

PHASE 1B CHM CORE-NK TRIAL ADVANCES TO INITIATE TREATMENT OF NEWLY DIAGNOSED AML PATIENTS

- Dose escalation has been completed successfully with 6 relapsed or refractory Acute Myeloid Leukemia (AML) patients completing treatment with no dose-limiting toxicities or unexpected safety findings
- Dose expansion is open to enrol up to 20 study subjects with newly diagnosed AML who are not eligible for chemotherapy or allogeneic stem cell transplant
- This trial combines standard of care AML treatment with CHM's CORE-NK to test a novel and potentially transformative new paradigm for AML patients

Melbourne, Australia, 16 December 2024: Chimeric Therapeutics (ASX:CHM, "Chimeric" or the "Company"), an Australian leader in cell therapy, is pleased to announce the ADVENT-AML Phase 1B clinical trial has advanced to initiate enrolment of newly diagnosed older or unfit AML patients.

ADVENT-AML is the first clinical trial to evaluate the synergy of CORE-NK in combination with the current standard of care for AML patients. The Phase 1B ADVENT-AML clinical trial has completed enrolment of relapsed/refractory AML subjects in the dose finding portion of the trial. In the next phase of the trial, newly diagnosed AML subjects who are elderly or otherwise unsuitable for transplantation and have not been previously treated for AML, will be eligible for enrolment.

The ADVENT-AML (NCT05834244) Phase 1B clinical trial is an investigator-initiated study currently open to enrolment at The University of Texas MD Anderson Cancer Center under Principal Investigator Abhishek Maiti MD, Assistant Professor in the Department of Leukemia. The study is evaluating the synergy of NK cell therapy in combination with the current standard of care, Azacitidine and Venetoclax. Since the combination has demonstrated safety in subjects with relapsed or refractory disease, the study is now open to enrol up to 20 subjects with newly diagnosed AML who are not eligible for intensive chemotherapy or allogeneic stem cell transplant.

The CORE-NK cells used in the ADVENT-AML clinical trial were manufactured and cryopreserved for "off-the-shelf" accessibility at the Cellular Therapy Integrated Services Laboratory at Case Western Reserve University where the CHM 0201 cells were developed.

"We are proud to open this phase of the study, where CHM CORE-NKs will be incorporated into standard therapy for newly diagnosed AML patients," said Dr Rebecca McQualter, CEO of Chimeric Therapeutics.



“This novel combination has the potential to transform first line AML therapy and improve outcomes for cancer patients as this is the first time cell therapy has been evaluated in a first line setting in AML.”

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.

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

Chimeric currently has a diversified portfolio that includes first in class autologous CAR T cell therapies and best in class allogeneic NK cell therapies. Chimeric assets are being developed across multiple different disease areas in oncology with 4 clinical stage programs.

CHM CDH17 is a first-in-class, 3rd generation CDH17 CAR T invented at the world-renowned cell therapy centre, the University of Pennsylvania (Penn) in the laboratory of Dr. Xianxin Hua, professor in the Department of Cancer Biology in the Abramson Family Cancer Research Institute at Penn. Preclinical evidence for CDH17 CAR T was published by Dr. Hua and his colleagues in March 2022 in Nature Cancer demonstrating complete eradication of tumours in 7 types of cancer in mice. CHM CDH17 is currently being studied in a phase 1/2 clinical trial in gastrointestinal and neuroendocrine tumours that was initiated in 2024.

CHM CLTX is a novel and promising CAR T therapy developed for the treatment of patients with solid tumours. CLTX CAR T is currently being studied in a phase 1B clinical trial in recurrent / progressive glioblastoma. Positive preliminary data from the investigator-initiated phase 1A trial in glioblastoma was announced in October 2023.

CHM CORE-NK is a potentially best-in-class, clinically validated NK cell platform. Data from the complete phase 1A clinical trial was published in March 2022, demonstrating safety and efficacy in blood cancers and solid tumours. Based on the promising activity signal demonstrated in that trial, two additional Phase 1B clinical trials investigating CORE-NK in combination regimens have been initiated. From the CORE-NK platform, Chimeric has initiated development of new next generation NK and CAR NK assets.

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

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