

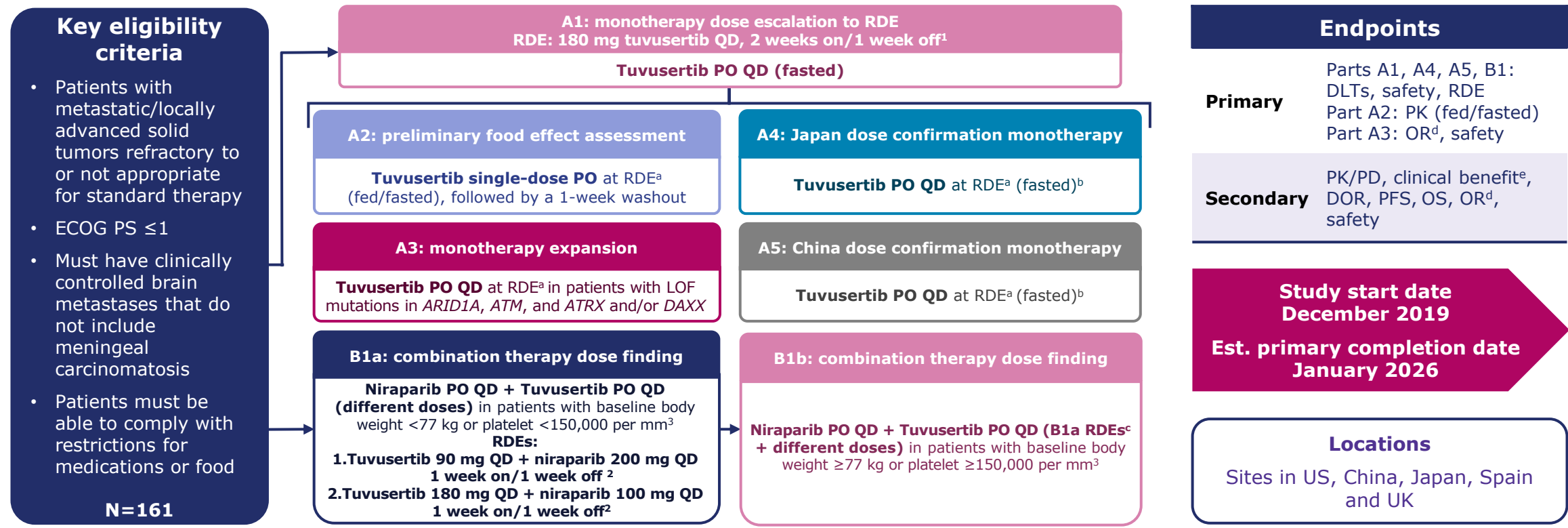
DNA Damage Response Inhibitors (DDRi) Phase 1 study: tuvusertib—advanced solid tumors



Tuvusertib is investigational and not approved for use. Niraparib in combination with tuvusertib is not approved for use. The safety and efficacy of this combination in advanced solid tumors has not been established. There is no guarantee tuvusertib will be approved in any indication by any health authority worldwide.

Sponsor: Affiliates of Merck KGaA, Darmstadt, Germany Study design (NCT04170153) [Active, not recruiting]

DDRiver Solid Tumors 301: Phase 1, first-in-human, open-label study



¹180 mg tuvusertib QD, 2 weeks on/1 week off. ²Additional schedules may be evaluated if needed. ³Tuvusertib 90 mg QD + niraparib 200 mg QD 1 week on/1 week off and Tuvusertib 180 mg QD + niraparib 100 mg QD 1 week on/1 week off. ⁴Assessed by investigator per RECIST version 1.1. ⁵Defined as OR or SD for ≥6 months. DLT, dose-limiting toxicity; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; Est. estimated; LOF, loss of function; OR, objective response; OS, overall survival; PD, pharmacodynamics; PFS, progression-free survival; PK, pharmacokinetics; PO, orally; QD, once daily; RDE, recommended dose for expansion; SD, stable disease. 1. Yap TA, et al. *Clin Cancer Res.* 2024;30(10):2057-2067. 2. Yap TA, et al. *J Clin Oncol.* 2024;42(16_suppl). This information is current as of March 2025. This material is intended for healthcare professionals only. ©2025 Merck KGaA, Darmstadt, Germany or its affiliates. All rights reserved. EMD Serono is the Healthcare business of Merck KGaA, Darmstadt, Germany in the U.S. and Canada.



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



DNA Damage Response Inhibitors (DDRi) Phase 1b study: tuvusertib—advanced solid tumors



Tuvusertib and lartesertib (M4076) are investigational and not approved for use. Lartesertib and avelumab in combination with tuvusertib is not approved for use. The safety and efficacy of this combination in advanced solid tumors has not been established. There is no guarantee tuvusertib and lartesertib (M4076) will be approved in any indication by any health authority worldwide.

Sponsor: Affiliates of Merck KGaA, Darmstadt, Germany

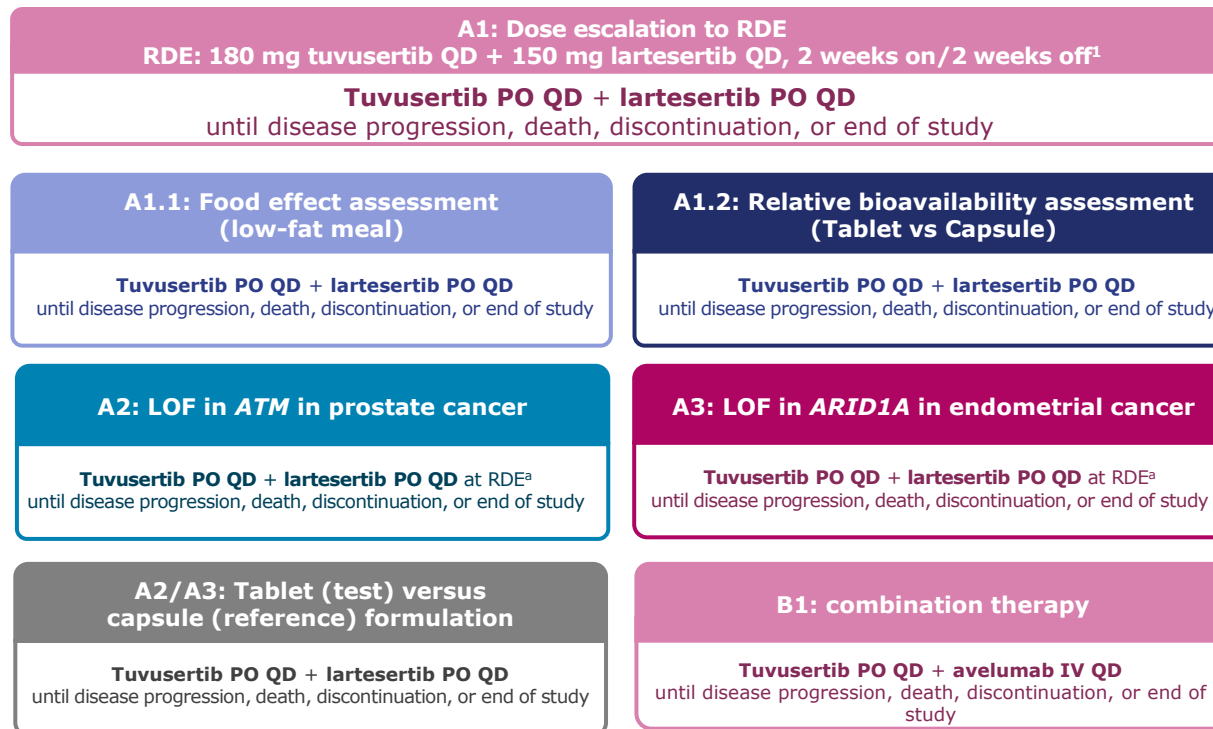
Study design (NCT05396833) [recruiting]

DDRiver Solid Tumors 320: Phase 1b, open-label, multicenter study

Key eligibility criteria

- Patients with unresectable locally advanced or metastatic solid tumors refractory to standard therapy, or for whom no standard therapy is judged appropriate by the investigator, or who cannot tolerate standard of care treatment
- ECOG PS ≤1

N=72



Endpoints

Primary	Parts A1, B1: DLTs, safety, PD (biomarker) Part A1.1: PK (fed/fasted) Part A1.2: PK Part A2/A3: OR ^b , safety
Secondary	Parts A1, B1: PK, ECG changes, OR ^b , ADA (part B1 only) Part A1.1: PK (fed/fasted), Part A1.1, A1.2, A2/A3: safety Part A2/A3: PK, DOR ^b , clinical benefit ^c , PFS ^d

Study start date
June 2022

Est. primary completion date
March 2026

Locations

Sites in US, Canada, Spain, and Republic of Korea

^a180 mg tuvusertib QD + 150 mg lartesertib QD, 2 weeks on/2 weeks off. ^bPer RECIST v1.1. ^cDefined as OR or SD for ≥6 months; ^dAssessed by investigator per RECIST v1.1, modified according to PCWG-3. ADA, anti-drug antibody; DLT, dose-limiting toxicity; DOR, duration of response; ECG, electrocardiogram; ECOG PS, Eastern Cooperative Oncology Group performance status; Est. estimated; IV, intravenous; OR, objective response; OS, overall survival; PD, pharmacodynamics; PFS, progression-free survival; PK, pharmacokinetics; PCWG-3, Prostate Cancer Working Group 3; PO, orally; QD, once daily; RDE, recommended dose for expansion; SD, stable disease.

1. Siu LL, et al. *Cancer Research* 2024;84(7_Supplement):CT063.

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