M7437 in advanced solid tumors

M7437 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 (NCT07360314) *recruiting*

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

Key eligibility criteria

- Unresectable locally advanced or metastatic solid tumor with known prevalent and high Ly6E expression that is refractory to standard therapies
- NSCLC, TNBC, SCCHN, PDAC, GC, EOC
- ECOG PS ≤1
- Acceptable CBC and liver and kidney function

N≈58[a,b]

Part 1: Dose escalation

M7437 at multiple DLs (3-4 patients per DL)

DLT period: 21 days

Part 2: Dose expansion

M7437 at RDE per Part 1

Planned

Endpoints[a]	
Primary	DLTs, TEAEs, AEs
Secondary	Plasma concentration of M7437, overall response[c], ΔQTc at predefined time points per ECG

Study start date[a]: February 2026

Est. primary completion date: September 2028

Locations[a]

US, Canada, Japan, Spain

[a]Only applicable for Part 1. [b]Total planned enrollment: N≈138. [c]Per RECIST v1.1, as assessed by Investigator.
AE, adverse event; CBC, complete blood count; DL, dose level; DLT, dose-limiting toxicity; ECG, electrocardiogram; ECOG PS, Eastern Cooperative Oncology Group performance status; EOC, epithelial ovarian cancer; Est., estimated; FiH, first-in-human; GC, gastric cancer; Ly6E, lymphocyte antigen 6E; NSCLC, non-small cell lung cancer; PDAC, pancreatic ductal adenocarcinoma; ΔQTc, change from baseline in corrected QT interval; RDE, recommended dose for expansion; SCCHN, squamous cell carcinoma of the head and neck; TEAE, treatment-emergent adverse event; TNBC, triple negative breast cancer; US, United States.

US-MULOP-00107 | March 2026

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

EMD SERONO