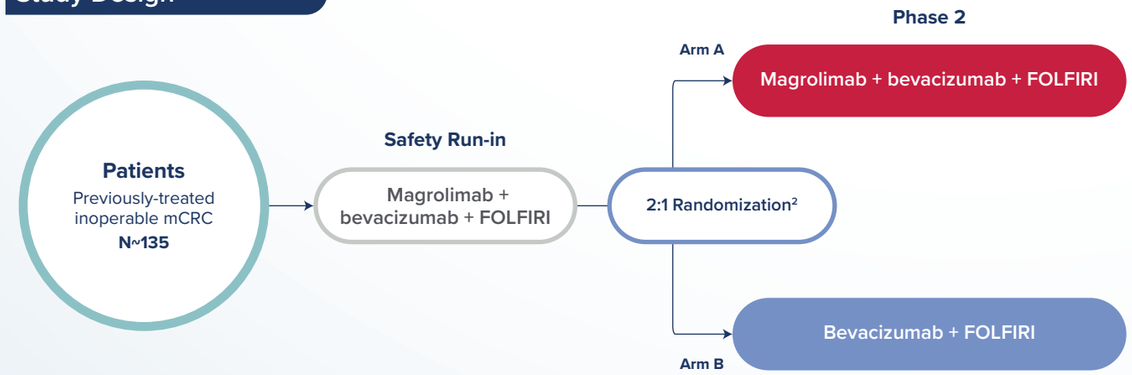
ClinicalTrials.gov Identifier: NCT05330429

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[1,2]

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.

GILEAD | Oncology

ELEVATE CRC is active, not recruiting

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 have not been established, and they have not received marketing authorization in this setting. There is no guarantee that these investigational agents and/or uses will receive Health Authority approval and/or become commercially available.

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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

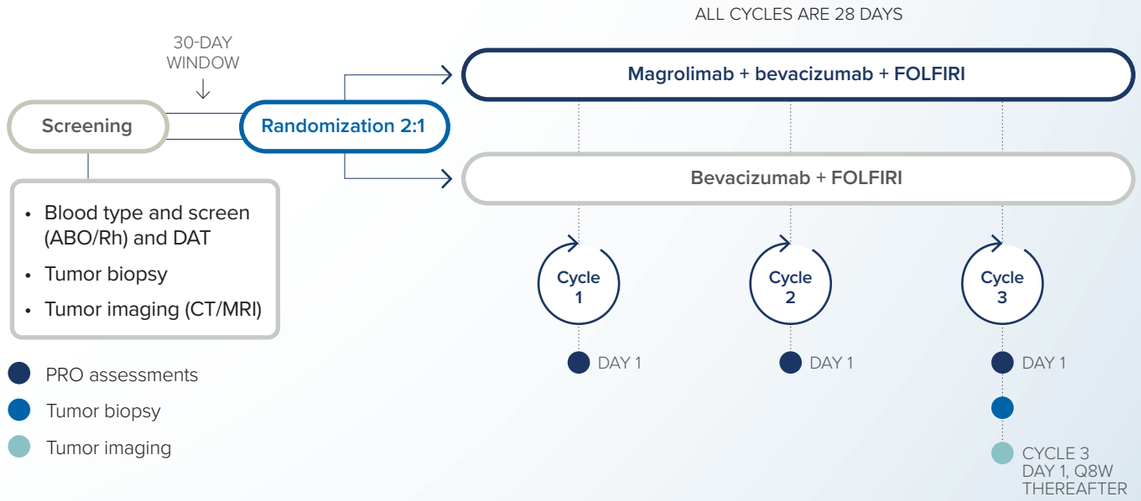
- Magrolimab concentration versus time
- ADAs to magrolimab

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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