

## CHM CDH17 RECEIVES FDA FAST TRACK

- **CHM CDH17 granted Fast Track for gastroenteropancreatic neuroendocrine tumours (GEP-NETs)**
- **Creating a faster development pathway with increased US FDA interaction**
- **5 patients treated & 7 successful manufacturing runs completed**

Melbourne, Australia, 4 June 2025: Chimeric Therapeutics (ASX:CHM, “Chimeric” or the “Company”), is pleased to announce that the US Food and Drug Administration (FDA) has granted CHM CDH17 Fast Track Designation.

CHM CDH17 was granted Fast Track Designation based on the FDA’s assessment of CHM-CDH17’s potential to improve outcomes for patients with gastroenteropancreatic neuroendocrine tumours (GEP-NETs) who have progressed beyond at least one prior line of therapy in the advanced or metastatic setting.

Fast Track Designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. This designation by the US FDA is intended to get important new drugs to patients earlier. With this designation, Chimeric will benefit from more frequent meetings with the FDA to discuss the drug’s development plan, more frequent written communication from the FDA and potential eligibility for Accelerated Approval, Priority Review and Rolling BLA Review.

“We are thrilled to announce that the US FDA has granted this designation and acknowledged the important unmet need that CHM CDH17 may serve for patients with GEP-NETs,” said Jason B Litten MD, Chief Medical Officer at Chimeric.

Elyse Gellerman, MHS, Chief Executive Officer of the Neuroendocrine Tumor Research Foundation (NETRF) said, “It is really gratifying to see scientific research that NETRF has supported at The University of Pennsylvania since 2014 is now in the clinic and is being recognised for its potential to be an effective treatment for neuroendocrine tumour patients.”

The ongoing Phase 1/2 trial (NCT06055439) is a two-stage study designed to determine a recommended Phase 2 dose of CHM CDH17 and evaluate its safety and objective response rate in patients with advanced colorectal cancer, gastric cancer, and intestinal neuroendocrine tumours (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.

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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.

“We are gaining significant momentum on CHM CDH17 and look forward to our interactions with the FDA to get our advanced therapy to patients in need”, said Dr Rebecca McQualter CEO of Chimeric.

### **ABOUT CHIMERIC THERAPEUTICS**

Chimeric Therapeutics, a clinical stage cell therapy company 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 at 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 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 Executive Chairman Paul Hopper.*

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