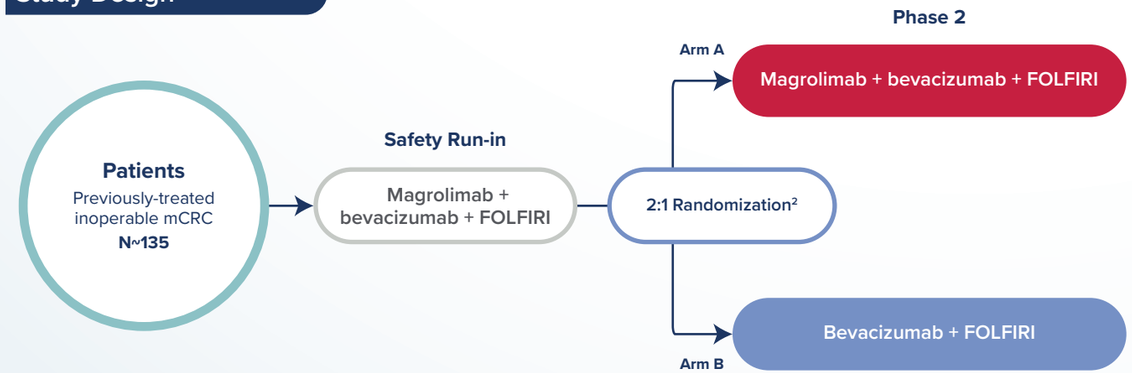
ClinicalTrials.gov Identifier: NCT05330429

ELEVATE Colorectal Cancer: A Phase 2, Randomized, Open-Label Study Evaluating the Safety and Efficacy of Magrolimab in Combination With Bevacizumab and FOLFIRI Versus Bevacizumab and FOLFIRI in Previously Treated Advanced Inoperable Metastatic Colorectal Cancer (mCRC)

Study Design[1,2]



Enrollment

Study Population

Previously treated patients with inoperable metastatic CRC who:

- Progressed on or after 1 prior systemic therapy
- Are ineligible for checkpoint inhibitor therapy

CRC, colorectal cancer; FOLFIRI, folinic acid, fluorouracil, and irinotecan.

Key Eligibility Criteria[1,2,a]

Key Inclusion Criteria

- Histologically or cytologically confirmed adenocarcinoma originating in the colon or rectum (excluding appendiceal and anal canal cancers) who have progressed on or after 1 prior systemic therapy in the setting where curative resection is not indicated. This therapy must have included chemotherapy based on 5-FU or capecitabine with oxaliplatin and either bevacizumab, or for patients with RAS wild-type and left-sided tumors, bevacizumab or cetuximab or panitumumab
- Measurable disease (≥1 measurable metastatic lesion by RECIST v1.1 criteria)
- ECOG performance status of 0 or 1
- Life expectancy of at least 12 weeks

Key Exclusion Criteria

- Thromboembolic event in the 6 months before inclusion (eg, transitory ischemic stroke, stroke, subarachnoid hemorrhage) except peripheral deep vein thrombosis treated with anticoagulants
- Prior anticancer therapy within 3 weeks or within at least 4 half-lives prior to magrolimab dosing (up to a maximum of 4 weeks), whichever is shorter
- Known *BRAF V600E* or *MSI-H* mutations or mismatch repair deficiency (dMMR)
- Persistent Grade 2 or more gastrointestinal bleeding
- Prior irinotecan therapy
- Significant disease or medical conditions, as assessed by the investigator and sponsor, that would substantially increase the risk-benefit ratio of participating in the study
- Secondary malignancy, except treated basal cell or localized squamous skin carcinomas, or localized prostate cancer
- Active CNS disease. Individuals with asymptomatic and stable, treated CNS lesions (radiation and/or surgery and/or other CNS-directed therapy who have not received corticosteroids for at least 4 weeks) are allowed
- RBC transfusion dependence

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[a]Other protocol-defined inclusion/exclusion criteria may apply.

5-FU, fluorouracil; BRAF, v-raf murine sarcoma viral oncogene homolog B1; CNS, central nervous system; ECOG, Eastern Cooperative Oncology Group; MSI-H, high microsatellite instability; RBC, red blood cell; RECIST, Response Evaluation Criteria in Solid Tumors.

The safety and efficacy of these investigational agents and/or uses have not been established. There is no guarantee that they will become commercially available. Visit clinicaltrials.gov for more information. Clinicaltrials.gov: NCT05330429

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Endpoints[1,2]

Primary Endpoints

Safety Run-in Cohort

- DLTs, AEs, and lab abnormalities

Randomized Cohort

- PFS, investigator assessed

Secondary Endpoints

Safety Run-in and Randomized Cohort

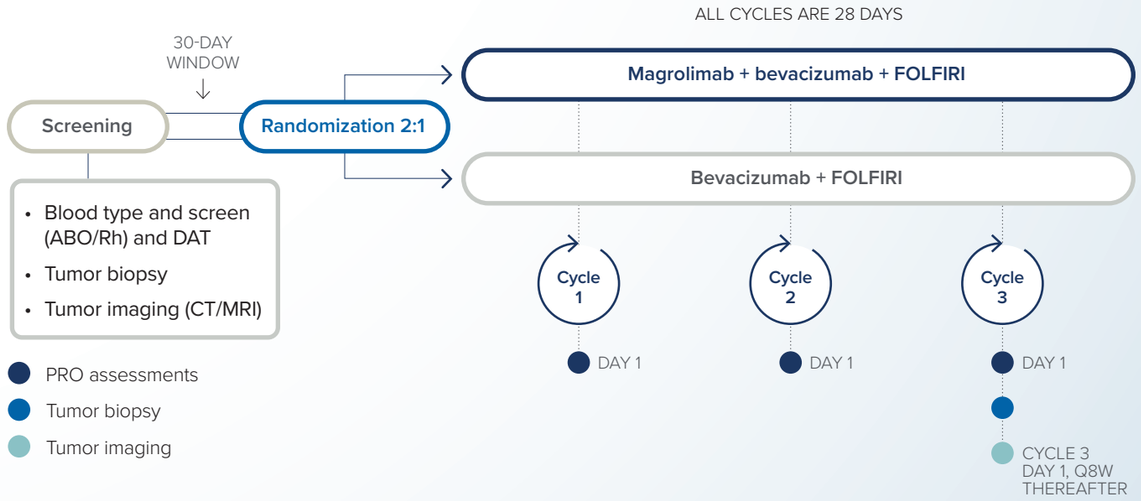
- Magrolimab concentration versus time
- ADAs to magrolimab

Randomized Cohort

- ORR, investigator assessed
- DOR, investigator assessed
- OS
- PRO assessments

ADA, antidrug antibody; AE, adverse event; DLT, dose-limiting toxicity; DOR, duration of response; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PRO, patient reported outcome.

Timeline with Key Assessments (for Randomized Cohort)[1,2]



ABO, any of the 4 blood groups A, B, AB, and O comprising the ABO system; CT, computed tomography; DAT, direct antiglobulin test; FOLFIRI, folinic acid, fluorouracil, and irinotecan; MRI, magnetic resonance imaging; PRO, patient reported outcome; Q8W, every 8 weeks; Rh, Rhesus factor.

References

1. Clinicaltrials.gov website. Accessed October 27, 2023. https://clinicaltrials.gov/ct2/show/NCT05330429
2. Fakih M, et al. Poster presentation at ESMO Annual Meeting 2022 (439 TiP).

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