

Precentabart 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

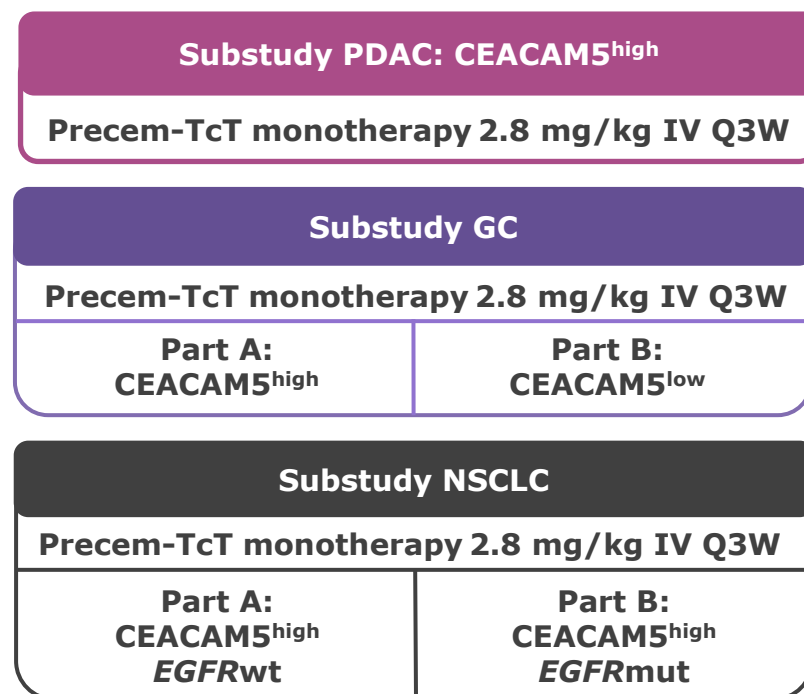
Study design (NCT06710132) *recruiting*

Phase 1b/2, open-label, multicenter study in advanced PDAC, GC/GEJC, and NSCLC¹

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



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. ^aPer 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; CEACAM5^{high}, ≥50% of tumor cells (of ≥100 viable tumor cells present) exhibit IHC ≥2+ membrane staining; CEACAM5^{low}, <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.

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