PROCEADE®
CRC-03 PHASE 3

Precemtabart tocentecan (Precem-TcT)* in 3L 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 NCT07549412 *Not yet recruiting*

Phase 3, randomized, open-label, multicenter study in 3L metastatic CRC

Key eligibility criteria

- Histopathologically confirmed metastatic CRC
- Intolerant to or progressed after not more than 2 prior systemic treatment regimens for metastatic disease
- Must have been treated with a fluoropyrimidine, irinotecan, a platinum agent (e.g.,oxaliplatin), and bevacizumab, along with additional treatments based on biomarker status†
- ECOG PS ≤1

N≈1020

R 1:1:1

Arm 1
Precem-TcT monotherapy (2.8 mg/kg Q3W)

Arm 2
Precem-TcT (2.8 mg/kg Q3W) + bevacizumab (7.5 mg/kg Q3W)

Arm 3
Trifluridine/tipiracil (FTD-TPI; D1-D5, D8-D12, oral, twice daily, Q4W) + bevacizumab (5.0 mg/kg, D1+D15, Q4W)

Stratification by Region (North America vs East Asia vs ROW); **ECOG PS** (0 vs 1); **Presence of liver metastases** (Yes vs No)

Endpoints	
Primary	OS (Arm 1 vs Arm 3; Arm 2 vs Arm 3)
Secondary	OS, PFS, OR[a], DoR[a] (Arm 1 and Arm 2 separately)
	PFS, OR[a], DoR[a] (Arm 1 vs Arm 3; Arm 2 vs Arm 3)
	AEs, TRAEs, PK, ECG changes, QoL, ADA against Precem-TcT

Est. study start date: May 2026

Est. primary completion date: December 2028

Locations

North America, South America, Asia, Europe

*Previously known as M9140. [a]Assessed by investigator per RECIST v1.1. †These include an anti-EGFR agent (if clinically indicated, i.e. *RAS*/*BRAF* wt and left-sided tumors), an immune checkpoint inhibitor for participants with a known MSI-H status, encorafenib and cetuximab or encorafenib, cetuximab, and binimetinib for participants with known *BRAF*^{V600E} mutation, HER-2 targeted therapy (e.g. trastuzumab plus tucatinib) for participants with known HER-2 positive CRC, or a NTRK inhibitor (e.g. larotrectinib and entrectinib) for participants with NTRK gene fusion-positive CRC.
3L, third line; ADA, anti-drug antibody; AE, adverse event; CEACAM5, carcinoembryonic antigen-related cell adhesion molecule 5; CRC, colorectal cancer; D, day; DoR, duration of response; ECG, electrocardiogram; ECOG PS, Eastern Cooperative Oncology Group performance status; Est. estimated; FTD-TPI, trifluridine/tipiracil; mCRC, metastatic colorectal cancer; OR, objective response; OS, overall survival; PFS, progression-free survival; PK, pharmacokinetics; Q3W, once every 3 weeks; Q4W, once every 4 weeks; QoL, quality of life; RECIST v1.1, Response Evaluation Criteria In Solid Tumors version 1.1; ROW, rest of the world; US, United States. This information is current as of March 2026. This material is intended for healthcare professionals only.

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

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