PROCEADE

PanTumor | PHASE 1b/2

# Precemtabart tocentecan (M9140) in advanced solid tumors

**Precemtabart tocentecan is investigational and not approved for use. The safety and efficacy of precemtabart tocentecan in advanced solid tumors has not been established. There is no guarantee precemtabart tocentecan will be approved in the sought-after indication by any health authority worldwide.**

**Sponsor: Affiliates of Merck KGaA, Darmstadt, Germany**

## Study design (NCT06710132) *recruiting*

**Phase 1b/2, open-label, multicenter study**

### Key eligibility criteria

- Patients with confirmed la/m CEACAM5-expressing tumors
  - Substudy GC: Advanced/metastatic *HER2*-negative GC/GEJC (2 or 3L)
  - Substudy NSCLC: Advanced (Stage III; ineligible for resection/curative radiation) or metastatic NSCLC (2, 3, or 4L)
  - Substudy PDAC: Advanced/metastatic PDAC (2 or 3L)
- ECOG PS ≤1

**N≈250**

**Substudy GC: Part A CEACAM5$^{high}$**
**Precemtabart tocentecan monotherapy 2.8 mg/kg IV Q3W**

**Substudy GC: Part B CEACAM5$^{low}$**
**Precemtabart tocentecan monotherapy 2.8 mg/kg IV Q3W**

**Substudy NSCLC: Part A CEACAM5$^{high}$ *EGFR*wt**
**Precemtabart tocentecan monotherapy 2.8 mg/kg IV Q3W**

**Substudy NSCLC: Part B CEACAM5$^{high}$ *EGFR*mut**
**Precemtabart tocentecan monotherapy 2.8 mg/kg IV Q3W**

**Substudy PDAC: CEACAM5$^{high}$**
**Precemtabart tocentecan monotherapy 2.8 mg/kg IV Q3W**

| Endpoints | |
|---|---|
| **Primary** | All substudies: OR[a] |
| **Secondary** | All substudies: Safety (AEs, TRAEs), DoR[a], DCR, TTR[a], PFS[a], PK, ADA against M9140<br>Substudy GC: Optimize CEACAM5 expression cutoff point |

**Est. study start date**
**February 2025**

**Est. primary completion date**
**January 2029**

**Planned Locations**

North and South America, EU, and Asia

ADA, anti-drug antibody; AE, adverse event; CEACAM5, carcinoembryogenic antigen-related cell adhesion molecule; CEACAM5$^{high}$, ≥50% of tumor cells (≥100 viable tumor cells present) exhibiting IHC ≥2+ staining; CEACAM5$^{low}$, <50% of tumor cells exhibiting IHC ≥2+ staining; DCR, disease control rate; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; *EGFR*mut, epidermal growth factor receptor mutated; *EGFR*wt, epidermal growth factor receptor wild type; Est. estimated; EU, European Union; GC, gastric cancer; GEJC, gastroesophageal junction cancer; *HER2*, human epidermal growth factor receptor 2; IHC, immunohistochemistry; IV, intravenous; L, line; la/m, locally advanced or metastatic; 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. [a]Per RECIST v1.1 according to investigator assessment.



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

EMD SERONO