

Precentabart tocentecan (Precem-TcT)* in mCRC

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 (NCT05464030) *recruiting*

Phase 1, FiH, open-label, multicenter study in advanced CRC^{1,2}

Key eligibility criteria

- Patients with confirmed locally advanced or metastatic CRC, intolerant/refractory to or progressing after standard systemic therapies
- ECOG PS \leq 1
- Patients with MSI-H status must have received treatment with an ICI unless contraindicated

N \approx 200

Dose escalation 3L+ mCRC¹

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

**Precem-TcT at
escalated DLs
until MTD and/or a
safe RDE is determined**

Dose expansion 3L+ mCRC¹

Part 2A: Dose Optimization

Precem-TcT monotherapy (IV), Q3W¹

Arm A1: 2.8 mg/kg

Arm A2: 2.4 mg/kg

Part 2B: Alternative regimen

Precem-TcT monotherapy

Part 2C: Combination regimen

Precem-TcT + bevacizumab \pm capecitabine

Part 2D: Combination regimen

Precem-TcT + 5-fluorouracil + folinic acid + bevacizumab

Endpoints

	1: DLTs, AEs, RDE
Primary	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 2027**

Locations

US, Canada, Japan, Republic of Korea, and Spain

Previously known as M9140. ^aAssessed by investigator per RECIST v1.1.

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; mCRC, metastatic colorectal cancer; MSI-H, microsatellite instability high; MTD, maximum tolerable dose; OR, objective response; OS, overall survival; PFS, progression-free survival; PK, pharmacokinetics; 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.

References: 1. Kopetz S, et al. J Clin Oncol. 2024;42(16_Suppl):3000. 2. Kopetz S, et al. J Clin Oncol. 2025;43(16_Suppl):3038.

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