

ASX ANNOUNCEMENT 14 MARCH 2024

# CHIMERIC HIGHLIGHTS 2023 SUCCESSES AND KEY CLINICAL MILESTONES FOR 2024

- Reported positive preliminary data for CHM 1101 in heavily pretreated glioblastoma patients,
   confirming advancement to next phase of CHM 1101 development
- FDA IND clearance for CHM 2101 enabling clinical trial initiation in 2024
- All 2023 milestones successfully accomplished establishing the foundation for multiple significant clinical catalysts in 2024
- Continued focus on cashflow preservation, program prioritization and advancing business development opportunities

**Sydney, Australia, 14 March 2024:** Chimeric Therapeutics (ASX:CHM, "Chimeric" or the "Company"), a clinical-stage cell therapy company advancing novel autologous and allogeneic cell therapy technologies for patients with cancer, is pleased to highlight recent successes and provided insight into key clinical catalysts for 2024.

"In 2023, Chimeric made incredible progress advancing our mission to bring the promise of cell therapy to more patients, setting up the foundation for us to achieve multiple key clinical catalysts in 2024," said Jennifer Chow, CEO and Managing Director of Chimeric Therapeutics. "With positive Phase 1A data for CHM 1101, FDA clearance for CHM 2101 and the initiation of the ADVENT AML Phase 1B clinical trial, we are truly excited about delivering on key clinical catalysts in 2024. We are proud to have now treated over 30 patients across all of our clinical programs and remain focused on further advancing our clinical programs to create value realization for patients and shareholders in 2024."

## **2024 Anticipated Milestones**:

Chimeric plans to provide ongoing updates on the advancement of all platform technologies and highlight below key clinical updates expected in 2024:

- CHM 1101: Initiation of the Recurrent / Progressive Glioblastoma Phase 1B Expansion Cohort with preliminary data
- CHM 2101: Initiation of Phase 1A Dose Escalation Clinical Trial in Colorectal Cancer, Gastric Cancer and Neuroendocrine Tumours with preliminary data
- CHM 0201: Initiation of the ADVENT- AML Phase 1B clinical trial in Acute Myeloid Leaukemia with preliminary clinical data

These milestones, along with those that will advance the Company's next generation technologies, provide meaningful catalysts for value realisation for Chimeric in 2024.



## **Program Highlights:**

#### **CHM 1101**

In 2023, Chimeric achieved multiple milestones that all contributed to the advancement of the CHM 1101 clinical program. Of particular note, in October 2023, Chimeric was pleased to present positive preliminary dose escalation data from the City of Hope Phase 1A clinical trial.

The Phase 1A clinical study demonstrated both safety and a highly promising efficacy signal.

- CHM 1101 was studied in a heavily pretreated patient population with patients receiving CHM 1101, on average, as 4<sup>th</sup> line therapy. The vast majority of recurrent / progressive glioblastoma trials include only patients receiving therapy in 2<sup>nd</sup> line.
- CHM 1101 patients (n=11) across all dose levels, achieved a highly promising Disease Control Rate (DCR) of 55%, exceeding historical disease control rates of 20–37%.
- While survival expectations for 2<sup>nd</sup> line patients are generally ~7 months, the median overall survival for the heavily pretreated CHM 1101 patients that achieved disease control was shown to be an encouraging 9.9 months.
- Notably, two patients demonstrated a remarkable 14-month overall survival, with one of the two patients alive and in ongoing follow up.
- CHM 1101 was generally well tolerated with no dose limiting toxicities, no cytokine release syndrome and no tumor lysis syndrome being observed.

In 2023, the company also initiated a phase 1B clinical trial with CHM 1101 in recurrent / and or progressive glioblastoma. The first clinical site was opened with the first patient treated in November 2023 at the St David's South Austin Medical Center in Austin, Texas.

Based upon the encouraging Phase 1A clinical data, the Company announced plans to advance to the Phase 1B dose expansion cohort in 2024. The Company anticipates key milestones in 2024 including the FDA clearance of the dose expansion cohort, initiation of the dose expansion cohort and early clinical data from the cohort.

## **CHM 2101**

Following on from the prestigious Nature Cancer journal publication of the CHM 2101 pre-clinical data demonstrating complete eradication of seven types of cancer, Chimeric was focused in 2023 on completing the necessary technical operations and pre-clinical requirements to support an IND submission.

In October 2023, the company was pleased to announce that the FDA had provided IND clearance for CHM 2101 to be studied in Colorectal Cancer, Gastric Cancer and Neuroendocrine Tumours in a Phase 1A clinical trial.



In 2024, the company will be focused on initiating the multi-site Phase 1A clinical trial at leading US institutions in mid-2024 and providing a clinical update on patients treated with CHM 2101 at the initial dose level prior to the end of 2024.

# CHM 0201, 0301, 1301

Based upon the promising activity demonstrated in the CHM 0201 Phase 1A clinical trial published in the Transplantation and Cellular Therapy journal in 2022, Chimeric defined three avenues of development of CHM 0201:

- (1) investigating CHM 0201 in combination with other therapies;
- (2) developing CHM 0301, a next generation armoured NK platform; and
- (3) developing CHM 1301 and CHM 2301, CAR NK therapies utilising Chimeric's existing CLTX and CDH 17 CAR's.

# (1) CHM 0201 Combination Clinical Trials

CHM 0201 + Vactosertib Phase 1B Clinical Trial at Case Western Reserve University

In January 2023, the first patient was treated in a Phase 1B clinical trial studying CHM 0201 in combination with IL-2 and Vactosertib, an oral TGF- $\beta$  receptor. The trial was designed to study 12 patients with colorectal cancer or Acute Myeloid Leukemia and is the first study to explore NK cells in combination with Vactosertib. Although the trial was paused in early 2024 due to a lack of staff resources at Case Western, the company expects the clinical trial to be resumed shortly and anticipates completion of the clinical trial in 2024.

#### ADVENT AML Phase 1B Clinical Trial at MD Anderson Cancer Center

In September 2023, Chimeric announced a clinical collaboration with the world-renowned MD Anderson Cancer Centre in Houston, Texas. The collaboration supports the ADVENT AML Phase 1B clinical trial investigating CHM 0201 NK cells in combination with the current standard of care therapy for patients with newly diagnosed Acute Myeloid Leukemia (AML).

In February 2024, the company was pleased to be able to announce that the first patient was treated in the Phase 1B clinical trial. This trial will study an initial dose confirmation cohort of AML patients in the relapse / refractory setting. Chimeric anticipates completion of this cohort of patients in 2024 with preliminary clinical data available in late 2024.

# (2) <u>CHM 0301</u>

Building upon the foundation of the CHM 0201 NK cell platform, CHM 0301 integrates IL-15 as well as a dnTGFB receptor 2 armouring, designed to overcome immunosuppressive cytokines that inhibit NK and T cell functioning in cancer.

In 2023, Chimeric was pleased to announce that preclinical studies with CHM 0301 demonstrated 3x more resistance to suppression by TGF-beta, up to 25% relative increase in potency in the absence of TGF-beta and up to 80% relative increase in potency in the presence of TGF-beta. Additional preclinical



experiments will be completed and announced in 2024 to prepare CHM 0301 for the clinic.

## (3) CHM 1301 (CLTX CAR NK)

CHM 1301 combines the synergies of Chimeric's CHM 0201 NK platform and Chimeric's CHM 1101 CLTX CAR T for a next generation allogeneic chlorotoxin chimeric antigen receptor NK cell therapy.

In 2023, Chimeric announced that initial preclinical work for CHM 1301 had been completed in ovarian and pancreatic cancers. A 260% increase in cell killing was observed in ovarian cancer and a 300% increase was observed in pancreatic cancer, compared to first generation CHM 0201 cells. The results add weight for expansion with chlorotoxin into new disease areas beyond glioblastoma.

In 2024, preclinical work will continue with progress announced throughout the year.

#### **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. Positive preliminary data from the investigator-initiated phase 1A trial in glioblastoma was announced in October 2023.

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 tumours 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 Phase 1B 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.

## **CONTACT**

# <u>Investors</u>

Jennifer Chow Chief Executive Officer and Managing Director 
Executive Chairman **Chimeric Therapeutics** 

T: + 1 9087238387

E: jchow@chimerictherapeutics.com W: www.chimerictherapeutics.com

## <u>Media</u>

Matthew Wright **NWR Communications** P: +61 451 896 420

E: matt@nwrcommunications.com.au

**Paul Hopper** 

**Chimeric Therapeutics** T: +61 406 671 515

E: paulhopper@lifescienceportfolio.com