M0324 in advanced solid tumors (TITER study)

M0324 is an investigational drug in clinical development. FDA and other regulatory authorities have not approved this investigational drug. Safety and efficacy have not been established.

Sponsor: Affiliates of Merck KGaA, Darmstadt, Germany

Study design (NCT07166601) *recruiting*

Phase 1, FiH, open-label, multicenter study in advanced solid tumors

Key eligibility criteria

- **Part 1[a]:** Patients with certain advanced/metastatic solid tumor types known to overexpress MUC-1
- **Part 2[b]:** Patients with certain advanced/metastatic tumor types known to overexpress MUC-1. Prior treatment with ICIs and documented disease progression on or after ICIs
- **Part 3[c]:** Patients with previously untreated metastatic PDAC

N≈77

Part 1: M0324 monotherapy

Dose escalation until MTD or a safe RDE is determined

Part 2: M0324 + pembrolizumab

Combination regimen
Dose escalation until MTD or a safe RDE is determined

Part 3: M0324 + mFOLFIRINOX

Combination regimen
Dose escalation until MTD or a safe RDE is determined

Endpoints

Primary	DLTs, TEAEs
Secondary	PK, PD, OR[d], DoR[d], PFS[e], OS (Part 3), ADAs

Study start date: October 2025

Est. primary completion date: February 2029

Planned Locations

US, Canada, Japan

[a]Patients who are intolerant or refractory to standard therapy or for whom no standard therapy is judged appropriate by the investigator. [b]Patients must be intolerant or refractory to standard therapy and no other further standard therapy should be judged appropriate by the investigator. Patients must have had prior treatment with ICIs and must have experienced documented disease progression on or after ICIs. [c]Patients who are judged by investigator as eligible for treatment with mFOLFIRINOX. Patients with prior Whipple surgery and/or adjuvant chemotherapy are not permitted. [d]Assessed by investigator per RECIST v1.1. [e]Assessed per RECIST v1.1.

ADA, anti-drug antibody; DLT, dose-limiting toxicity; DoR, duration of response; Est., estimated; FiH, first-in-human; ICI, immune checkpoint inhibitor; mFOLFIRINOX, modified folinic acid, fluorouracil, irinotecan, and oxaliplatin regimen; MTD, maximum tolerable dose; MUC-1, mucin-1; OR, objective response; OS, overall survival; PD, pharmacodynamics; PDAC, pancreatic ductal adenocarcinoma; PFS, progression-free survival; PK, pharmacokinetics; RDE, recommended dose for expansion; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1; TEAE, treatment-emergent adverse event; US, United States.

For more information on this clinical trial, scan the QR code.