



# PROCEADE Precentabart tocentecan (M9140) in advanced solid tumors

PanTumor

PHASE 1b/2

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

Sponsor: Affiliates of Merck KGaA, Darmstadt, Germany

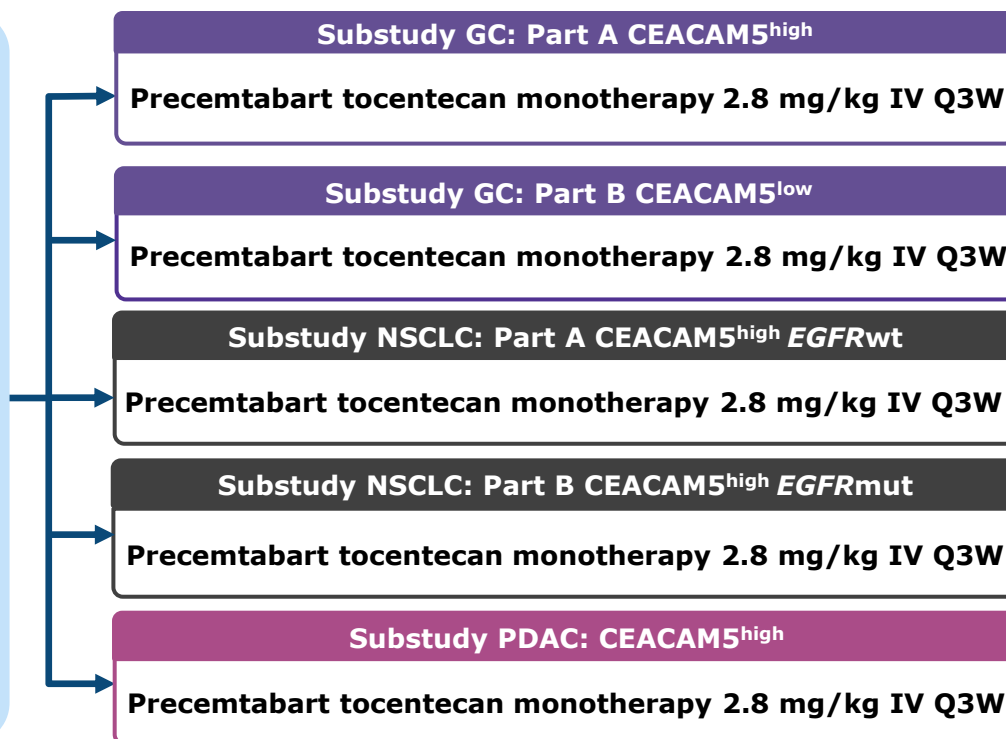
Study design (NCT06710132) **recruiting**

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

### Key eligibility criteria

- Patients with confirmed Ia/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**



### Endpoints

#### Primary

All substudies: OR<sup>a</sup>

#### Secondary

All substudies:  
Safety (AEs, TRAEs), DoR<sup>a</sup>, DCR, TTR<sup>a</sup>, PFS<sup>a</sup>, PK, ADA against M9140

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<sup>high</sup>, ≥50% of tumor cells (≥100 viable tumor cells present) exhibiting IHC ≥2+ staining; CEACAM5<sup>low</sup>, <50% of tumor cells exhibiting IHC ≥2+ staining; DCR, disease control rate; 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; EU, European Union; GC, gastric cancer; GEJC, gastroesophageal junction cancer; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; IV, intravenous; L, line; Ia/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. <sup>a</sup>Per RECIST v1.1 according to investigator assessment.

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

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