DNA Damage Response Inhibitors (DDRi)

Phase 1 study: M9466 + carboplatin—solid tumors; M9466 + carboplatin + etoposide + atezolizumab—SCLC

DDRiver SCLC 521™

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 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

NCT06719973 [Not yet recruiting]

DDRiver 521: Phase 1, open-label, multicenter study

Key eligibility criteria

Module 1

- Patients with refractory LA/M solid tumors[a]
- Received ≤3 lines of prior anti-cancer therapy for advanced/metastatic disease

Module 2

- Patients with treatment-naïve extensive stage-SCLC[b]

ECOG PS ≤1 (ECOG PS 2 if related to SCLC tumor load in module 2)

N~54

Module 1 (Dose finding)

M9466 + carboplatin

Module 2 Part A (Dose reassessment)

M9466 + carboplatin + etoposide + atezolizumab

Module 2 Part B (Dose expansion)

M9466 + carboplatin + etoposide + atezolizumab

Endpoints

Primary	Module 1 and 2: Safety (TEAEs, DLT)
Secondary	Module 1 and 2: PK, OR[c], DoR[c], PFS[c]

Est. study start date
July 2025

Est. primary completion date
October 2027

Locations

Japan

[a]Patients who have exhausted all standard of care options according to international guidelines; [b]Patients who have no history of systemic treatment for the disease and must be considered suitable to receive carboplatin, etoposide, and atezolizumab as first-line treatment for extensive stage-SCLC; [c]Per RECIST version 1.1 (as assessed by investigator).
DLT, dose-limiting toxicity; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; Est., estimated; LA/M, locally advanced or metastatic; OR, objective response; PFS, progression-free survival; PK, pharmacokinetic; RECIST, Response Evaluation Criteria in Solid Tumors; SCLC, small-cell lung cancer; TEAEs, treatment-emergent adverse events; USA, United States of America

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

EMD SERONO