PROCEADE

CRC-01 | PHASE 1

Precemtabart tocentecan (M9140) in mCRC

Precemtabart tocentecan is investigational and not approved for use. The safety and efficacy of precemtabart tocentecan in CRC 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 (NCT05464030) *recruiting*

Phase 1, FiH, open-label study of precemtabart tocentecan in patients with la/m CRC

Key eligibility criteria

- Patients with confirmed la/m CRC, intolerant/refractory to or progressing after standard systemic therapies
- ECOG PS ≤1
- Patients with MSI-H status must have received treatment with an ICI unless contraindicated

N≈200

Dose escalation 3L+ mCRC[1]

Part 1: Dose escalation, monotherapy (IV), Q3W

Precemtabart tocentecan at escalated DLs until MTD and/or a safe RDE is determined

Dose expansion 3L mCRC[1]

Part 2A: Dose Optimization

Precemtabart tocentecan monotherapy (IV), Q3W[1]

Arm A1: 2.8 mg/kg	Arm A2: 2.4 mg/kg

Part 2B: Alternative regimen

Precemtabart tocentecan monotherapy

Part 2C: Combination regimen

Precemtabart tocentecan + bevacizumab ± capecitabine

Part 2D: Combination regimen

Precemtabart tocentecan + 5-fluorouracil + folinic acid + bevacizumab

Endpoints

Primary	**1:** DLTs, AEs, RDE
	2A: AEs, OR[a], DoR[a]
	2B–D: DLTs, AEs
Secondary	**1:** PK, OR[a], PFS[a], DoR[a], ECG changes, ADA
	2A: PK, OS, PFS[a], TTR, AEs, ECG changes, DC, ADA
	2B–D: PK, OR[a], PFS[a], DoR[a], TTR, DC, ADA

Study start date: August 2022

Est. primary completion date: February 2026

Locations

US, Canada, Asia, and Europe

3L, third line; 3L+, third- or later-line; ADA, anti-drug antibody; AE, adverse event; CRC, colorectal cancer; DC, disease control; DL, dose level; DLT, dose-limiting toxicity; DoR, duration of response; ECG, electrocardiogram; ECOG PS, Eastern Cooperative Oncology Group performance status; Est. estimated; FiH, first-in-human; ICI, immune checkpoint inhibitor; IV, intravenous; la/m, locally advanced/metastatic; MSI-H, microsatellite instability high; MTD, maximum tolerable dose; OR, objective response; OS, overall survival; PFS, progression-free survival; PK, pharmacokinetics; Q2W, every 2 weeks; Q3W, every 3 weeks; RDE, recommended dose for expansion; RECIST v1.1, Response Evaluation Criteria In Solid Tumors version 1.1; TTR, time to response; US, United States.

[a]Assessed by investigator per RECIST v1.1. 1. Kopetz S, et al. *J Clin Oncol.* 2024;42(16_Suppl):3000.

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

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