M3554 in advanced solid tumors

M3554 is investigational and not approved for use. The safety and efficacy of M3554 in advanced solid tumors has not been established. There is no guarantee M3554 will be approved in the sought-after indication by any health authority worldwide.

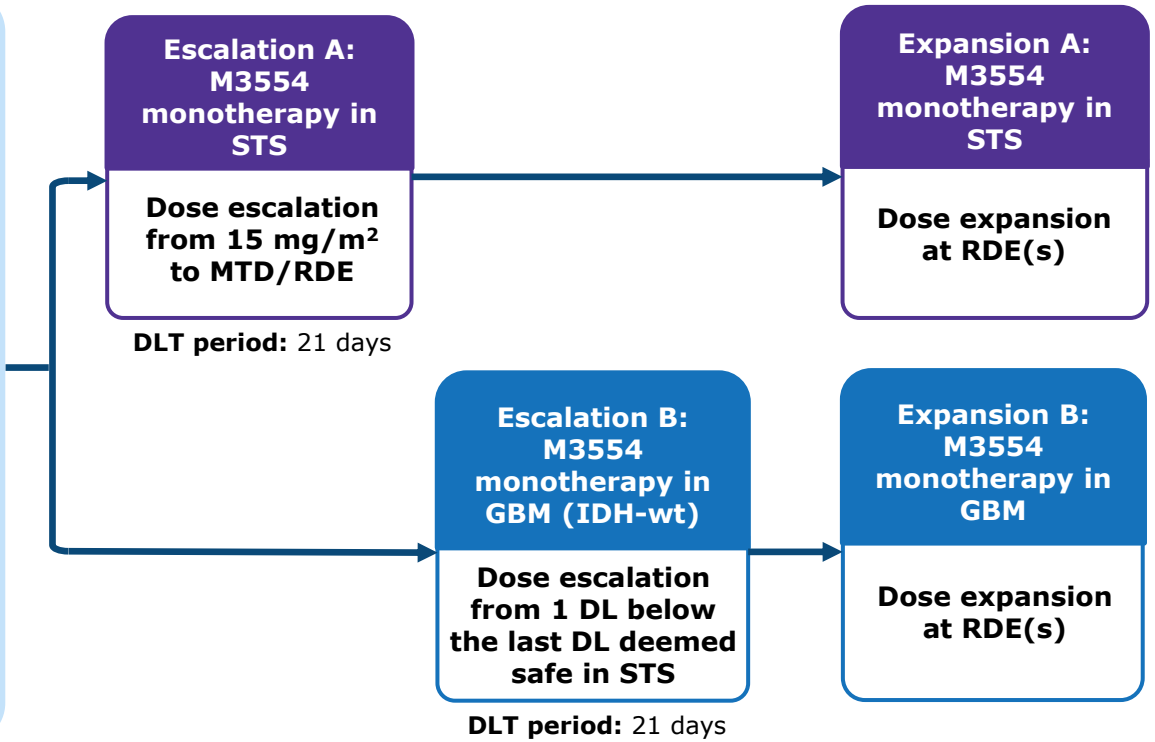
Sponsor: Affiliates of Merck KGaA, Darmstadt, Germany

Study design (NCT06641908) *recruiting*

Phase 1, first-in-human, open-label, multicenter study

Key eligibility criteria

- ECOG PS ≤1
- **Phase 1a Escalation A[a]:** Locally advanced or metastatic STS with unresectable disease that has progressed after ≥1 prior line of systemic therapy for metastatic disease, including anthracyclines[a]
- **Phase 1a Escalation B:** Glioblastoma, IDH-wt, with progression after only 1 prior line of therapy (including radiotherapy ± temozolomide, depending on MGMT status) and relapse ≥3 months after the end of the radiotherapy



Phase 1a endpoints	
Primary	DLTs, AEs
Secondary	PK, OR[b,c], DoR[b,c], PFS[b,c], ECG changes

Est. study start date: November 2024

Est. primary completion date: September 2026

Locations

US, Belgium, France, and Japan

2L, second-line; AE, adverse event; DL, dose level; DLT, dose-limiting toxicity; DoR, duration of response; ECG, electrocardiogram; ECOG PS, Eastern Cooperative Oncology Group performance status; Est. estimated; MGMT, O6-methylguanine-DNA-methyltransferase; MTD, maximum tolerated dose; IDH, isocitrate dehydrogenase; IV, intravenous; OR, objective response; PK, pharmacokinetics; PFS, progression-free survival; Q3W, every 3 weeks; RDE, recommended dose for expansion; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1; STS, soft tissue sarcoma; US, United States; wt, wild-type. [a]Previous ≥2L treatments with drugs approved for different STS subtypes will not be required for enrollment, but will be allowed (e.g., trabectedin, pazopanib for LMS; ifosfamide, gemcitabine-based combinations, trabectedin, eribulin, pazopanib for LPS; trabectedin, gemcitabine, docetaxel, pazopanib for UPS). Participants with resectable, locally advanced or metastatic disease who had surgery before study entry will be allowed if there is residual disease after surgery and if surgery was performed ≥4 weeks before the first dose. [b]According to RECIST v1.1 (STS). [c]According to RANO v2.0 criteria (GBM).

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

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