

Liminatus Pharma LLC  
GCC CAR-T

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**Phase I Trial Plan**



Liminatus Pharma



## GCC CAR-T Phase I Trial Plan

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**Name of Sponsor:** Thomas Jefferson University

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**Name of Investigational Product:** GUCY2C-Targeted CAR-T Cells

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**Name of Active Ingredient:** Guanylyl Cyclase C (GUCY2C)-Targeted 3rd Generation Chimeric Antigen Receptor-Encoded Lentivirus

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**Title of Study:** A Phase 1 Study of GUCY2C-Targeted CAR-T Cells in Adults with GUCY2C-Expressing Metastatic Gastrointestinal Adenocarcinomas

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**Short Title:** Phase 1 Study of GUCY2C-Targeted CAR-T Cells in Gastrointestinal Malignancies

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**Study Center(s):** Thomas Jefferson University

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**Principal Investigator:** Babar Bashir, M.D.

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**Co-Investigators:** Scott A. Waldman, M.D., Ph.D., Adam E. Snook, Ph.D., Scott Goldstein, M.D., Jonathan R. Brody, Ph.D., James A. Posey, M.D., Walter K. Kraft, M.D., Babar Bashir, M.D., Charles Yeo, M.D., Ben Phillips, M.D., Gerald Isenberg, M.D.

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**Studied Period (years):** Estimated date first patient enrolled: 10/01/20,  
Estimated date last patient completed: 12/01/21

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**Phase of Development:** Phase 1

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**Study Rationale:** This is an open-label, safety and tolerability, Phase 1 study of GUCY2C-Targeted CAR-T Cells to treat GUCY2C-expressing metastatic tumors (pancreatic, colorectal, esophageal, and gastric adenocarcinomas) in patients with established metastases. Patients will be given a single administration of GUCY2C-Targeted CAR-T Cells intravenously at a single dose level. Treatment-related toxicity, persistence and expansion of CAR-T Cells, and development of tumor responses will be evaluated at weeks 2, 3, 5, 9, and 13 after the initial vaccination (week 1). Primary safety endpoints will examine adverse events (AEs), injection site reactions and clinically significant changes in safety laboratory tests. Primary efficacy endpoints include the persistence and expansion of GUCY2C-Targeted CAR-T Cells and changes in tumor dimensions by imaging (weeks 5, 9, 13).

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**Primary Objectives:**

- 1) Evaluate the safety and tolerability of sequential GUCY2C-Targeted CAR-T Cells, delivered intravenously (IV) at one dose level in subjects with metastatic colorectal, pancreatic, gastric, or esophageal adenocarcinomas expressing GUCY2C.
  - 2) Evaluate the cellular (CAR-T cell) responses (persistence, expansion) in subjects with metastatic colorectal, pancreatic, gastric, or esophageal adenocarcinomas expressing GUCY2C.
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