PROCEADE®
PanTumor | PHASE 1b/2

Precemtabart tocentecan (Precem-TcT)* in advanced solid tumors

Precem-TcT 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 (NCT06710132) *recruiting*

Phase 1b/2, open-label, multicenter study in advanced PDAC, GC/GEJC, and NSCLC[1]

Key eligibility criteria

- Patients with confirmed locally-advanced or metastatic CEACAM5-expressing tumors
  - Substudy PDAC: Advanced or metastatic PDAC (2 or 3L)
  - Substudy GC: Advanced or metastatic *HER2*-negative GC/GEJC (2 or 3L)
  - Substudy NSCLC: Advanced (Stage III; ineligible for resection/curative radiation) or metastatic NSCLC (≥2L)
- ECOG PS ≤1

N≈250

Substudy PDAC: CEACAM5^{high}
Precem-TcT monotherapy 2.8 mg/kg IV Q3W

Substudy GC
Precem-TcT monotherapy 2.8 mg/kg IV Q3W

Part A: CEACAM5^{high}	Part B: CEACAM5^{low}

Substudy NSCLC
Precem-TcT monotherapy 2.8 mg/kg IV Q3W

Part A: CEACAM5^{high} *EGFR*wt	Part B: CEACAM5^{high} *EGFR*mut

Endpoints	
Primary	All substudies: OR[a]
Secondary	All substudies: Safety (AEs, TRAEs), DoR[a], DCR, TTR[a], PFS[a], PK, ADA against Precem-TcT Substudy GC: Optimize CEACAM5 expression cutoff level

Study start date: January 2025
Est. primary completion date: December 2027

Locations
US, France, Austria, Italy, Spain, Japan, Republic of Korea, Australia

*Previously known as M9140. [a]Per RECIST v1.1 according to investigator assessment.
2L, second-line; 3L, third-line; 4L fourth-line; ADA, anti-drug antibody; AE, adverse event; CEACAM5, carcinoembryonic antigen-related cell adhesion molecule 5; CEACAM5high, ≥50% of tumor cells (of ≥100 viable tumor cells present) exhibit IHC ≥2+ membrane staining; CEACAM5low, <50% of tumor cells (of ≥100 viable tumor cells present) exhibit IHC ≥2+ membrane staining; DC, disease control; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFRmut, epidermal growth factor receptor mutated; EGFRwt, epidermal growth factor receptor wild type; Est. estimated; GC, gastric cancer; GEJC, gastroesophageal junction cancer; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; IV, intravenous; NSCLC, non-small cell lung cancer; OR, objective response; PDAC, pancreatic ductal adenocarcinoma; PK, pharmacokinetics; PFS, progression-free survival; Q3W, every 3 weeks; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1; TRAE, treatment-related adverse event; TTR, time to response; US, United States.

Reference: 1. Wainberg Z, et al. American Society of Clinical Oncology (ASCO) Annual Meeting 2025. Abstract TPS3165.

US-MULOP-00106 | March 2026

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

EMD SERONO