ForPatients
by Roche

Colorectal Cancer (CRC)Pancreatic CancerGastric CancerBreast CancerRenal Cell CarcinomaNon Small Cell Lung CarcinomaOvarian Cancer

P-MUC1C-ALLO1 Allogeneic CAR-T Cells in the Treatment of Subjects With Advanced or Metastatic Solid Tumors

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	1 Country	NCT05239143 GO46329 P-MUC1C-ALLO1-001

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

A Phase 1 Dose Escalation and Expanded Cohort Study of P-MUC1C-ALLO1 in Adult Subjects With Advanced or Metastatic Solid Tumors

Trial Summary:

A Phase 1, open label, dose escalation and expanded cohort study of P-MUC1C-ALLO1 in adult subjects with advanced or metastatic epithelial derived solid tumors, including but not limited to the tumor types listed below.

Genentech, Inc.
Sponsor

Phase 1
Phase

NCT05239143 GO46329 P-MUC1C-ALLO1-001
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

Inclusion Criteria:

- Males or females, Subjects #18 years with life expectancy >3 months
- Must have a confirmed diagnosis of unresectable, locally advanced or metastatic epithelial-derived cancer

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- Must have progressed during or after last therapy, developed intolerance/toxicity to current treatment, or ineligible or refused other existing treatment options, and have measurable disease
- Must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 or Karnofsky performance status #70%
- Must have adequate vital organ function within pre-determined parameters
- Must have archived tumor tissue available or consent to a biopsy collection
- Must be willing to practice birth control
- Must have a negative pregnancy test at screening and prior to initiating lymphodepletion chemotherapy or study drug administration
- Must have recovered from toxicities due to prior therapies

Exclusion Criteria:

- Has inadequate venous access
- Has an active second malignancy (not disease free for at least 5 years) in addition to the studied malignancy, excluding low-risk neoplasms such as non-metastatic basal cell or squamous cell skin carcinoma
- Is pregnant or lactating
- Has a history of or active autoimmune disease
- Has a history of significant central nervous system (CNS) disease, such as stroke, epilepsy
- Has an active systemic (viral, bacterial, or fungal) infection
- Has New York Heart Association (NYHA) Class III or IV heart failure, unstable angina, or a history of myocardial infarction or significant arrhythmia
- Has any psychiatric or medical disorder that would preclude safe participation in and/or adherence to the protocol
- Has received anticancer medications within 2 weeks of the time of initiating lymphodepletion
- Has received immunosuppressive medications within 2 weeks of administration of P-MUC1C-ALLO1, and/or expected to require them while enrolled in the study
- Has received systemic corticosteroid therapy within 1 week of the administration of P-MUC1C-ALLO1 or is expected to require it during the course of the study
- Has known CNS metastases or symptomatic CNS involvement
- Has a history of significant liver disease or active liver disease
- Has a history of known genetic predisposition to HLH/MAS
- Has received anti-cancer monoclonal antibody therapy within 4 weeks of initiating LD therapy

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