

## CHM announces positive Phase 1/2 data at ASCO

- 9 of 11 evaluable patients (82%) achieved stable disease per RECIST, with one patient maintaining stable disease for over 15 months, another 12 months
- After infusion, CHM CDH17 expanded and persisted in the peripheral blood of all treated patients
- CHM CDH17 is tolerable in heavily pre-treated metastatic patients
- Dose level 3 enrolment is ongoing; a recommended Phase 2 dose is expected to follow
- Webinar to be held at 11am AEST today, register at:  
[https://us02web.zoom.us/webinar/register/WN\\_Rh7aWNIJQSinr5MUnXqGIA](https://us02web.zoom.us/webinar/register/WN_Rh7aWNIJQSinr5MUnXqGIA)

Sydney, Australia, 1 June 2026: Chimeric Therapeutics (ASX:CHM, “Chimeric” or the “Company”), an Australian leader in cell therapy, is pleased to announce that the CHM CDH17 clinical trial was presented at the American Society of Clinical Oncology (ASCO) in the United States (NCT0605543).

Nine of 11 evaluable patients (82%) achieved stable disease per RECIST (Response Evaluation Criteria In Solid Tumours), with one patient maintaining stable disease for over 15 months, another 12 months; with three patients remaining on study. RECIST 1.1 is measured by changes in tumour size seen on scans. A Complete Response (CR) means all visible tumours have disappeared. A Partial Response (PR) means the total tumour size has shrunk by at least 30%. Stable Disease (SD) means the cancer has shrunk up to 30% or has not grown more than 20% from nadir. Progressive Disease (PD) indicates tumour growth of 20% or more, or the appearance of new tumours<sup>1</sup>.

As of 12 May 2026, 16 subjects have been enrolled with 2 screen failures. 100% successful manufacturing runs enabled treatment of 12 subjects to date; 4 at Dose Level 1, 6 at Dose Level 2, and 2 at Dose Level 3. All subjects have demonstrated expansion and persistence of CHM CDH17 CART+ cells for up to 15 months to date, which significantly de-risks this asset.

There was one Dose-Limiting Toxicity (DLT); Grade 3 Treatment-Related Adverse Events (TRAEs) were Cytokine Release Syndrome (CRS), enterocolitis, neutropenic fever, and fatigue that have resolved. There were no grade 4 or 5 TRAEs. All patients experienced Treatment Emergent Adverse Events (TEAEs) of grade 4 associated with lymphodepletion prior to receiving therapy. The abovementioned toxicities have been well documented in all cell therapies treatments regardless of target or indication<sup>2</sup>.

CHM CDH17 is tolerable in heavily pre-treated metastatic cancer patients with evidence of disease control. The pharmacokinetic data suggests robust expansion and persistence beyond 30



days. Enrolment to Dose Level 3 is on-going with initial signs of efficacy observed. These results extend the interim data reported on 13 November 2025, which described 75% disease control at the 28-day assessment in 6 of 8 evaluable patients. This current update reflects additional patients treated, the commencement of Dose Level 3, translational data and longer follow-up.

Dr Rebecca McQualter, CEO of Chimeric Therapeutics, said: “It’s very pleasing to see these continued positive results and a proud moment for the company to have them presented at ASCO. We look forward to continuing at Dose Level 3 and determining the dose appropriate for Phase 2.”

The 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.

The Phase 1 portion of this study is expected to enrol up to 15 evaluable patients and lead to dose selection and expansion with indication-specific Phase 2 cohorts.

## **INVESTOR WEBINAR**

Chimeric’s CEO Dr Rebecca McQualter will conduct an investor webinar regarding today’s announcement of CHM CDH17 data presented at ASCO.

When: 11am AEST, Monday 1 June 2026

Register at: [https://us02web.zoom.us/webinar/register/WN\\_Rh7aWNIJQSInr5MUnXqGIA](https://us02web.zoom.us/webinar/register/WN_Rh7aWNIJQSInr5MUnXqGIA)

Upon registering attendees will receive an email containing information about joining the webinar. A recording will be available at the above link soon after the conclusion of the live session, with the replay to also be made available via Chimeric’s website and social media channels.

Questions can be sent in advance of the webinar to [matt@nwrcommunications.com.au](mailto:matt@nwrcommunications.com.au)

<sup>1</sup> <https://dctd.cancer.gov/research/ctep-trials/for-sites/recist-guidelines-v11.pdf>

<sup>2</sup> <https://www.nature.com/articles/s41408-024-01167-8>



## **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 3 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 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.

*Authorised on behalf of the Chimeric Therapeutics board of directors.*

### **Contact**

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Study Overview NCT06055439

### **Brief Summary**

The goal of this clinical trial is to evaluate CHM-2101, an autologous CDH17 CAR T-cell therapy for the treatment of advanced gastrointestinal (GI) cancers that are relapsed or refractory to at least 1 standard treatment regimen in the metastatic or locally advanced setting.

### **Detailed Description**

This is a Phase 1/2 open-label study to evaluate CHM-2101, an autologous CDH17 CAR T-cell therapy for the treatment of advanced gastrointestinal (GI) cancers that are relapsed or refractory to at least 1 standard treatment regimen in the metastatic or locally advanced setting.

The study has 2 parts: Phase 1, Dose Escalation and Expansion, and Phase 2. Potential participants will provide written consent and be screened for study eligibility prior to undergoing any screening procedures, including leukapheresis. Protocol-specified criteria must be met prior to the start of leukapheresis for collection of peripheral blood mononuclear cells (PBMCs). Eligible participants will undergo leukapheresis to collect PBMCs for product manufacturing, which comprises enrichment of T cells, lentiviral transduction, ex vivo expansion, and cryopreservation of the CHM-2101 cell product. Participants who have a leukapheresis or manufacturing failure may be permitted a second attempt at leukapheresis.

Bridging chemotherapy (treatment between the time of leukapheresis and first dose of lymphodepleting chemotherapy [LDC]) is permitted at the discretion of the investigator, if needed to maintain disease stability during CHM-2101 manufacturing time. Bridging chemotherapy is prohibited within the 2 weeks prior to leukapheresis and 2 weeks prior to planned CHM-2101 infusion. Specific criteria to proceed should be reviewed prior to leukapheresis, LDC, and CHM-2101 infusion. Participants will be followed in this study for 18 months or until disease progression.

### **Official Title**

A Phase 1/2 Study to Evaluate CHM-2101, an Autologous Cadherin 17 (CDH17) Chimeric Antigen Receptor (CAR) T Cell Therapy for the Treatment of Relapsed or Refractory Gastrointestinal Cancers

### **Conditions**

Neuroendocrine Tumors Colorectal Cancer Gastric Cancer

### **Intervention / Treatment**

- Biological: CHM-2101 CAR-T cells

### **Other Study ID Numbers**

- CHM-2101-001

### **Participation Criteria**

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](#).

### **Eligibility Criteria**

#### **Description**

Inclusion Criteria:



1. Documented informed consent of the participant and/or legally authorized representative.
2. Confirmed histologic diagnosis of one of the following solid tumors of GI origin:
  1. Gastric adenocarcinoma Note: for gastric adenocarcinoma patients only, central laboratory confirmation of CDH17+ tumor expression is required.
  2. Colon and/or rectal adenocarcinoma
  3. G1, G2, and well-differentiated G3 neuroendocrine tumors of the midgut and hindgut (ileal, jejunal, cecal, distal colonic, or rectal; with  $\leq 55\%$  Ki67 expression)
3. Availability of unstained tumor tissue slides from archived tumor tissue or a new tumor biopsy, if medically feasible. Note: for gastric adenocarcinoma patients only, confirmation of CDH17+ is required prior to study inclusion.
4. Have received at least 1 prior line of systemic anti-cancer treatment in the locally advanced or metastatic setting, as defined by National Comprehensive Cancer Network (NCCN) guidelines. Participants must have received or declined FDA-approved and available treatment options, including targeted therapies for disease mutation or antigen expression status.
5. Age  $\geq 18$  years and  $\leq 85$  years.
6. For Phase 1 Dose Expansion and Phase 2 only: Measurable disease as per RECIST v1.1 criteria (Note: Measurable disease is NOT required for Phase 1 Dose Escalation).
7. Eastern Cooperative Oncology Group (ECOG)  $\leq 1$ .
8. Life expectancy  $\geq 12$  weeks.
9. No known contraindications to leukapheresis, cyclophosphamide, fludarabine, or steroids.
10. Baseline laboratory values as shown in the following table:

Minimum Laboratory Values for Study Entry Laboratory Assessment Criteria White blood cell count  $> 4,000/\text{mm}^3$  Absolute neutrophil count (ANC)  $\geq 1,500/\text{mm}^3$  Platelets  $\geq 100,000/\text{mm}^3$  Hemoglobin  $\geq 10 \text{ g/dL}$  Total bilirubin  $\leq 1.5 \times$  upper limit of normal (ULN) Aspartate amino transferase (AST)  $\leq 3 \times$  ULN Alanine transaminase (ALT)  $\leq 3 \times$  ULN Creatinine clearance by Cockcroft-Gault equation  $60 \text{ mL/min}$  Oxygen saturation  $\geq 92\%$  on room air Albumin  $\geq 3 \text{ g/dL}$

11. Left ventricular ejection fraction  $\geq 50\%$ .
12. Seronegative for human immunodeficiency virus (HIV) by antigen/antibody (Ag/Ab) testing.
13. Seronegative for hepatitis B and/or hepatitis C virus.
14. Women of childbearing potential (WOCBP) must have a negative urine or serum pregnancy test. If the urine test is positive or cannot be confirmed as negative, a serum pregnancy test is required.
15. Agreement by women and men of childbearing potential to use an effective method of birth control or abstain from heterosexual activity through at least 3 months after the last dose of CHM-2101.

#### Exclusion Criteria:

1. Previous treatment with CDH17-targeted therapies.
2. Unresolved toxicities from prior therapy except for chronic toxicity no greater than Grade 1 and stable  $> 30$  days (Note: alopecia of any grade is not exclusionary).
3. Uncontrolled seizure activity and/or known central nervous system (CNS) metastases.
4. History of allergic reactions attributed to compounds of similar chemical or biologic composition to study agent.
5. Uncontrolled Crohn's disease, ulcerative colitis, or other autoimmune or inflammatory disorders of the GI tract. "Uncontrolled" is defined as requiring hospitalization, corticosteroids, or chronic medication increase (dosage or frequency) within the previous 6 months.
6. Liver involvement  $\geq 50\%$ .
7. Active infection requiring oral or IV antibiotics.

8. Current diagnosis of pleural effusions, interstitial lung disease, or heart failure of New York Heart Association Classification of Heart Failure Class III or IV.
9. Ongoing treatment with systemic corticosteroid therapy at doses of prednisone  $\geq$  20 mg/day or equivalent (lower doses of corticosteroid therapy are allowed until 7 days prior to leukapheresis).
10. No prior malignancy within 5 years except for non-melanomatous skin cancer or cervical cancer treated with curative intent
11. Currently breastfeeding or planning to become pregnant within 9 months of study enrollment.
12. Any other clinically significant uncontrolled illness or other comorbid condition that would, in the investigator's judgment, contraindicate the participant's participation in the clinical study.

**Ages Eligible for Study**

18 Years to 85 Years (Adult, Older Adult )

**Sexes Eligible for Study**

All

**Accepts Healthy Volunteers**

No

**Arms and Interventions**

Participant Group/Arm	Intervention/Treatment
<p>Experimental: Autologous CDH17CAR T-cell Therapy</p> <p>After receiving three daily doses of IV fludarabine and cyclophosphamide, participants will receive a single dose of IV CHM-2101.</p> <p>The dose of CHM-2101 during Phase 1 will be based on "3+3" rules of dose escalation.</p> <p>The recommended Phase 2 dose will be based on results from the Phase 1.</p>	<p>Biological: CHM-2101 CAR-T cells</p> <ul style="list-style-type: none"> <li>• Cadherin 17 (CDH17) Chimeric Antigen Receptor (CAR)-positive T cells</li> </ul>

What is the study measuring?

**Primary Outcome Measures**

Outcome Measure	Measure Description
Dose-Limiting Toxicity (DLT)	Assessed according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 5.0.



<b>Outcome Measure</b>	<b>Measure Description</b>
Rates and Grades of Cytokine Release Syndrome (CRS)	Assessed per American Society for Transplant and Cellular Therapy (ASTCT) consensus grading guideline
All other adverse events and toxicities	Assessed per NCI CTCAE v5.0
Objective Response Rate (ORR)	Assessed by RECIST v 1.1

#### **Secondary Outcome Measures**

<b>Outcome Measure</b>	<b>Measure Description</b>
Disease control rate (DCR)	Assessed as the percentage of patients with advanced or metastatic cancer who have achieved complete response, partial response, and stable disease to a therapeutic intervention in clinical trials of anticancer agents.
Time to response (TTR)	Measured as the amount of time elapsed until drug response is achieved for the first time.
Duration of response (DOR)	Measured as the amount of time a patient responds to a treatment before disease progresses or the patient dies.
Progression-free survival (PFS)	Measured from the date of first infusion of CAR-T cells until the first date when progressive disease (PD) is objectively documented or death from any cause, whichever is earlier.
Overall survival (OS)	Measured from the date of first infusion of CAR-T cells until death.

ABSTRACT  
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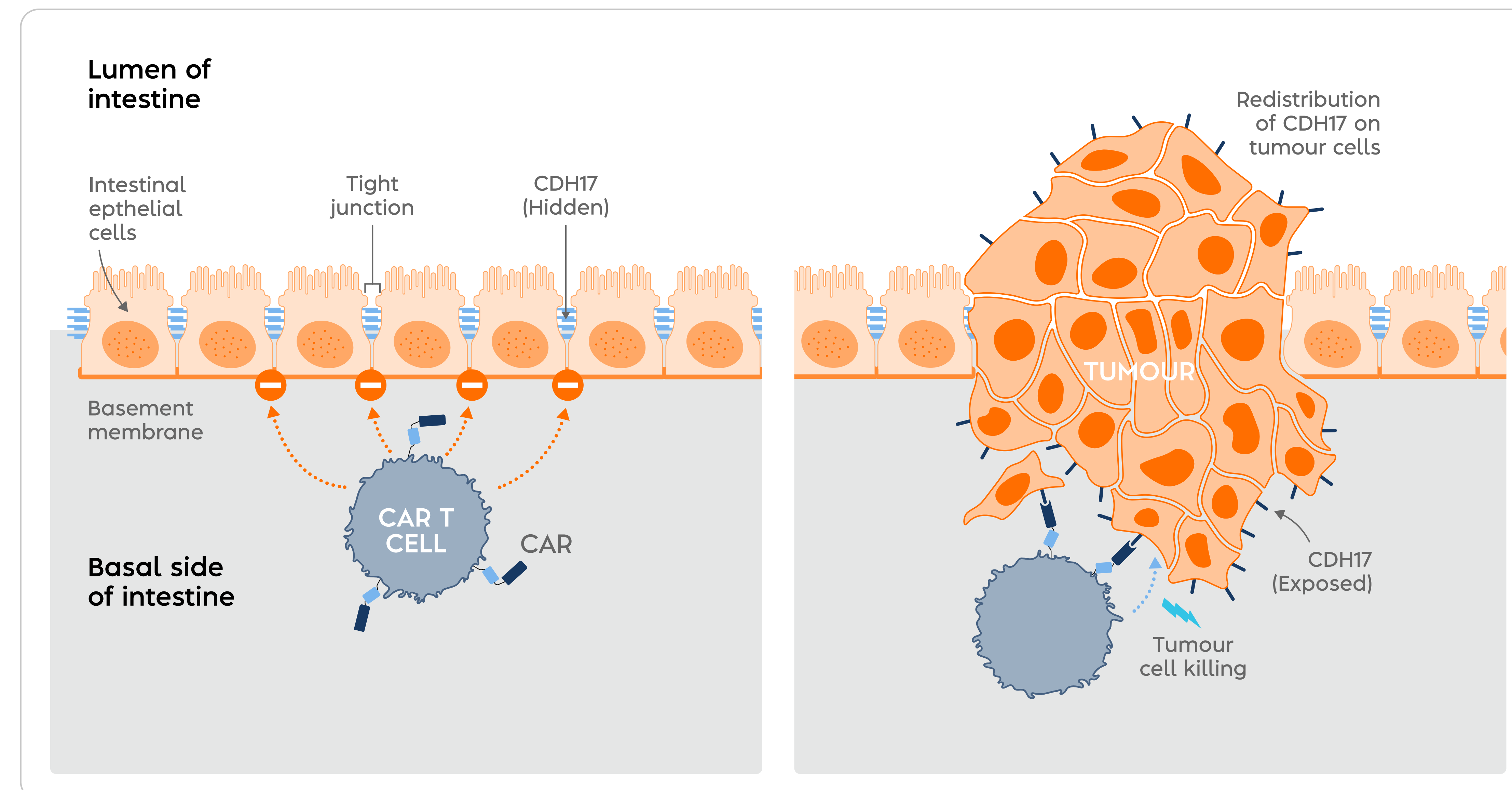
# Clinical and translational results from the phase 1 portion of the phase 1/2 study to evaluate CHM-2101, an autologous Cadherin 17 (CDH17) Chimeric Antigen Receptor (CAR) T cell therapy for the treatment of relapsed or refractory gastrointestinal cancers

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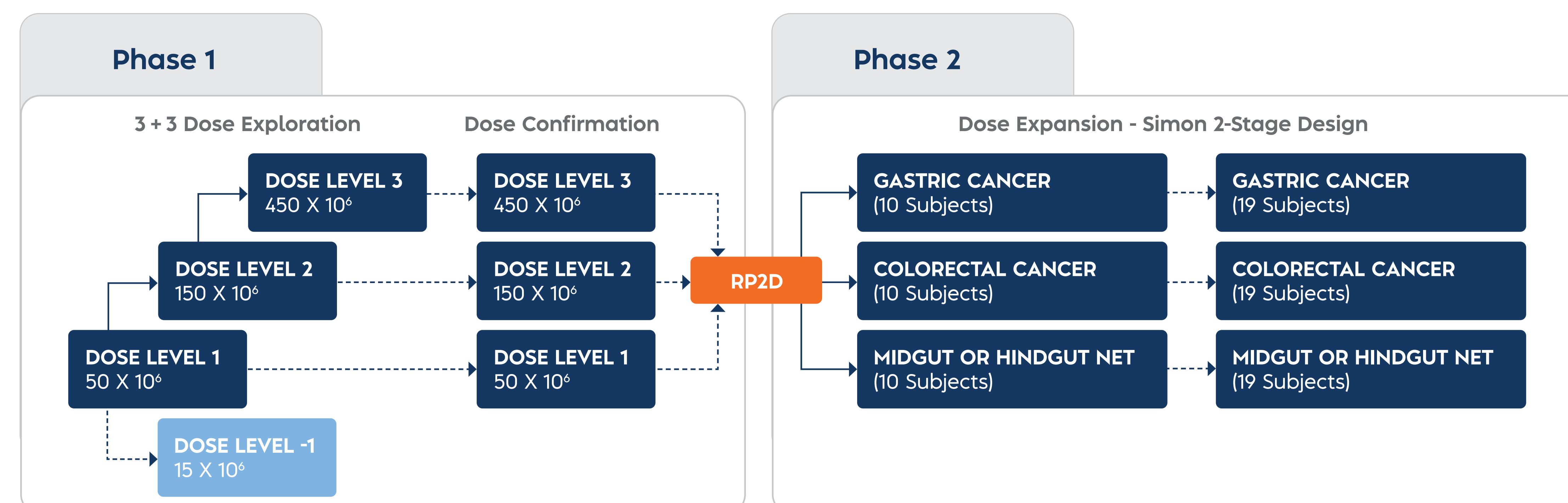
## BACKGROUND

CHM-2101 is a Cadherin 17 directed third-generation autologous CAR T-cell product being developed to address the continuing unmet medical need for effective therapy against relapsed or refractory gastrointestinal (GI) cancers. Solid tumors of the GI tract such as gastric cancer, colorectal cancer (CRC) and neuroendocrine tumors (NETs) are devastating diseases associated with poor outcomes and more than 1.3 million global deaths annually. Despite advances in surgical and medical treatment of these solid tumors, the prognosis for patients with relapsed or refractory disease remains poor. There remains a need for innovative and effective treatments for patients with advanced and treatment-recalcitrant GI malignancies.



## METHODS

The ongoing clinical trial is a seamless phase 1/2 study enrolling subjects with gastric cancer, CRC, or NETs of the midgut or hindgut. Enrolled subjects undergo screening and apheresis to enable manufacturing of CHM-2101. After completing apheresis, bridging therapy is permitted to provide disease control. After CHM-2101 manufacturing and washout of bridging therapy, subjects receive three days of lymphodepleting chemotherapy (fludarabine 30mg/m<sup>2</sup>/day and cyclophosphamide 500mg/m<sup>2</sup>/day). After two days rest, subjects receive a one-time intravenous infusion of CHM-2101.



A phase 1/2 clinical trial is evaluating the safety and efficacy of CHM-2101 in subjects with advanced GI cancers.

At all dose levels, CHM-2101 demonstrated expansion, persistence, and tolerability.

Enrollment of subjects at dose level 3 is ongoing at U.S. cancer centers.

## RESULTS

As of May 12, 2026, 16 subjects have been enrolled with 2 screen failures. Fifteen of 15 successful manufacturing runs enabled treatment of 12 subjects to date (4 at Dose Level 1, 6 at Dose Level 2, and 2 at Dose Level 3).

Database snapshot: May 12, 2026

	Dose Level 1	Dose Level 2	Dose Level 3	TOTAL
Age*	49.5 (27 - 63)	49 (37 - 76)	52.5 (45 - 60)	49 (27 - 76)
Gender	1M / 3F	4M / 2F	1M / 1F	6M / 6F
Diagnosis (Grade)	1 NET (3) 3 CRC (2)	3 NET (2 & unk) 3 CRC (2)	0 NET 2 CRC (2)	4 NET / 8 CRC
Prior lines of Therapy*	4 (1 - 8)	4 (2 - 12)	4 (3 - 5)	4 (1 - 12)

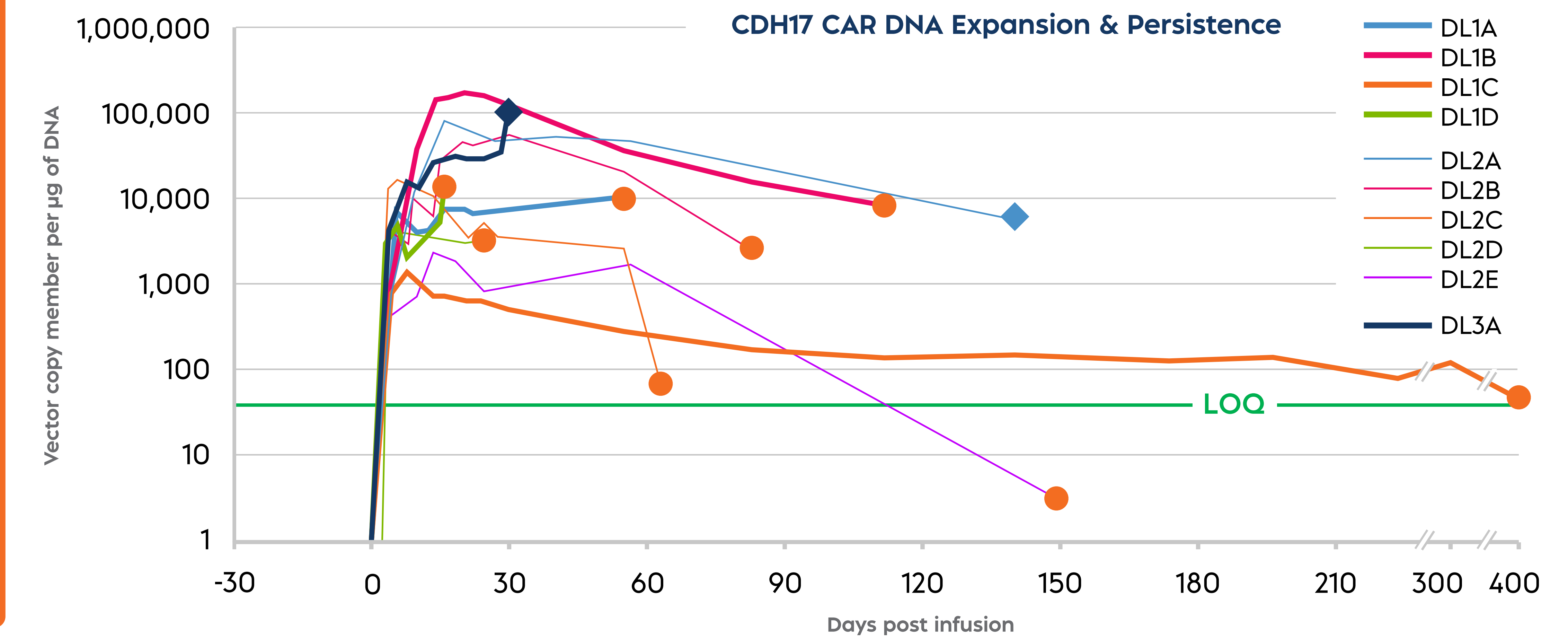
\* Median (range); unk = unknown

All subjects experienced grade 3 or 4 TEAEs and 30% of all AEs were grade 3 or higher. Most grade 3 - 4 events were hematologic toxicities associated with lymphodepleting chemotherapy. There was one DLT. Grade 3 TRAEs were CRS, enterocolitis, neutropenic fever, and fatigue. There were no grade 5 TRAEs.

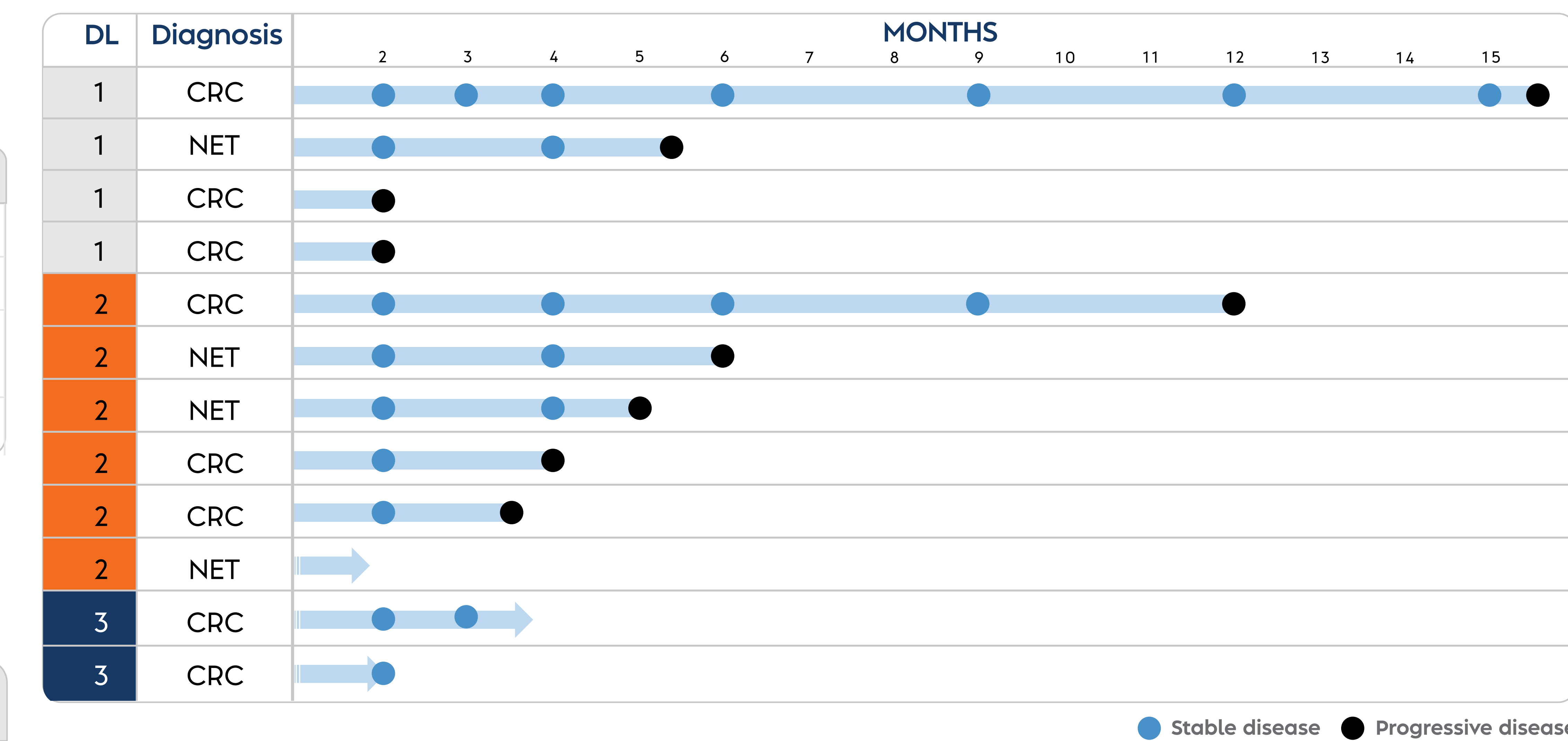
	Dose Level 1 n = 4	Dose Level 2 n = 6	Dose Level 3 n = 2	TOTAL n = 12
<b>Treatment-emergent AEs (TEAEs)</b>	n (%)	n (%)	n (%)	n (%)
TEAEs (all grades)	4 (100)	6 (100)	2 (100)	12 (100)
TEAEs (Grades 3-4)	4 (100)	5 (83.3)	2 (100)	11 (91.7)
<b>Treatment-related AEs (TRAEs)</b>	n (%)	n (%)	n (%)	n (%)
TRAEs (all grades)	2 (50)	5 (83.3)	2 (100)	9 (75)
TRAEs (Grades 3-4)	0	1 (16.7)	2 (100)	3 (25)
Serious Adverse Events	2 (50)	3 (50)	2 (100)	7 (58.3)
Cytokine Release Syndrome (CRS)	1 (25)	2 (33.3)	2 (100)	5 (41.7)

% of n = percentage of subjects with at least one event. Not all data has been source database verified.

After infusion, CHM-2101 expanded and persisted in the peripheral blood of all treated subjects.



Nine of 11 evaluable subjects (82%) achieved stable disease per RECIST, with one subject maintaining stable disease for over 15 months.



## CONCLUSIONS

CHM2101 is tolerable in heavily pre-treated metastatic cancer subjects with evidence for disease control. The pharmacokinetic data suggests robust expansion and persistence beyond 30 days. Enrollment to Dose level 3 is on-going with initial signs of efficacy observed.

## STUDY CONTACTS / SPONSOR

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