



ASX ANNOUNCEMENT

8 DECEMBER 2025

CHM CDH17 granted FDA Orphan Drug Designation for Gastric Cancer

- Phase 1/2 trial of CHM CDH17 is ongoing with 9 patients treated, 10 patients enrolled

Sydney, Australia, 8 December 2025: Chimeric Therapeutics (ASX:CHM, “Chimeric” or the “Company”), an Australian leader in cell therapy, is pleased to announce it has been granted Orphan Drug Designation from the US Food and Drug Administration (FDA) for CHM CDH17 in the treatment of Gastric Cancer.

Orphan Drug Designation qualifies CHM CDH17 for incentives including tax credits for qualified clinical trials, exemption from user fees and a potential seven years of market exclusivity after approval¹.

“This is a great step forward in the development of CHM CDH17 to serve patients with gastric cancer, where there is a significant unmet need.” said Dr Rebecca McQualter, CEO of Chimeric Therapeutics.

The Phase 1/2 trial (NCT06055439) of CHM CDH17 is a two-stage study designed to determine a recommended Phase 2 dose and evaluate its safety and objective response rate in patients with advanced colorectal cancer, gastric cancer, and gastrointestinal NETs. CHM CDH17 is a 3rd generation, novel CAR-T cell therapy that targets CDH17, a cancer biomarker associated with poor prognosis and metastases in the most common gastrointestinal tumours. The Phase 1 portion of this study is expected to enrol up to 15 patients and lead to dose selection and expansion with indication-specific Phase 2 cohorts.

¹ <https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products#:~:text=The%20FDA%20has%20authority%20to,Exemption%20from%20user%20fees>

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 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.

CHM CLTX is a novel and promising CAR T therapy developed for the treatment of patients with solid tumours. CLTX CAR T is 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.

Authorised on behalf of the Chimeric Therapeutics Board of Directors.

Contact

Investors

Dr Rebecca McQualter
Chief Executive Officer
Chimeric Therapeutics
E: investors@chimerictherapeutics.com
W: www.chimerictherapeutics.com

Media

Matthew Wright
NWR Communications
T: +61 451 896 420
E: matt@nwrcommunications.com.au