A study of M3554 in advanced solid tumors

M3554 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

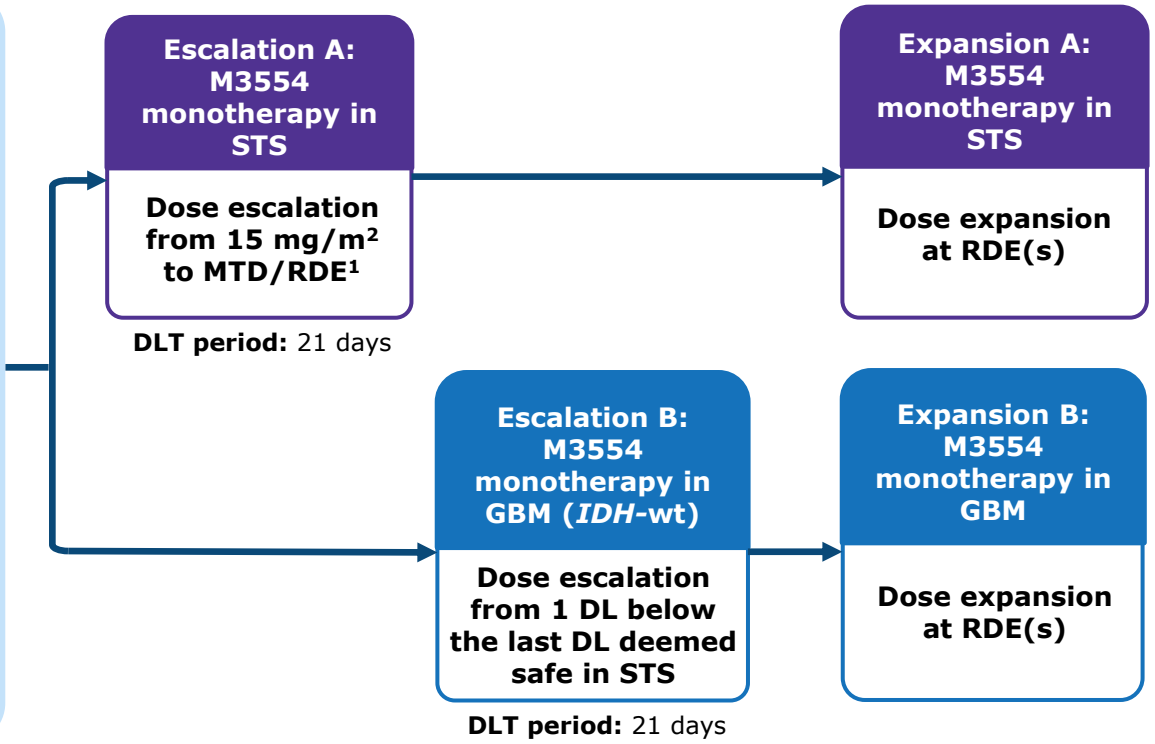
Study design (NCT06641908) *recruiting*

Phase 1, FiH, open-label, multicenter study in STS and GBM

Key eligibility criteria

- ECOG PS ≤1
- **Phase 1a Escalation A:** Locally advanced or metastatic STS with unresectable disease that has progressed after ≥1 prior line of anthracycline-containing systemic therapy for the locally advanced/metastatic setting[a]
- **Phase 1a Escalation B:** GBM, *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

N≈52



Phase 1a endpoints	
Primary	DLTs, AEs
Secondary	PK, OR[b,c], DoR[b,c], PFS[b,c], ΔQTc at predefined time points

Study start date: November 2024

Est. primary completion date: October 2026

Locations

US, Belgium, France, Japan, Switzerland, UK

[a]Patients 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 the surgery was performed ≥4 weeks before the first dose. [b]According to RECIST v1.1 (STS). [c]According to RANO v2.0 criteria (GBM).
AE, adverse event; DL, dose level; DLT, dose-limiting toxicity; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; Est., estimated; FiH, first-in-human; GBM, glioblastoma; *IDH-wt*, isocitrate dehydrogenase-wild type; *MGMT*, O-6-methylguanine-DNA-methyltransferase; MTD, maximum tolerated dose; OR, objective response; PK, pharmacokinetics; PFS, progression-free survival; ΔQTc, change from baseline in corrected QT interval; RANO v2.0, Response Assessment in Neuro-oncology version 2.0; RDE, recommended dose for expansion; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1; STS, soft tissue sarcoma; UK, United Kingdom; US, United States.
Reference: 1. Italiano A, et al. American Association for Cancer Research (AACR) Annual Meeting 2025. Poster CT113.

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