DNA Damage Response Inhibitors (DDRi)

Phase 1 study: M9466 + FOLFIRI + Bevacizumab—CRC

DDRiver COLORECTAL 511™

Merck KGaA, Darmstadt, Germany entered into a collaboration with Jiangsu Hengrui Pharmaceuticals Co. Ltd., China, including an exclusive license worldwide (ex-China) to develop, manufacture and commercialize M9466. Within China, M9466 is known as HRS-1167.
M9466 is investigational and not approved for any use. The safety and efficacy of M9466 in advanced solid tumors and CRC has not been established.
There is no guarantee M9466 will be approved in the sought-after indication by any health authority worldwide.

Sponsor: Affiliates of Merck KGaA, Darmstadt, Germany

NCT06509906 [Suspended (Sponsor Decision)]

M9466 in combination with topoisomerase 1 inhibitors-based regimens in advanced solid tumors and CRC (DDRiver 511)

Key eligibility criteria[a]

Patients LA/M CRC whose disease was intolerant/refractory to or progressed after standard systemic therapies[b]

ECOG PS ≤1

Received ≤1 prior treatment for metastatic disease[c]

N~54

Irinotecan Cohort

M9466
+
irinotecan

Dose Finding Cohorts

M9466

+

FOLFIRI

(Folinic acid, 5-FU, irinotecan)

+

Bevacizumab

Endpoints

Primary	Safety (TEAEs, DLT)
Secondary	PK, OR[d]

Study start date
October 2024

Est. primary completion date
April 2026

Locations

Sites in USA, Australia, Japan, Republic of Korea, and Spain

[a]Eligibility criteria of Irinotecan Cohort: Patients with LA/M disease whose disease was refractory to standard therapy; [b]Oxaliplatin and fluoropyrimidine (administration in the adjuvant setting fulfills this criterion if progression occurred ≤12 months of the last dose); either an anti-EGFR or an anti-VEGF agent (not applicable if oxaliplatin administered in the adjuvant setting); ICI in patients with known MSI-H status; cetuximab and encorafenib ± binimetinib, if locally available, for patients with *BRAF*V600E mutations. Note: Prior irinotecan use is permitted; [c]With the exception of patients with MSI-H disease or *BRAF*+ disease who are allowed up to 2 previous lines of treatment; [d]Per RECIST v1.1 (as assessed by investigator).
CRC, colorectal cancer; DLT, dose-limiting toxicity; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; Est., estimated; FOLFIRI, folinic acid, 5-FU, and irinotecan; ICI, immune checkpoint inhibitors; LA/M, locally advanced or metastatic; MSI-H, microsatellite instability biomarker-high; OR, objective response; PK, pharmacokinetic; RECIST, Response Evaluation Criteria in Solid Tumors; TEAE, treatment-emergent adverse event; USA, United States of America; VEGF, Vascular endothelial growth factor; 5-FU, fluorouracil.

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

US-MULOP-00089 I March 2025

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