



ASX ANNOUNCEMENT

31 OCTOBER 2023

## **CHIMERIC THERAPEUTICS ANNOUNCES FDA CLEARANCE OF IND APPLICATION FOR CHM 2101, A NOVEL CDH17 CAR T CELL THERAPY FOR ADVANCED GASTROINTESTINAL CANCERS**

- FDA IND Clearance for CHM 2101, a novel 3<sup>rd</sup> generation CDH17 CAR T cell therapy
- Anticipated to be the first CDH17 CAR T cell therapy to enter the clinic
- Phase 1A clinical trial to initiate patient enrolment in 2024
- Phase 1A clinical trial will enroll patients with advanced Colorectal Cancer, Gastric Cancer and Neuroendocrine Tumours

**Sydney, Australia, 31 October 2023:** Chimeric Therapeutics (ASX:CHM, “Chimeric” or the “Company”), an Australian leader in cell therapy, announced today that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application of CHM 2101, Chimeric’s first in class CDH17 CAR T cell therapy for gastrointestinal cancers.

The company plans to investigate CHM 2101 in a multi center, open label Phase 1A/B clinical trial for patients with advanced Colorectal Cancer, Gastric Cancer and Neuroendocrine Tumours.

CHM 2101 is a 3<sup>rd</sup> generation, novel CDH17 CAR T cell therapy that targets CDH17, a cancer target associated with poor prognosis and metastasis in the most common gastrointestinal tumors including Colorectal Cancer, Gastric Cancer and Neuroendocrine Tumours.

The clinical program for CHM 2101 builds upon the preclinical studies published in the preeminent scientific journal, Nature Cancer in March 2022 by leading immunotherapy scientist Xianxin Hua, MD, PhD, and his team at the Abramson Family Cancer Research Institute at the University of Pennsylvania. These experiments demonstrated that CHM 2101 was able to eradicate established tumours in seven cancer models with no toxicity to normal tissues.

“It is exciting to see the advancement from discovery of the CDH17 target and CAR T therapy in preclinical studies to the initiation of clinical trials in patients with GI-cancers and neuroendocrine tumors,” said Xianxin Hua, MD, PhD, Professor of Cancer Biology in Penn’s Perelman School of Medicine, an investigator at the Abramson Family Cancer Research Institute and a Harrington Scholar Innovator. “This is a critical step forward in developing an entirely new CAR T therapy for GI-cancers and neuroendocrine tumors, providing new hopes for the cancer patients who are refractory to the existing therapies.”



With the FDA IND clearance Chimeric will now begin the initiation of a phase 1 /2 multi-site clinical trial in patients with advanced Colorectal Cancer, Gastric Cancer and Neuroendocrine Tumours. The study is planned to begin patient enrollment in 2024. (ClinicalTrials.gov ID: NCT06055439)

“I am really excited about the planned Phase 1 clinical trial of CHM 2101 and the opportunity to bring a potentially transformative new investigational agent to cancer patients who need them most,” said Michael R. Bishop, MD, Professor of Medicine and Director, The David and Etta Jonas Center for Cellular Therapy, University of Chicago.

## **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.

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 3 current clinical programs and plans to open additional clinical programs in 2023.

CHM 1101 (CLTX CAR T) is a novel and promising CAR T therapy developed for the treatment of patients with solid tumours. CHM 1101 is currently being studied in a phase 1B clinical trial in recurrent / progressive glioblastoma. Initial positive data from the investigator-initiated phase 1A trial has been presented on patients treated in the first two dose levels of the trial.

CHM 2101 (CDH17 CAR T) is a first-in-class, 3rd generation CDH17 CAR T invented at the world-renowned cell therapy centre, the University of Pennsylvania. Preclinical evidence for CHM 2101 was published in March 2022 in Nature Cancer demonstrating complete eradication of tumors in 7 types of cancer. CHM 2101 (CDH17 CAR T) is currently in preclinical development with a planned phase 1A clinical trial in gastrointestinal and neuroendocrine tumours.



CHM 0201 (CORE-NK platform) 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, an additional Phase1B clinical trial investigating CHM 0201 in combination with IL2 and Vactosertib is now underway. From the CHM 0201 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 Chairman Paul Hopper.

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