^6 (n=3) and 50×10^6 (n=3).

The results saw all three of the patients with blood cancers that were treated achieve a best response of stable disease at day 28. 1 of the 3 patients deepened their response to achieve a Complete Response (CR) by the 100-day assessment. This patient received an allogeneic transplant as a consolidation therapy and more than 15 months later remains in remission. Of the other two patients who achieved stable disease at day 28, one had progressed by day 100 while the other maintained their disease stability.

Of the 6 patients with solid tumors (Colorectal cancer and Colon cancer) treated with Chimeric's CORE NK, a 33% Disease Control Rate (DCR) was demonstrated with 2 of the 6 patients achieving a best response of stable disease by day 28. 1 of the 2 patients who had achieved stable disease at day 28 maintained their disease stability at day 100.



All patients tolerated CORE NK well, with no dose limiting toxicities, no cytokine release syndrome, and no graft versus host disease. All observed events were expected events attributable to the lymphocyte-depleting chemotherapy regimen.

The CORE NK cells are ex vivo expanded “universal donor” NK cells that utilize a novel feeder cell line (NKF) generated through the expression of membrane-bound interleukin 21 (mbIL-21) on the acute myeloid leukemia cell line, OCI-AML3. The CORE NK cell products generated using this novel feeder cell platform exhibited in vivo persistence for 4 weeks promoted by preparative lymphodepletion alone in the phase 1 clinical trial.

Chimeric is now advancing the development of its CORE NK platform with plans to increase the administered NK cell doses, provide optimized exogenous cytokine support or other complementary agents and promote tumor bed infiltration in solid tumors through the development of CAR NK therapies.

“We are incredibly excited to share these data as we believe that it demonstrates the transformational potential for our CORE NK platform,” said Jennifer Chow, Chimeric Therapeutics Chief Executive Officer.

“By establishing safety without GvHD, substantial efficacy with a highly durable CR, robust ex vivo expansion and promising persistence of cells without exogenous cytokine support we now have a strong foundation upon which to amplify our therapeutic efficacy. We look forward to rapidly advancing the multiple development paths planned for CORE NK in both blood cancers and solid tumors.”

“The data from our Phase 1 study are extremely encouraging, demonstrating an optimal safety profile and strong early signs of clinical benefit for patients. I look forward to collaborating with Chimeric to continue advancing this program for blood cancers and to further optimize the platform for solid tumors through the incorporation of specific CARs and other enhancements,” said inventor and study investigator David Wald, M.D., Ph.D., Associate Professor of Pathology Case Western Reserve University School of Medicine and Member, Immune Oncology Program, Case Comprehensive Cancer Center, Associate Director for Basic Research, University Hospitals, Wesley Center for Immunotherapy.

Authorised on behalf of the Chimeric Therapeutics board of directors by Chairman Paul Hopper.

CORE NK (CHM 0201) Platform Trial Background

The Phase 1 trial with the CORE NK platform (also known as CHM 0201) was an open label, single center clinical trial designed primarily to establish that escalating doses of off-the-shelf CORE NK cell products generated from third-party adult donors can be infused without inducing GvHD or other significant toxicities.



The trial studied patients with blood cancers and solid tumors across 3 dose levels of CORE NK cells (10×10^6 , 25×10^6 and 50×10^6). Patients received a 6-day lymphodepletion with Fludarabine and Cyclophosphamide prior to infusion with CORE NK cells on Day 0 and Day 14. Response was assessed at day 28 and day 100.

In November 2021, Chimeric secured the exclusive option to license the NKF technology invented by Dr. Wald from Case Western Reserve University.

Results of the phase 1 clinical trial, completed in mid-2021 at the Case Comprehensive Cancer Centre, have been accepted and published online in pre-proof format in the journal Transplantation and Cellular Therapy (Otegbeye et al. *A Phase I study to determine maximum tolerated dose of ex vivo expanded natural killer cells derived from unrelated, HLA-disparate adult donors*. Transplantation and Cellular Therapy, 2022, ISSN 2666-6367, <https://doi.org/10.1016/j.jtct.2022.02.008>).

Additional ASX related disclosure:

The primary objective of the trial was safety – “to demonstrate that escalating doses of off-the-shelf NK cell products generated on the NKF expansion platform from third-party adult donors can be infused without inducing GvHD or other significant toxicities”.

“The secondary goals of the study were to examine if the proposed lymphocyte depleting preparative regimen would prevent immediate rejection of the HLA-mismatched NK cell product thereby allowing for demonstrable anti-tumor effect”.

This above release and associated slide presentation note the persistence of the cells and the efficacy results.

For the size and nature of this phase 1A dose escalation trial there is no comparator so there would be no p value.

INVESTOR WEBINAR

Chimeric Therapeutics CEO and Managing Director Jennifer Chow will hold an investor webinar today, Monday 7 March 2022, at 11am AEDT to elaborate on this announcement and take questions.

Click the link below to register:

https://us02web.zoom.us/webinar/register/WN_h7PoDzBsQiaENKkm1rb0mQ

After registering, you will receive a confirmation email about how to join the webinar. A recording of the webinar will be available at the same link shortly after the conclusion of the session.



ABOUT CHIMERIC THERAPEUTICS

Chimeric Therapeutics, a clinical stage cell therapy company and an Australian leader in cell therapy, is focused on bringing the promise of cell therapy to life for more patients with cancer. We believe that cellular therapies have the promise to cure cancer not just delay disease progression.

To bring that promise to life for more patients, Chimeric's world class team of cell therapy pioneers and experts is focused on the discovery, development, and commercialization of the most innovative and promising cell therapies.

CHM 1101 (CLTX CAR T) is a novel and promising CAR T therapy developed by scientists at the City of Hope Medical Centre in California for the treatment of patients with solid tumours. CHM 1101 is currently being studied in a phase 1 clinical trial in recurrent/ progressive glioblastoma. A 2nd CLTX CAR T phase 1 clinical trial is planned to begin in 2022 in additional solid tumours.

CHM 2101 (CDH17 CAR T) is a novel, 3rd generation CDH17 CAR T invented at the University of Pennsylvania. CHM 2101 (CDH17 CAR T) is currently in preclinical development with a planned phase 1 clinical trial in 2022 in Neuroendocrine Tumours, Colorectal, Pancreatic and Gastric Cancer.

Recently Chimeric announced the addition of the CORE-NK platform, a clinically validated, off the shelf natural killer (NK) cell therapy platform to their portfolio (CHM 0201). From the CORE-NK platform, Chimeric will initiate development of four new next generation NK and CAR NK assets with plans for phase 1 clinical trials to begin in 2023 in solid tumours and blood cancers.

Chimeric Therapeutics continues to be actively engaged in further developing its oncology pipeline with new and novel cell therapy assets that will bring the promise of cell therapy to life for more patients with cancer.

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